Philippine National Drug Formulary

ESSENTIAL MEDICINES LIST

Volume I
7th Edition
2008

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Volume I, 7th Edition
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PHILIPPINE NATIONAL DRUG FORMULARY
Volume I, 7th Edition
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MESSAGE

Republic Act 9502 , also known as the Universally Accessible Cheaper and Quality Medicines Act of 2008, and its Implementing Rules and Regulations (IRR) have been signed. As stated in IRR Rule #36, "All government agencies, including local government units, shall procure drugs and medicines within the Philippine National Drug Formulary (PNDF) current edition in accordance with Republic Act 9184 and any other pertinent procurement reforms".

Likewise, pursuant to Executive Order 49, that "all government entities concerned are mandated to use the current PNDF (Volume I) as the basis for procurement of drug products".

The National Drug Policy-Pharmaceutical Management Unit 50 of the Department of Health (DOH) proudly presents the 7th edition of the PNDF, Volume I, Essential Medicines List.

The PNDF is a dynamic list which is regularly reviewed and updated to make it truly relevant to the health needs of the majority of the population.

In behalf of the DOH, we would like to thank and recognize the dedication and support of all members of the National Formulary Committee and the National Drug Information Center, and various resource persons in the preparation and completion of this edition.

FRANCISCO T. DUQUE III, M.D., M.Sc.
Secretary of Health

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April 16, 2009 Manila, Philippines

THE PHILIPPINE NATIONAL DRUG POLICY

The Philippine National Drug Policy (PNDP) is the government's response to the problem of inadequate provision of good quality essential drugs to the people. Part of the problem is the high cost drugs, which renders them inaccessible to the majority of the population. The PNDP stands on five pillars designed to eventually bring about the availability and affordability of safe, effective, and good quality drugs for all sectors of the country, especially for the poor who need them most, but who can least afford them. These five pillars form an integral unit, mutually complementary and supportive of each other.

The first pillar is the assurance of the safety, efficacy and usefulness of pharmaceutical products through quality control. This will involve the regulation of the importation, manufacture, marketing, and consumer utilization of all drugs and their intermediates.

The second pillar rests on the promotion of the rational use of drugs by both health professionals and the general public. Rational use of drugs refer to a carefully considered pattern of behavior on the part of the prescriber and the consumer. This will limit the use of medicines to situations where there are clear valid indications for them. Furthermore, only the most necessary and scientifically proven efficacious drugs should be used.

A key strategy under the rational drug use pillar is the development and implementation of a Philippine National Drug Formulary (PNDF) which shall list those drugs which are most essential for the diseases and conditions encountered in the Philippines, and describe the appropriate use of these essential drugs. Aside from this, the rules and regulations governing the promotion and advertising of pharmaceutical products shall be reviewed and amended in order to contribute towards the promotion of rational use of drugs. With these twin moves, consumers will now be properly guided as to which drugs to use for their particular needs and conditions.

The third pillar is the development of self-reliance in the local pharmaceutical industry. This pillar seeks to strengthen Filipino capabilities for the manufacture of basic and intermediate ingredients for drugs and medicines. By developing a capability to produce strategic essential drugs locally, the country's dependence on imported drugs can be greatly reduced. This will also enable local drug manufacturers to be competitive with the transnational drug firms.

The fourth pillar relates to the tailored or targeted procurement of drugs by government with the objective of making available to its own clientele, particularly the lower-income sectors of the society, the best drugs at the lowest possible cost. It is widely acknowledged that the government is the single largest purchaser of drugs in the country, allocating major part of its health budget for drugs and medicines.

The fifth pillar is on people empowerment. This cuts across all the four pillars and aims to assist people in exercising an informed choice in the purchase of cost-effective medicines.

The five pillars of the PNDP form a dynamic whole and each pillar is meant to be mutually reinforcing. Quality assurance is a prerequisite for any National Drug Policy. The tenets of rational use will serve as bases for regulation in both government and private sectors. In turn, fair and thorough regulation should promote rational use. The active participation of government in the procurement, distribution and use of drugs will lead the way towards some measures of self-reliance and self-sufficiency. This should also provide impetus for private enterprise to move towards the manufacture of some basic ingredients of drugs, if private industry is to retain its competitive edge. Finally, the PNDP recognizes the value of all sectors of society and seeks their support in the implementation of the National Drug Policy (NDP). The NDP relates to the health and welfare of each and every Filipino and certainly deserves the support of all.

P R E F A C E
to the 7th edition

The Philippine National Drug Formulary (PNDF) is an integral component of the Philippine National Drug Policy, aimed at making available and accessible, essential medicines of proven efficacy, safety and quality at affordable cost. It's formulation by the Department of Health (DOH) through the National Formulary Committee (NFC), formerly called the National Drug Committee, has been mandated by R.A. 6675, otherwise known as the Generics Act of 1988.

The PNDF Volume I, the Essential Medicines List, is a major step towards rational use of medicines in the country. The medicines are selected with due regard to public health relevance, evidence of efficacy and safety and comparative cost-effectiveness. The national list of essential medicines is a subset of registered medicines divided according to different levels of care. A carefully selected limited list of essential medicines leads to higher quality of care, better management of medicines including improved quality control, more cost-effective use of health resources and ensures regular supply of essential medicines, resulting in real health gain and increased confidence on the health system.

The 7th edition of the PNDF Volume I has maintained basically the same objectives and organization as in the previous editions. However, measures have been adopted to simplify the listing by limiting the numbering to a maximum of three, whenever possible. Further, the NFC has adopted the World Health Organization (WHO) recommendation to replace the word "drug" with "medicines". The algorithms for deletion and addition of medicines have been followed strictly and the evaluation of the efficacy and safety by an unbiased agency, the National Drug Information Center (NDIC) has been made a requirement for the decision making process. The NFC followed the same consultative and participative process in its formulation through a series of deliberation meetings with different panels of experts from the medical schools, Philippine Medical Association, various specialty and subspecialty societies and government and private hospitals. Inputs from the pharmaceutical companies and other stakeholders have also been considered.

A major revision in this 2008 edition is the incorporation of the WHO listing of immediate release solid oral dosage forms of multisource (generic) pharmaceutical products/active ingredients which should be subjected to *in-vivo* bioequivalence studies (list B medicines). Forty five (45) medicines have been added to the PNDF, while thirty six (36) medicines have been deleted based on the approved guidelines and criteria. This 7th edition includes a total of 627 medicines, 351 in the core list and 276 in the complementary list.

The NFC gratefully acknowledges the invaluable assistance of the NDIC headed by Dr. Isidro C. Sia and Mr. Rainier Galang, the various resource persons and the NDP-PMU 50 staff in the preparation and completion of this edition. As in the 6th edition, the completed sections signed by the Secretary of Health are released on a staggered basis and posted at the DOH website for the information of all concerned and for immediate implementation.

The PNDF is a very dynamic list which is regularly reviewed and updated to make it truly relevant in meeting the health needs of the great majority of the population. The NFC encourages and welcomes the active participation of all stakeholders to achieve our goal of promoting rational use of medicines in the delivery of quality health care.

Prof. Estrella B. Paje-Villar, MD
Chair, National Formulary Committee

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PART

I

THERAPEUTIC CATEGORIES OF THE PNDF

PART II

SYMBOLS, ABBREVIATIONS AND SYSTEM OF MEASUREMENTS

LEGEND:

★	—	Not available in Philippine market
▼	—	New drug under "monitored release", which the National Formulary Committee (NFC) and the Bureau of Food and Drugs (BFAD) request that all Adverse Drug Events/Experiences (ADEs) be reported
●	—	Medicinal plant product registered with BFAD
+	—	Use with extreme caution in doses exceeding 30 mg per day; contraindicated in acute coronary events
■	—	Based on the requirement of Recommended Energy and Nutrient Intakes (RENI)
(1)	—	Specific expertise, diagnostic precision, or special equipment required for proper use
(2)	—	Limited indications or narrow spectrum of activity
(3)	—	Only for tertiary hospitals with DOH accredited antimicrobial resistance surveillance program
(A1)	—	Dangerous Drug Preparations to be prescribed and dispensed through the **DOH Official Prescription Form (Yellow Rx).** Only one (1) dangerous drug preparation shall be prescribed in one single prescription form. Partial filling allowed. **STRICTLY NO REFILL.** (*See* Appendix K)
⊗	—	To be prescribed using **Personalized Prescription** issued by the prescribing physician with the **S2 license #** indicated therein. Only one (1) drug preparation shall be prescribed in one single prescription form. Partial filling allowed. **STRICTLY NO REFILL.** (*See* Appendix K)
(A2)	—	Drug Preparations Containing Controlled Chemicals to be dispensed and prescribed through a **Personalized Prescription** issued by a prescribing physician with the **S2 license #,** among others, indicated therein. Only one (1) drug preparation shall be prescribed in one single prescription form. Partial filling allowed. **STRICTLY NO REFILL**. (*See* Appendix K)
(B)	—	List B medicines requiring *in vivo* bioequivalence studies (*see* Appendix I)
DDB	—	Dangerous Drugs Board
DDP	—	Dangerous Drug Preparations
DPI	—	Dry Powder Inhaler
equiv.	—	Equivalent
EU	—	ELISA Unit
FSH	—	Follicle Stimulating Hormone

g	**—**	Gram
HSA-free	**—**	Human Serum Albumin-free
(ID)	**—**	Intradermal Injection
(IM)	**—**	Intramuscular Injection
Inj.	**—**	Injection
IU	**—**	International Unit/s
(IV)	**—**	Intravenous Injection
L	**—**	Liter
LH	**—**	Luteinizing Hormone
mCi	**—**	Millicurie
MDI	**—**	Metered Dose Inhaler
mEq	**—**	Milliequivalent
mg	**—**	Milligram
mL	**—**	Milliliter
MR	**—**	Modified Release (includes Controlled Release (**CR**), Extended Release (**ER**) Sustained Release (**SR**), Long Acting (**LA**), etc.)
NSAID	**—**	Non-Steroidal Anti-Inflammatory Drug
pen. G	**—**	Penicillin G
PFU	**—**	Plaque Forming Unit
RE	**—**	Retinol Equivalent
Resp. Soln.	**—**	Respiratory Solution
S2	**—**	License required for prescription of Dangerous Drugs Preparations and Controlled Chemicals by the Physicians/Dentists/Veterinarians
(SC)	**—**	Subcutaneous Injection
Soln.	**—**	Solution
SVT	**—**	Supraventricular Tachycardia
Category A	—	Primary Care Medicines for all Rural Health Units (RHUs)
Category B	—	Primary Care Medicines for RHUs with physicians and other health workers

Measurements:

1 grain = 60 mg

1/2 grain = 30 mg

Quantities of 1 gram or more should be written as 1 g, etc.

Quantities less than 1 gram should be written in milligrams, e.g., 500 mg, not 0.5 g.

Quantities less than 1 milligram should be written in microgram/s,
e.g., 100 microgram/s, not 0.1 mg.

When decimals are unavoidable, a zero should be written before the decimal point where there is no figure, e.g., 0.5 mL, not .5 mL.

The term milliliter (mL) should be used and not cubic centimeters or cc or cm^3.

1 MEDICINES ACTING ON THE NERVOUS SYSTEM

1.1 ANESTHETICS

1.1.1 General anesthetics

Inhalational agents

Gas

NITROUS OXIDE (1) — Inhalation: Anesthetic gas

Volatile agents

ISOFLURANE (1) — Inhalation: 100 mL and 250 mL bottle

desflurane (1) — Inhalation: 240 mL bottle

halothane (1) — Inhalation: 250 mL bottle

▼ *sevoflurane* (1) — Inhalation: 250 mL bottle

Intravenous agents

KETAMINE (1, A1) — ⊗ Inj.: 50 mg/mL, 10 mL vial (IM, IV) (as hydrochloride)

THIOPENTAL SODIUM (1, A1) — Inj.: 500 mg vial (IV); 1 g vial + 50 mL diluent (IV)

propofol (1) — Inj.: 10 mg/mL, 20 mL ampul (IV); 10 mg/mL, 50 mL pre-filled syringe (IV); 10 mg/mL, 20 mL and 50 mL vial (IV); 20 mg/mL, 50 mL vial (IV) (as oil in water emulsion)

1.1.2 Adjuvants and oxygen

Non-opioid analgesics

diclofenac — Inj.: 25 mg/mL, 2 mL and 3 mL ampul (IM, IV) (as sodium salt); 25 mg/mL, 10 mL vial (IM, IV) (as sodium salt)

CORE LIST	Complementary List	Route of Administration	Pharmaceutical Forms and Strengths
			37.5 mg/mL, 2 mL ampul and pre-filled syringe (IM, IV) (as sodium salt)
	ketoprofen	★ Inj.:	50 mg/mL, 2 mL ampul (IM) lyophilized powder, 100 mg vial (IV infusion)
	ketorolac	Inj.:	30 mg/mL, 1 mL ampul (IM, IV) (as tromethamol)
Opioid analgesics (See Section 1.8.2)			
Neuromuscular blockers (See Section 2.5.2)			
Cholinesterase inhibitors			
★ *EDROPHONIUM*		Inj.:	10 mg/mL, 1 mL ampul (IM, IV) (as chloride)
NEOSTIGMINE		★ Oral: Inj.:	15 mg tablet (as bromide) 500 micrograms/mL, 1 mL ampul (IM, IV, SC) (as methyl sulfate)
PYRIDOSTIGMINE (1, 2)		Oral:	60 mg tablet (as bromide)
Anxiolytics			
DIAZEPAM (A1)		⊗ Oral: Inj.:	2 mg, 5 mg and 10 mg tablet 5 mg/mL, 2 mL ampul (IM, IV)
MIDAZOLAM (A1)		⊗ Oral: Inj.:	15 mg tablet 1 mg/mL, 5 mL ampul/vial (IM, IV) 5 mg/mL, 1 mL and 3 mL ampul (IM, IV)
Anticholinergic			
ATROPINE		Inj.:	500 micrograms/mL and 1 mg/mL, 1 mL ampul (IM, IV) (as sulfate)
Sympathomimetic			
EPHEDRINE (A1)		Inj.:	50 mg/mL, 1 mL ampul (IM, IV) (as sulfate)

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
Beta adrenoceptor blocker		
ESMOLOL (2)		Inj.: 100 mg/mL, 10 mL vial (IV) (as hydrochloride)
Oxygen		Inhalation: (medicinal gas)
1.1.3 Local anesthetics		
BUPIVACAINE (1)		Inj.: 0.5%, 5 mL and 10 mL ampul (local infiltration) (as hydrochloride) 0.5%, 5 mL, 10 mL, 20 mL and 50 mL ampul/vial (local infiltration) (as hydrochloride) 0.5% 4 mL ampul (spinal) with 8% dextrose (as hydrochloride) 0.5% (isobaric), 5 mL ampul (spinal) (as hydrochloride)
LIDOCAINE		Inj.: 1%, 5 mL ampul and 50 mL vial (local infiltration) (as hydrochloride) 2%, 5 mL, 10 mL and 50 mL vial (epidural, local infiltration) (as hydrochloride) 2%, 1.8 mL carpule (with epinephrine) (local infiltration) Jelly: 2%, 30 g (as hydrochloride) Ointment: 5%, 35 g and 50 g (as hydrochloride) Solution: 4%, 30 mL (topical solution) (as hydrochloride) Spray: 10%, 50 mL (as hydrochloride)
TETRACAINE		Inj.: 20 mg ampul (sterile powder) (spinal) (as hydrochloride)
	ropivacaine	Inj.: 10 mg/mL in 10 mL ampul (IV) (as hydrochloride)
1.2 ANTICONVULSANTS / ANTIEPILEPTICS		
CARBAMAZEPINE		Oral: 200 mg tablet **(B)** 200 mg and 400 mg MR tablet 100 mg/5 mL syrup, 120 mL

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
CLONAZEPAM (A1)		⊗ Oral: 2 mg tablet
DIAZEPAM (1, A1)		Inj.: 5 mg/mL, 2 mL ampul (IV) ★ Rectal: 5 mg/2.5 mL and 10 mg/2.5 mL in rectal tube
★ *LORAZEPAM* (1, A1)		Inj.: 4 mg/mL, 1 mL ampul (IV)
MAGNESIUM SULFATE (1) (for pre-eclampsia / eclampsia and hypomagnesemia)		Inj.: 250 mg/mL, 2 mL and 10 mL ampul and 20 mL vial (IM, IV) (as heptahydrate) 500 mg/mL, 2 mL and 10 mL ampul (IM, IV) (as heptahydrate)
PHENOBARBITAL (A1)		⊗ Oral: 15 mg, 30 mg, 60 mg and 90 mg tablet Inj.: 120 mg/mL (130 mg/mL), 1 mL ampul (IM, IV) (as sodium salt)
PHENYTOIN		Oral: 30 mg and 100 mg capsule (as sodium salt) **(B)** 30 mg/5 mL suspension, 120 mL (as sodium salt) Inj.: 50 mg/mL, 2 mL ampul (IV) (as sodium salt) (1)
VALPROATE DISODIUM/ VALPROIC ACID		Oral: 250 mg tablet (as disodium salt and valproic acid) 250 mg/5 mL syrup, 120 mL (as valproic acid)
	gabapentin	Oral: 100 mg, 300 mg and 400 mg capsule
	midazolam (A1)	⊗ Oral: 15 mg tablet Inj.: 1 mg/mL, 5 mL ampul/vial (IM, IV) 5 mg/mL, 1 mL, 2 mL, 3 mL, 5 mL and 10 mL ampul (IM, IV)
	thiopental sodium (1, A1)	Inj.: 500 mg vial (IV) 1 g vial + 50 mL diluent (IV)
	topiramate	Oral: 25 mg, 50 mg, 100 mg and 200 mg tablet 15 mg and 25 mg capsule
1.3 ANTIMIGRAINE		
ERGOTAMINE (1, 2, A2)		Oral: 1 mg tablet (as tartrate)

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
PROPRANOLOL		Oral: 10 mg, 40 mg, and 80 mg tablet (as hydrochloride) 40 mg and 80 mg MR capsule (as hydrochloride)
	flunarizine	Oral: 5 mg capsule (as hydrochloride)
	NSAIDs (See Section 2.4)	
	paracetamol	Oral: 300 mg and 500 mg tablet
	▼ *zolmitriptan*	Oral: 2.5 mg tablet

1.4 ANTIPARKINSONISM

1.4.1 Dopaminergics (only for idiopathic parkinsonism)

LEVODOPA + CARBIDOPA		Oral: 100 mg levodopa + 25 mg carbidopa per tablet 250 mg levodopa + 25 mg carbidopa per tablet
	piribedil	Oral: 50 mg MR tablet
	selegiline	Oral: 5 mg tablet (as hydrochloride)

1.4.2 Anticholinergics (for idiopathic and drug-induced parkinsonism)

BIPERIDEN		Oral: 2 mg tablet (as hydrochloride) Inj.: 5 mg/mL, 1 mL ampul (IM, IV) (as lactate)
DIPHENHYDRAMINE		Oral: 25 mg and 50 mg capsule (as hydrochloride) 12.5 mg/5 mL, 60 mL and 120 mL syrup Inj.: 50 mg/mL, 1 mL ampul (IM, IV) (as hydrochloride)

1.5 ANTIPYRETICS

IBUPROFEN		Oral: 200 mg and 400 mg tablet 100 mg/5 mL, 60 mL suspension
PARACETAMOL		Oral: 300 mg and 500 mg tablet 100 mg/mL drops, 15 mL (alcohol-free)

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
		120 mg/5 mL (125 mg/5 mL) syrup/suspension, 30 mL, 60 mL and 120 mL (alcohol-free) 250 mg/5 mL syrup/suspension, 30 mL, 60 mL and 120 mL (alcohol-free) Rectal: 125 mg and 250 mg suppository
1.6 ANTI-VERTIGO		
	betahistine	Oral: 6 mg tablet (as mesilate) 8 mg and 24 mg tablet (as hydrochloride)
	cinnarizine	Oral: 25 mg tablet 50 mg and 75 mg capsule
	meclozine *(meclizine)*	Oral: 12.5 mg chewable tablet (as hydrochloride) 25 mg tablet (as hydrochloride)
1.7 MEDICINES FOR ATTENTION DEFICIT HYPERACTIVITY DISORDER (ADHD)		
	imipramine	Oral: 25 mg tablet (as hydrochloride)
	▼ *methylphenidate* (1, 2, A1)	Oral: 18 mg and 36 mg MR tablet
1.8 MEDICINES FOR PAIN MANAGEMENT		
1.8.1 Non-opioid analgesics		
IBUPROFEN		Oral: 200 mg and 400 mg tablet 800 mg MR tablet 100 mg/5 mL, 60 mL syrup/ suspension
PARACETAMOL (See Section 1.5)		
	other NSAIDs (See Sections 2.4 and 1.1.2)	
	●★ *yerba buena* *[Mentha cordifolia Opiz* (Fam. Labiatae)]	Oral: 250 mg and 500 mg tablet

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
1.8.2 Opioid analgesics		
CODEINE (A1)		Oral: 30 mg MR capsule (as phosphate) 10 mg/5 mL, 60 mL suspension
MORPHINE (A1)		Oral: 10 mg, 20 mg and 30 mg tablet/ capsule (as sulfate) 10 mg, 30 mg, 60 mg and 100 mg MR tablet (as sulfate) Inj.: 10 mg/mL, 1 mL ampul (IM, IV, SC) (as sulfate) 15 mg/mL, 1 mL ampul (IM, IV, SC) (as sulfate)
NALBUPHINE (A1)		Inj.: 10 mg/mL, 1 mL ampul (IM, IV, SC) (as hydrochloride) 20 mg/mL, 10 mL vial (IM, IV, SC) (as hydrochloride)
PETHIDINE (A1) *(meperidine)*		Inj.: 50 mg/mL, 2 mL ampul (IM, IV, SC) (as hydrochloride) 50 mg/mL, 30 mL vial (IM, IV, SC) (as hydrochloride)
	butorphanol (A1)	Inj.: 2 mg/mL, 1 mL and 2 mL vial (IM, IV) (as tartrate)
	fentanyl (A1)	Inj.: 50 micrograms/mL, 2 mL, 10 mL and 20 mL ampul (IV) (as citrate) (The latter is restricted to pain management of terminal cancer patients)
	▼ *oxycodone* (A1)	Oral: 10 mg, 20 mg, 40 mg and 80 mg tablet (as hydrochloride)
	tramadol (1)	Oral: 50 mg capsule (as hydrochloride) 100 mg, 150 mg and 200 mg MR tablet (as hydrochloride) Inj.: 50 mg/mL, 1 mL and 2 mL ampul (IM, IV, SC) (as hydrochloride)
1.8.3 Medicines for neuropathic pain		
	carbamazepine	Oral: 200 mg tablet **(B)** 200 mg and 400 mg MR tablet 100 mg/5 mL syrup, 120 mL

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
	gabapentin	Oral: 100 mg, 300 mg and 400 mg capsule
	imipramine	Oral: 25 mg tablet (as hydrochloride)
1.9 MEDICINES TO REDUCE CEREBRAL EDEMA		
DEXAMETHASONE		Oral: 500 microgram and 4 mg tablet Inj.: 4 mg/mL, 1 mL and 2 mL ampul/vial (IM, IV) (as sodium phosphate) 5 mg/mL, 1 mL ampul (IM, IV) (as sodium phosphate)
GLYCEROL (glycerin)		Oral: USP grade (liquid)
MANNITOL		Inj.: 20%, 250 mL and 500 mL bottle (IV)
	furosemide	Oral: 20 mg and 40 mg tablet **(B)** Inj.: 10 mg/mL, 2 mL ampul (IM, IV)
1.10 MEDICINES FOR DEMENTIA		
RIVASTIGMINE		Oral: 1.5 mg, 3 mg, 4.5 mg and 6 mg capsule (as hydrogen tartrate)
	galantamine	Oral: ▼ 4 mg tablet 8 mg tablet ▼ 8 mg, 16 mg and 24 mg MR capsule
1.11 PSYCHOPHARMACOLOGIC AGENTS		
1.11.1 Antidepressants		
FLUOXETINE (1)		Oral: 20 mg dispersable tablet/capsule
SERTRALINE		Oral: 50 mg tablet (as hydrochloride)
	▼ *escitalopram*	Oral: 10 mg tablet (as oxalate)
	imipramine	Oral: 25 mg tablet (as hydrochloride)
1.11.2 Antipsychotics		
Atypical Antipsychotics		
RISPERIDONE		Oral: 1 mg, 2 mg, 3 mg, and 4 mg tablet 1 mg and 2 mg orodispersible tablet

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
		▼ 1 mg/mL oral solution, 100 mL Inj.: 25 mg and 37.5 mg MR powder for suspension, vial + 2 mL diluent in pre-filled syringe (IM)
	clozapine (1, 2)	Oral: 25 mg and 100 mg tablet (requires hematologic monitoring)
	olanzapine (1, 2)	Oral: 5 mg and 10 mg tablet Inj.: 10 mg vial (IM)
	quetiapine	Oral: 25 mg, 100 mg, 200 mg and 300 mg tablet (as fumarate)
Typical Antipsychotics		
CHLORPROMAZINE		Oral: 50 mg, 100 mg and 200 mg tablet (as hydrochloride) Inj.: 25 mg/mL, 1 mL ampul (IM, IV) (as hydrochloride)
FLUPENTIXOL (1)		Oral: 250 microgram, 500 microgram, 1 mg and 5 mg tablet (as dihydrochloride) Inj.: 20 mg/mL, 1 mL ampul and 10 mL vial (IM) (as decanoate)
FLUPHENAZINE (1)		Inj.: 25 mg/mL, 1 mL ampul and 10 mL vial (IM) (as decanoate)
HALOPERIDOL (1)		Oral: 500 microgram, 1.5 mg, 2 mg, 5 mg, 10 mg, and 20 mg tablet **(B)** Inj.: 5 mg/mL, 1 mL ampul (IM) 50 mg/mL, 1 mL (oily) ampul (IM) (as decanoate)
1.11.3 Anxiolytics		
DIAZEPAM (A1)		⊗ Oral: 2 mg, 5 mg and 10 mg tablet Inj.: 5 mg/mL, 2 mL ampul (IM, IV)
	alprazolam (A1)	⊗ Oral: 250 microgram, 500 microgram and 1 mg tablet
	bromazepam (A1)	⊗ Oral: 1.5 mg tablet
	clonazepam (A1)	⊗ Oral: 2 mg tablet

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
1.11.4 Hypnotics		
FLURAZEPAM (A1)		⊗ Oral: 15 mg capsule (as monohydrochloride)
	★ *chloral hydrate*	Oral: 500 mg/5 mL syrup
	midazolam (A1)	⊗ Oral: 15 mg tablet Inj.: 1 mg/mL, 5 mL ampul (IM, IV) 5 mg/mL, 1 mL, 2 mL, 3 mL, 5 mL and 10 mL ampul (IM, IV)
	zolpidem (A1)	⊗ Oral: 10 mg tablet
1.11.5 Mood Stabilizers		
CARBAMAZEPINE		Oral: 200 mg tablet **(B)** 200 mg and 400 mg MR tablet 100 mg/5 mL syrup, 120 mL
LITHIUM CARBONATE (1)		Oral: 450 mg MR tablet
	valproate disodium/ valproic acid	Oral: 250 mg tablet (as disodium salt or as valproic acid) 250 mg/5 mL syrup, 120 mL (as valproic acid)

2 MEDICINES ACTING ON THE MUSCULO-SKELETAL SYSTEM AND JOINTS

2.1 ANTIGOUT

For acute gout

COLCHICINE — Oral: 500 microgram tablet

NSAIDs
(See Section 2.4)

For chronic gout

ALLOPURINOL — Oral: 100 mg and 300 mg tablet

2.2 ANTI-OSTEOPOROSIS MEDICINES

2.2.1 Anti-resorptive agents

Bisphosphonates

alendronate — Oral: 10 mg and 70 mg tablet (as sodium salt)

▼ *alendronate + cholecalciferol (Vit. D3)* — Oral: 70 mg (as sodium salt) + 2800 IU tablet

Hormone replacement therapy

conjugated equine estrogen — Oral: 300 microgram, 625 microgram and 1.25 mg tablet

conjugated equine estrogen + medroxy-progesterone acetate — Oral: 625 microgram + 2.5 mg tablet
625 microgram + 5 mg tablet

medroxy-progesterone (2) — Oral: 2.5 mg, 5 mg, 10 mg, 100 mg, 250 mg, 400 mg, and 500 mg tablet (as acetate)

Selective estrogen receptor modulator (SERM)

raloxifene — Oral: 60 mg tablet (as hydrochloride)

2.2.2 Vitamins and minerals

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
CALCIUM CARBONATE		Oral: tablet/chewable tablet (equiv. to 500 mg and 600 mg elemental calcium)
CALCIUM CARBONATE + CHOLECALCIFEROL (VIT. D3)		Oral: 750 mg (equiv. to 300 mg elemental calcium) + 150 IU tablet 1.25 g (equiv. to 500 mg elemental calcium) + 250 IU tablet
2.3 DISEASE MODIFYING ANTIRHEUMATIC DRUGS (DMARDs)		
	azathioprine **(B)**	Oral: 50 mg tablet
	cyclophosphamide (1, 2)	Oral: 50 mg tablet (as anhydrous) Inj.: powder, 100 mg, 200 mg, 500 mg and 1 g vial (IV)
	▼ *hydroxychloroquine*	Oral: 200 mg tablet (as sulfate)
	methotrexate (1)	Oral: 2.5 mg, 5 mg and 10 mg tablet (as base) Inj.: 2.5 mg/mL, 2 mL ampul/vial (IM, IV, Intrathecal) (as base) 5 mg/mL, 3 mL vial (IM, IV) (as sodium salt) 25 mg/mL, 2 mL ampul/vial (IM, IV, Intrathecal) (as base) 10 mg/mL, 1 mL and 5 mL vial (as base) 50 mg/mL, 1 mL vial (as base) 100 mg/mL, 5 mL, 10 mL and 50 mL vial (as base)
2.4 NON-STEROIDAL ANTI-INFLAMMATORY DRUGS (NSAIDs)		
2.4.1 Non-selective COX inhibitors		
IBUPROFEN		Oral: 200 mg and 400 mg tablet 800 mg MR tablet 100 mg/5 mL suspension, 60 mL
NAPROXEN		Oral: 250 mg base (275 mg) and 500 mg base (550 mg) tablet (as sodium salt) 500 mg MR tablet (as sodium salt)
	aspirin	Oral: 300 mg tablet

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
	diclofenac	Oral: 25 mg and 50 mg tablet/capsule (as sodium or potassium salt) 50 mg enteric coated tablet or MR tablet (as sodium salt) 75 mg MR capsule/tablet (as sodium or potassium salt) 100 mg MR tablet/capsule (as sodium or potassium salt) Inj.: 25 mg/mL, 3 mL ampul (as sodium salt) (IM, IV) 37.5 mg/mL, 2 mL ampul (as sodium salt) (IM, IV)
	indometacin (1)	Oral: 25 mg capsule ★ Inj.: 200 micrograms/mL, 5 mL ampul (IV)
	ketoprofen	Oral: 100 mg tablet
	mefenamic acid	Oral: 250 mg and 500 mg tablet/capsule
2.4.2 Selective COX 2 inhibitor		
CELECOXIB		Oral: 100 mg, 200 mg and 400 mg capsule
2.5 SKELETAL MUSCLE RELAXANTS		
2.5.1 Spasmolytics		
BACLOFEN		Oral: 10 mg tablet
★ *DANTROLENE* (1)		Oral: 25 mg and 50 mg capsule (as sodium salt) Inj.: 20 mg (with 3 mg mannitol)/vial) (for reconstitution with 60 mL sterile water for injection) (IV) (as sodium salt)
DIAZEPAM (1, A1)		⊗ Oral: 2 mg, 5 mg and 10 mg tablet Inj.: 5 mg/mL, 2 mL ampul (IM, IV)
2.5.2 Neuromuscular blockers		
Depolarizing agents		
SUXAMETHONIUM (succinylcholine) (1)		Inj.: 20 mg/mL, 10 mL vial (IV) (as chloride)

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
Non-depolarizing agents		
ATRACURIUM		Inj.: 10 mg/mL, 2.5 mL and 5 mL ampul (IV) (as besilate)
PANCURONIUM (1)		Inj.: 2 mg/mL, 2 mL ampul (IM, IV) (as bromide)
VECURONIUM (1)		Inj.: freeze-dried powder, 4 mg/mL ampul + 1 mL solvent (IV) (as bromide)
	rocuronium (1)	Inj.: 10 mg/mL, 2.5 mL vial (IV) (as bromide) 10 mg/mL, 5 mL ampul/vial (IV) (as bromide) 10 mg/mL, 10 mL ampul (IV) (as bromide)

3 ANTI-INFECTIVES

3.1 ANTIBACTERIALS

3.1.1 Aminoglycosides

AMIKACIN		Inj.:	50 mg/mL, 100 mg/mL, 125 mg/mL and 250 mg/mL, 2 mL ampul/vial (IM, IV) (as sulfate) 100 mg, 250 mg and 500 mg vial (IM, IV) (as sulfate)
GENTAMICIN		Inj.:	10 mg/mL, 1 mL ampul and 2 mL vial (IM, IV) (as sulfate) 40 mg/mL, 1 mL, 1.5 mL and 2 mL ampul/vial (IM, IV) (as sulfate)
	netilmicin	Inj.:	25 mg/mL, 2 mL ampul (IM, IV) (as sulfate) 50 mg/mL, 2 mL vial (IM, IV) (as sulfate) 100 mg/mL, 1.5 mL and 2 mL ampul/vial (IM, IV) (as sulfate) 75 mg/mL, 2 mL ampul (IM, IV) (as sulfate)

3.1.2 Aminocyclitol

★	*spectinomycin* (2)	Inj.:	2 g vial (IM)

3.1.3 Carbapenems

	ertapenem (3)	Inj.:	1 g powder, vial (IM/IV) (as sodium salt)
▼	*meropenem* (3)	Inj.:	500 mg and 1 g powder, vial (IV) (as trihydrate)

3.1.4 Cephalosporins

First Generation

CEFALEXIN	Oral:	250 mg and 500 mg capsule (as monohydrate) 1 g tablet (as monohydrate)

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
		100 mg/mL, granules/powder for drops, 10 mL and 15 mL (as monohydrate) 125 mg/5 mL granules/powder for syrup/suspension, 30 mL and 60 mL (as monohydrate) 250 mg/5 mL granules/powder for syrup/suspension, 30 mL and 60 mL (as monohydrate)
CEFAZOLIN		Inj.: 500 mg and 1 g vial (IM, IV) (as sodium salt)
	cefadroxil	Oral: 250 mg and 500 mg capsule (as monohydrate) 125 mg/5 mL powder for syrup, 60 mL (as monohydrate) 250 mg/5 mL powder for suspension, 60 mL (as monohydrate)
Second Generation		
CEFOXITIN		Inj.: 1 g vial (IM, IV) (as sodium salt)
CEFUROXIME		Oral: 250 mg and 500 mg tablet (as axetil) 125 mg/5 mL granules for suspension, 50 mL and 70 mL (as axetil) 125 mg granules for suspension, per sachet (as axetil) 250 mg/5 mL granules for suspension, 60 mL Inj.: 250 mg and 750 mg vial (IM, IV) 1.5 g vial (IV infusion) (as sodium salt)
Third Generation		
CEFIXIME		Oral: 100 mg and 200 mg capsule **(B)** 20 mg/mL granules for drops (suspension), 10 mL 100 mg/5 mL granules for suspension, 30 mL and 60 mL
CEFOTAXIME		Inj.: 250 mg vial + 2 mL diluent (IM, IV) (as sodium salt) 500 mg vial + 2 mL diluent (IM, IV) (as sodium salt)

	CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
			1 g vial + 4 mL diluent (IM, IV) (as sodium salt)
	CEFTAZIDIME		Inj.: 250 mg, 500 mg and 1 g vial (IM, IV) (as pentahydrate) 2 g vial (IV infusion) (as pentahydrate)
	CEFTRIAXONE		Inj.: 250 mg vial + 2 mL 1% solution of lidocaine (IM) (as disodium/sodium salt) 500 mg vial + 2 mL 1% solution of lidocaine (IM) (as disodium/sodium salt) 250 mg vial + 5 mL diluent (IV) (as disodium/sodium salt) 500 mg vial + 5 mL diluent (IV) (as disodium/sodium salt) 1 g vial + 3.5 mL 1% solution of lidocaine (IM) (as disodium/sodium salt) 1 g vial + 10 mL diluent (IV) (as disodium/sodium salt)
	Fourth Generation		
		cefepime (3)	Inj.: 500 mg, 1 g and 2 g vial (IM, IV) (as hydrochloride)
3.1.5	***CHLORAMPHENICOL*** (also for rickettsiae)		Oral: 250 mg and 500 mg capsule 125 mg/5 mL suspension, 30 mL and 60 mL (as palmitate) Inj.: 1 g vial (IV; IM if recommended by manufacturer) (as sodium succinate)
3.1.6	**Glycopeptide**		
		vancomycin (3)	Inj.: 500 mg and 1 g vial (IV) (as hydrochloride)
3.1.7	**Lincosamide**		
		clindamycin	Oral: 150 mg and 300 mg capsule (as hydrochloride) 75 mg/5 mL granules for suspension, 60 mL (as palmitate hydrochloride)

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
		Inj.: 150 mg/mL, 2 mL ampul/vial and 4 mL ampul (IM, IV) (as phosphate)
3.1.8 Macrolides		
ERYTHROMYCIN (also for mycoplasma, chlamydiae)		Oral: 250 mg base tablet/capsule 250 mg and 500 mg tablet **(B)** (as stearate) 40 mg/mL granules/powder for drops (suspension), 30 mL (as ethyl succinate) 200 mg/5 mL granules/powder for suspension, 60 mL (as ethyl succinate) 400 mg/5 mL granules/powder for suspension, 50 mL and 60 mL (as ethyl succinate)
	azithromycin	Oral: 250 mg capsule (as base*/as dihydrate) 500 mg tablet (as base*/as dihydrate) **(B)** 200 mg/5 mL powder for suspension, 15 mL and 30 mL (as base*/as dihydrate) Inj.: 500 mg powder, vial (IV infusion) (as base*/as dihydrate)
	clarithromycin	Oral: 250 mg and 500 mg base tablet 500 mg MR tablet 125 mg/5 mL granules/powder for suspension, 25 mL, 50 mL and 70 mL
3.1.9 Nitroimidazole		
METRONIDAZOLE		Oral: 250 mg and 500 mg tablet 125 mg base/5 mL (200 mg/5 mL (as benzoate) suspension, 30 mL and 60 mL Inj.: 5 mg/mL, 100 mL vial (IV infusion) Rectal: 1 g suppository
3.1.10 Penicillins		
AMOXICILLIN		Oral: 250 mg and 500 mg capsule (as trihydrate)

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
		100 mg/mL granules/powder for drops (suspension), 10 mL and 15 mL (as trihydrate) 125 mg/5 mL granules/powder for suspension, 30 mL and 60 mL (as trihydrate) 250 mg/5 mL granules/powder for suspension, 30 mL and 60 mL (as trihydrate)
AMPICILLIN		Inj.: 125 mg, 250 mg, 500 mg and 1 g vial (IM, IV) (as sodium salt)
CLOXACILLIN		Oral: 250 mg and 500 mg capsule (as sodium salt) 125 mg/5 mL powder for syrup/ suspension, 60 mL (as sodium salt)
OXACILLIN		Inj.: 250 mg and 500 mg vial (IM, IV) (as sodium salt)
PENICILLIN G BENZATHINE (benzathine benzylpenicillin)		Inj.: 1,200,000 units vial (MR) (IM) 2,400,000 units vial (MR) (IM)
PENICILLIN G CRYSTALLINE (benzylpenicillin)		Inj.: 500,000 units vial (IM, IV) (as sodium salt) 1,000,000 units vial (IM, IV) (as sodium salt) 5,000,000 units vial (IM, IV) (as sodium salt)
PHENOXYMETHYLPENICILLIN (penicillin V)		Oral: 250 mg and 500 mg tablet/capsule (as potassium salt) 125 mg/5 mL granules/powder for syrup/suspension, 30 mL and 60 mL (as potassium salt) 250 mg/5 mL granules/powder for syrup/suspension, 60 mL (as potassium salt)
	ampicillin + sulbactam	Inj.: 250 mg ampicillin + 125 mg sulbactam (as sodium salt) per vial (IM, IV) 500 mg ampicillin + 250 mg sulbactam (as sodium salt) per vial (IM, IV)

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
	co-amoxiclav (amoxicillin + potassium clavulanate)	Oral: 500 mg amoxicillin (as trihydrate) + 125 mg potassium clavulanate per tablet 875 mg amoxicillin (as trihydrate) + 125 mg potassium clavulanate per tablet 125 mg amoxicillin (as trihydrate) + 31 mg potassium clavulanate per 5 mL granules/powder for suspension, 30 mL and 60 mL 200 mg amoxicillin (as trihydrate) + 28.5 mg potassium clavulanate per 5 mL granules/powder for suspension, 70 mL 250 mg amoxicillin (as trihydrate) + 62.5 mg potassium clavulanate per 5 mL granules/powder for suspension, 60 mL and 100 mL 400 mg amoxicillin (as trihydrate) + 57 mg potassium clavulanate per 5 mL granules/powder for suspension, 30 mL and 70 mL
	piperacillin + tazobactam (3)	Inj.: 2 g piperacillin + 250 mg tazobactam per vial (as sodium salt) (IV infusion) 4 g piperacillin + 500 mg tazobactam per vial (as sodium salt) (IV infusion)

3.1.11 Quinolones

First Generation (non-fluorinated)

NALIDIXIC ACID	Oral: 500 mg tablet 250 mg/5 mL suspension, 60 mL

Second Generation (fluorinated)

ciprofloxacin	Oral: 250 mg and 500 mg tablet (as hydrochloride) Inj.: 2 mg/mL, 50 mL and 100 mL vial (IV infusion) (as lactate)
ofloxacin	Oral: 200 mg and 400 mg tablet Inj.: 2 mg/mL, 100 mL vial (IV infusion)

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
Third Generation (flourinated)		
	levofloxacin (3)	Oral: 250 mg, 500 mg and 750 mg tablet Inj.: 5 mg/mL solution for IV infusion, 100 mL vial
3.1.12 Sulfonamide		
COTRIMOXAZOLE (sulfamethoxazole + trimethoprim) (also for *Pneumocystis jiroveci (carinii) and chlamydiae)*		Oral: 400 mg sulfamethoxazole + 80 mg trimethoprim per tablet/capsule **(B)** 800 mg sulfamethoxazole + 160 mg trimethoprim per tablet **(B)** 200 mg sulfamethoxazole + 40 mg trimethoprim per 5 mL suspension, 30 mL, 60 mL and 100 mL 400 mg sulfamethoxazole + 80 mg trimethoprim per 5 mL suspension, 30 mL and 60 mL Inj.: 400 mg sulfamethoxazole + 80 mg trimethoprim, 5 mL ampul (IV infusion)
3.1.13 Tetracyclines (also for chlamydiae, mycoplasma, and rickettsiae)		
DOXYCYCLINE		Oral: 50 mg and 100 mg capsule (as hyclate)
	tetracycline	Oral: 250 mg and 500 mg capsule
3.1.14 Anti - *H. pylori* (in conjunction with bismuth subcitrate or proton pump inhibitor)		
AMOXICILLIN		Oral: 250 mg and 500 mg capsule (as trihydrate) 250 mg/5 mL powder/granules for suspension, 60 mL
CLARITHROMYCIN		Oral: 250 mg and 500 mg base tablet 500 mg MR tablet 125 mg/5 mL granules/powder for suspension, 25 mL, 50 mL and 70 mL
METRONIDAZOLE		Oral: 250 mg and 500 mg tablet 125 mg base/5 mL (200 mg/5 mL) (as benzoate) suspension, 30 mL and 60 mL

	CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
3.1.15	**Antileprosy medicines**		
	★ *CLOFAZIMINE* **(B)**		Oral: 50 mg and 100 mg capsule (available under DOH program)
	DAPSONE **(B)**		Oral: 100 mg tablet
	RIFAMPICIN		Oral: 150 mg, 300 mg, 450 mg and 600 mg tablet/capsule **(B)** 100 mg/5 mL suspension, 30 mL, 60 mL and 120 mL 200 mg/5 mL suspension, 30 mL, 60 mL and 120 mL
		minocycline	Oral: 50 mg and 100 mg capsule
3.1.16	**Antituberculosis medicines**		
	ETHAMBUTOL		Oral: 200 mg and 400 mg tablet (as hydrochloride)
	ISONIAZID		Oral: 100 mg, 300 mg and 400 mg tablet 100 mg/5 mL syrup, 60 mL and 120 mL 200 mg/5 mL syrup, 60 mL and 120 mL
	PYRAZINAMIDE		Oral: 500 mg tablet 250 mg/5 mL suspension, 60 mL and 120 mL
	RIFAMPICIN		Oral: 300 mg, 450 mg and 600 mg tablet/capsule **(B)** 100 mg/5 mL suspension, 30 mL, 60 mL and 120 mL 200 mg/5 mL suspension, 60 mL and 120 mL
	STREPTOMYCIN		Inj.: 1 g vial (IM) (as sulfate)
	ISONIAZID + ETHAMBUTOL		Oral ★ 150 mg + 400 mg tablet ★ 200 mg + 500 mg tablet
	ISONIAZID + RIFAMPICIN **(B)**		Oral ★ 30 mg + 60 mg tablet (pediatric) 60 mg + 60 mg tablet (pediatric) (For intermittent use three times weekly)

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
		★ 75 mg + 150 mg tablet ★ 150 mg + 150 mg tablet (For intermittent use three times weekly) 100 mg + 150 mg tablet 150 mg + 300 mg tablet ★ 200 mg + 225 mg tablet 300 mg + 450 mg tablet 400 mg + 450 mg tablet ★ 600 mg + 400 mg tablet/film coated tablet
ISONIAZID + RIFAMPICIN + ETHAMBUTOL **(B)**		Oral: 75 mg + 150 mg + 275 mg tablet
ISONIAZID + RIFAMPICIN + PYRAZINAMIDE **(B)**		Oral ★ 30 mg + 60 mg + 150 mg tablet (pediatric) (For intermittent use three times weekly) 75 mg + 150 mg + 400 mg tablet ★ 150 mg + 150 mg + 500 mg tablet 300 mg + 450 mg + 500 mg tablet
ISONIAZID + RIFAMPICIN + PYRAZINAMIDE + ETHAMBUTOL **(B)**		Oral: 60 mg + 120 mg + 300 mg + 225 mg tablet 75 mg + 150 mg + 400 mg + 275 mg tablet 200 mg + 450 mg + 500 mg + 400 mg tablet (restricted for 60 days use only)
★ *ISONIAZID + THIACETAZONE*		Oral: 300 mg + 150 mg tablet
<u>For MDR TB (proven isoniazid (H) and rifampicin (R) resistant)</u>		**Restricted to DOH DOTS PLUS Program only**
	amikacin	Inj.: 50 mg/mL, 100 mg/mL, 125 mg/mL, and 250 mg/mL, 2 mL ampul/vial (as sulfate) (IM, IV) 250 mg and 1 g vial (as sulfate) (IM, IV)
	kanamycin	Inj.: 1 g vial (IM) (as sulfate)
	levofloxacin	Oral: 250 mg, 500 mg and 750 mg tablet Inj.: 5 mg/mL, solution for IV infusion 100 mL vial

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
	ofloxacin	Oral: 200 mg and 400 mg tablet Inj.: 2 mg/mL, 100 mL vial (IV)
	★ *rifabutin*	Oral: 150 mg capsule (for HIV/AIDS patient on concomittant protease inhibitor therapy, in lieu of rifampicin)
	★ *terizodone*	Oral: 250 mg capsule
	★ *thiacetazone*	Oral: 150 mg tablet
3.1.17 Urinary antiseptics		
NALIDIXIC ACID		Oral: 500 mg tablet 250 mg/5 mL suspension, 60 mL
NITROFURANTOIN **(B)**		Oral: 50 mg and 100 mg capsule (as macrocrystals)
	norfloxacin	Oral: 200 mg and 400 mg tablet
3.2 ANTIFUNGALS		
AMPHOTERICIN B (1)		
Lipid Complex		Inj.: 50 mg and 100 mg vial (IV infusion) (as cholesteryl complex, colloidal dispersion)
Non-Lipid Complex		Inj.: 50 mg lyophilized powder, vial (IV infusion)
FLUCONAZOLE		Oral: 50 mg, 150 mg and 200 mg capsule Inj.: 2 mg/mL, 100 mL vial (IV infusion)
KETOCONAZOLE		Oral: 200 mg tablet
NYSTATIN		Oral: 500,000 units per tablet 100,000 units/mL suspension, 30 mL
	★ *flucytosine* (1) *(5-fluorocytosine)*	Oral: 500 mg tablet
	griseofulvin (2, **B**)	Oral: 125 mg and 500 mg tablet (microsize)
	itraconazole	Oral: 100 mg capsule

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths

3.3 ANTIPARASITICS

3.3.1 Anthelmintics

Medicines for common roundworm infections

ALBENDAZOLE		Oral: 400 mg chewable tablet **(B)** 200 mg/5 mL suspension, 10 mL, 15 mL, 30 mL and 60 mL
MEBENDAZOLE		Oral: 100 mg tablet/capsule 500 mg tablet/chewable tablet 50 mg/mL suspension, 10 mL 100 mg/5 mL suspension, 30 mL and 60 mL
OXANTEL + PYRANTEL		Oral: 100 mg oxantel + 100 mg pyrantel (as embonate) per tablet 100 mg oxantel + 100 mg pyrantel (as embonate) per 5 mL suspension, 10 mL

Antifilarials

★ *DIETHYLCARBAMAZINE*		Oral: 50 mg and 100 mg tablet (available under DOH program)
★ *ivermectin* **(B)**		Oral: 6 mg tablet (available under DOH program)

Antischistosoma

★ *PRAZIQUANTEL* **(B)** (also for fluke and tapeworm infections including *Cysticercus cellulosae)*		Oral: 600 mg tablet (available under DOH program)

3.3.2 Antiprotozoals

Amebicides

★ *DILOXANIDE*		Oral: 500 mg tablet (as furoate) **(B)** 125 mg/5 mL syrup/suspension, 30 mL and 60 mL (as furoate)

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
METRONIDAZOLE (also for giardiasis, trichomoniasis, balantidiasis, blastocystiasis, and dientamoebiasis)		Oral: 250 mg and 500 mg base tablet 125 mg base/5 mL (200 mg/5 mL) (as benzoate) suspension, 30 mL and 60 mL
	chloroquine	Oral: 250 mg (150 mg base) tablet (as phosphate or diphosphate) Inj.: 50 mg/mL, 20 mL vial (IM, IV) (as phosphate or diphosphate)
Antimalarials		
ARTEMETHER + LUMEFANTRIN **(B)**		Oral: 20 mg artemether + 120 mg lumefantrin tablet
CHLOROQUINE		Oral: 250 mg (150 mg base) tablet (as phosphate or diphosphate) Inj.: 50 mg/mL, 20 mL vial (IM, IV) (as phosphate or diphosphate)
PRIMAQUINE (for radical cure in relapsing malaria)		Oral: 26.3 mg (15 mg base) tablet (as diphosphate)
QUININE		Oral: 325 mg (300 mg base) tablet (as sulfate) Inj.: 300 mg/mL, 1 mL ampul (IV) (as dihydrochloride) 250 mg/mL, 1 mL ampul (IV) (as dihydrochloride)
SULFADOXINE + PYRIMETHAMINE **(B)** (not for prophylaxis; only for clinical suppression)		Oral: 500 mg sulfadoxine + 25 mg pyrimethamine per tablet
TETRACYCLINE (must be used with quinine in chloroquine-resistant falciparum malaria)		Oral: 250 mg and 500 mg capsule
	doxycycline	Oral: 50 mg and 100 mg capsule (as hyclate)
	mefloquine **(B)**	Oral: 250 mg tablet (as hydrochloride)

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
Antipneumocystosis (also antitoxoplasmosis)		
	★ *pyrimethamine* **(B)**	Oral: 25 mg tablet
3.4 ANTIVIRALS		
3.4.1 Antiherpes agents		
ACICLOVIR		Oral: 200 mg, 400 mg and 800 mg tablet 200 mg/5 mL suspension, 60 mL and 120 mL Inj.: 25 mg/mL, 10 mL vial (IV infusion)
	▼ *famciclovir*	Oral: 125 mg tablet 250 mg tablet
	▼ *valaciclovir*	Oral: 500 mg tablet (as hydrochloride)
3.4.2 Anticytomegalovirus		
	ganciclovir (1, 2)	Inj.: 500 mg vial (IV infusion) (as sodium)
3.4.3 Antiretroviral agents		
Nucleoside Reverse Transcriptase Inhibitors (NRTIs)		
	▼ *didanosine*	Oral: 250 mg MR capsule 200 mg chewable and dispersable tablet
	lamivudine	Oral: 100 mg tablet
	stavudine	Oral: 20 mg, 30 mg and 40 mg capsule
	zalcitabine	Oral: 375 microgram tablet
	zidovudine	Oral: 100 mg capsule
Non-Nucleoside Reverse Transcriptase Inhibitor (NNRTI)		
	nevirapine	Oral: 200 mg tablet **(B)** 50 mg/5 mL suspension, 240 mL
Protease Inhibitors (PIs)		
	indinavir **(B)**	Oral: 200 mg and 400 mg capsule (as sulfate)

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
	nelfinavir	Oral: 250 mg film coated tablet (as mesilate) **(B)** ▼ 250 mg tablet (as mesilate) **(B)** ▼ 50 mg/scoop (1 g) powder, 144 g bottle to be mixed with water, milk or food (as mesilate)
	★ *ritonavir* **(B)**	Oral: 100 mg capsule
	saquinavir **(B)**	Oral: 200 mg capsule (as base or mesilate)
3.4.4 Anti-influenza A & B		
	oseltamivir	Oral: 75 mg capsule (as phosphate) 12 mg/mL powder for suspension, 60 mL

4 IMMUNOLOGICALS

4.1 DIAGNOSTIC AGENT

TUBERCULIN, PURIFIED PROTEIN DERIVATIVE (PPD)	Inj.:	2 TU/0.1 mL solution, 5 mL vial (ID) 5 TU/0.1 mL, freeze-dried powder, vial + 2 mL diluent ampul (ID)

4.2 SERA AND IMMUNOGLOBULINS

COBRA ANTIVENIN	Inj.:	800 MU/ 4.8 mL, 1 mL ampul (for IV infusion)
★ *DIPHTHERIA ANTITOXIN*	Inj.:	10,000 IU and 20,000 IU, 5 mL and 10 mL (IV)
HEPATITIS B IMMUNOGLOBULIN (human)	Inj.:	0.5 mL, 1 mL and 2 mL vial (IM)
IMMUNOGLOBULIN NORMAL, HUMAN (IGIM)	Inj.:	160 mg/mL, 2 mL, 5 mL and 10 mL vial (IM)
RABIES IMMUNOGLOBULIN (human)	Inj.:	150 IU/mL, 2 mL and 5 mL vial (IM) 150 IU/mL, 2mL, 5 mL and 10 mL ampul (IM)
TETANUS IMMUNOGLOBULIN (human)	Inj.:	1000 IU/mL, 1.5 mL vial (IM) 1500 IU/mL, 1 mL ampul (IM) 250 IU/mL, 1 mL, 2 mL and 4 mL ampul (IM) 250 IU/mL, 1 mL pre-filled syringe (IM) 250 units/mL, 1 mL and 2 mL vial (IM)
anti-D immunoglobulin (human anti-D immunoglobulin)	Inj.:	200 micrograms/mL, 1.5 mL ampul (IM)
+ *anti-rabies serum (equine)*	Inj.:	200 IU/mL, 5 mL vial (IM) 400 IU/mL, 5 mL vial (IM)
+ *anti-tetanus serum (equine)*	Inj.:	4000 IU/mL, 2.5 mL vial (IM) 1500 IU/mL, 1 mL and 1.5 mL vial/ampul (IM)

+ - Use with extreme caution as alternative to human immunoglobulin (tetanus or rabies) when unavailable; informed consent and skin test required.

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths	
	immunoglobulin normal, human (IGIV) (1)	Inj.:	50 mg/mL, 10 mL, 20 mL, 50 mL, 100 mL and 200 mL vial (IV) freeze-dried powder, 1 g/bottle + 33 mL and 50 mL reconstitution fluid (IV) freeze-dried powder, 2.5 g/bottle + 100 mL reconstitution fluid (IV) freeze-dried powder, 5 g/bottle + 100 mL diluent vial (IV) freeze-dried powder, 10 g/bottle + 260 mL diluent vial (IV)
	★ *varicella zoster immunoglobulin (VZIG)*	Inj.:	125 units/1.25 mL vial (IM)
4.3 VACCINES			
BCG VACCINE		Inj.:	freeze-dried powder, 100 micrograms/0.1 mL, 1 mL, 1.5 mL and 2 mL vial (ID) 500 micrograms/mL vial + 1 mL diluent in ampul (ID) 20 doses
DIPHTHERIA-TETANUS TOXOIDS AND PERTUSSIS VACCINE (DTP)		Inj.:	0.5 mL ampul (IM) 0.5 mL pre-filled syringe (IM) 0.5 mL, 5 mL, 7.5 mL and 10 mL vial (IM)
DIPHTHERIA-TETANUS TOXOIDS (DT)		Inj.:	30 IU diphtheria toxoid + 40 IU tetanus toxoid per 0.5 mL ampul (IM) (For less than 10 yrs. old)
DIPHTHERIA-TETANUS TOXOIDS (Td)		Inj.:	2 IU diphtheria toxoid + 20 IU tetanus toxoid per 0.5 mL ampul (IM) (For 10 yrs. old and above)
DIPHTHERIA-TETANUS TOXOIDS AND ACELLULAR PERTUSSIS VACCINES (DTaP)		Inj.:	0.5 mL pre-filled syringe (IM)
HEMOPHILUS INFLUENZAE type b CONJUGATE VACCINE (Hib)		Inj.:	10 micrograms/0.5 mL, 1 dose vial + 0.5 mL diluent with tetanus protein (IM) 10 micrograms/0.5 mL vial + 0.9% sodium chloride with diphtheria CRM 197 protein (IM)

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths	
			0.5 mL vial with meningococcal protein (IM)
DTP + Hib		Inj.:	0.5 mL DTP diluent in pre-filled syringe + freeze-dried, 10 microgram Hib vial (IM, SC)
DTP + INACTIVATED POLIO VACCINE (IPV)		Inj.:	0.5 mL monodose vial (IM, SC) 0.5 mL pre-filled syringe (IM, SC)
DTP + IPV + Hib		Inj.:	0.5 mL pre-filled syringe (IM, SC)
DTaP + Hib		Inj.:	0.5 mL pre-filled syringe (IM)
DTP + HEPATITIS B VACCINE (recombinant)		Inj.:	0.5 mL vial (IM, SC)
HEPATITIS A INACTIVATED VACCINE		Inj.:	viral antigen not less than 720 EU in 0.5 mL monodose vial (IM) (junior) viral antigen not less than 1440 EU in 1.0 mL monodose vial (IM) (adult) 80 units/0.5 mL (GBM strain) pre-filled syringe single dose (IM) (pediatric) 160 units/0.5 mL (GBM strain) pre-filled syringe single dose (IM) (adult)
HEPATITIS B VACCINE (recombinant DNA)		Inj.:	10 micrograms/0.5 mL monodose vial (IM) (pediatric) 20 micrograms/mL monodose vial (IM) adult (For more than 10 years old) 20 micrograms/mL, 1 mL, 5 mL and 10 mL vial (IM) N.B.: Formulations of different manufacturers are of equal or similar immunogenicity. Follow strictly the recommended dose of each manufacturer.
INFLUENZA POLYVALENT VACCINE		Inj.:	0.5 mL vial + pre-filled syringe diluent (IM)

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
		0.5 mL suspension in a pre-filled syringe or ampul (IM) (adult) N.B.: Strains as recommended by WHO
	LIVE ATTENUATED MEASLES VACCINE	Inj.: monodose vial + 0.5 mL diluent (SC) multidose vial + 5 mL diluent (SC)
	LIVE ATTENUATED MEASLES, MUMPS, AND RUBELLA (MMR) VACCINE	Inj.: monodose vial + 0.5 mL diluent (SC) multidose vial + 5 mL diluent (SC)
	LIVE ATTENUATED MUMPS VACCINE	Inj.: monodose vial + 0.5 mL diluent (SC)
	LIVE ATTENUATED RUBELLA VACCINE	Inj.: monodose vial + 0.5 mL diluent (SC) multidose vial + 5 mL diluent (SC)
	LIVE ATTENUATED TRIVALENT ORAL POLIO VACCINE	Oral: 0.5 mL plastic tube and 0.5 mL vial 1 mL vial (10) doses and 2 mL vial (20) doses or plastic tube with vaccine vial monitor (For DOH Mass Immunization Program Only)
	LIVE ATTENUATED VARICELLA VACCINE	Inj.: freeze-dried powder, not less than 2000 PFU (OKA strain varicella zoster virus) monodose vial + diluent (0.5 mL water for injection) ampul (SC only)
▼	*PNEUMOCOCCAL CONJUGATE VACCINE*	Inj.: 7- valent suspension, pre-filled syringe (IM)
	PNEUMOCOCCAL POLYVALENT VACCINE	Inj.: 25 micrograms/0.5 mL (polysaccharide from each capsular type) in 0.5 mL pre-filled syringe (IM, SC)
	RABIES VACCINES	
	CHICK EMBRYO CELL (purified, inactivated)	Inj.: lyophilized powder, 2.5 IU/mL, 1 dose vial + 1 mL diluent (ID, IM)
	VERO CELL (purified)	Inj.: lyophilized powder, 2.5 IU/ 0.5 mL, vial + diluent (ID, IM) 2.5 IU/mL suspension, 1 mL vial (IM)

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
TETANUS TOXOID		Inj.: 0.5 mL ampul (IM) 5 mL and 10 mL vial (IM)
TYPHOID VACCINE		Oral: live-attenuated *S. typhi* (not less than 109) viable strain, enteric coated tablet (encapsulated) Inj.: Vi-capsular polysaccharide *S. typhi* 25 micrograms in 0.5 mL pre-filled syringe (IM)
YELLOW FEVER VACCINE		Inj.: 1000 DL 50 mouse min (attenuated) vial + 0.5 mL solvent syringe (IM, SC) (For Bureau of Quarantine Use Only)
	meningococcal polysaccharide (Neisseria meningitidis) vaccine	Inj.: lyophilized powder, 50 micrograms/ 0.5 mL dose (Group A + C) multidose (10 doses) + 5 mL diluent vial (IM, SC) lyophilized powder, 50 micrograms/ 0.5 mL dose (Group A + C) single dose + 0.5 mL diluent syringe (IM, SC) lyophilized powder, 50 micrograms/ 0.5 mL dose (Serogroup A + Serogroup B + Serogroup W135 + Serogroup Y) multidose (10 doses) + diluent vial (IM, SC)
	▼ *human papillomavirus quadrivalent (types 6, 11, 16, 18) recombinant vaccine*	Inj.: 0.5 mL suspension, glass pre-filled syringe (IM)

5 CARDIOVASCULAR MEDICINES

5.1 CARDIOACTIVE AGENTS

5.1.1 Inotropic agents

Cardiac glycoside

DIGOXIN (2) (also for supraventricular tachycardia)	Oral: 250 microgram tablet 50 micrograms/mL elixir, 60 mL Inj.: 250 micrograms/mL, 2 mL ampul (IM, IV)

Adrenergic agents

DOBUTAMINE (1, 2)	Inj.: 12.5 mg/mL, 20 mL vial (IV) (as hydrochloride) 50 mg/mL, 5 mL ampul (concentrate) (IV infusion) (as hydrochloride) 1 mg/mL, 250 mL D5W (pre-mixed) (IV) (as hydrochloride) 2 mg/mL, 250 mL D5W (pre-mixed) (IV) (as hydrochloride) 4 mg/mL, 250 mL D5W (pre-mixed) (IV) (as hydrochloride)
DOPAMINE (1, 2)	Inj.: 40 mg/mL, 5 mL vial/ampul (IV) (as hydrochloride) 80 mg/mL, 5 mL vial (IV) (as hydrochloride) 800 micrograms/mL, 250 mL D5W (pre-mixed) (IV) (as hydrochloride) 1.6 mg/mL, 250 mL D5W (pre-mixed) (IV) (as hydrochloride) 3.2 mg/mL, 250 mL D5W (pre-mixed) (IV) (as hydrochloride)
EPINEPHRINE (2) *(adrenaline)*	Inj.: 1 mg/mL, 1 mL ampul (IM, SC) (as hydrochloride)
NOREPINEPHRINE (1)	Inj.: 1 mg/mL, 2 mL ampul (IV infusion) (as bitartrate)

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
5.1.2 Antianginal agents		
Nitrates		
GLYCERYL TRINITRATE (nitroglycerin)		Inj.: 1 mg/mL, 5 mL, 10 mL, 25 mL ampul and 50 mL glass vial (IV infusion) (only for unstable angina) (1, 2) Patch: 5 mg and 10 mg Sublingual: 400 microgram tablet
ISOSORBIDE DINITRATE		Oral: 5 mg, 10 mg and 20 mg tablet 20 mg and 40 mg MR tablet/capsule Sublingual: 5 mg tablet Inj.: 1 mg/mL, 10 mL ampul (IV) (1)
ISOSORBIDE - 5 - MONONITRATE		Oral: 20 mg and 40 mg tablet 60 mg MR tablet/capsule
Beta-adrenoceptor blockers		
ATENOLOL (cardioselective/no ISA)		Oral: 50 mg and 100 mg tablet
METOPROLOL (cardioselective/no ISA)		Oral: 50 mg and 100 mg tablet (as tartrate)
PROPRANOLOL (non-cardioselective/no ISA)		Oral: 10 mg and 40 mg tablet (as hydrochloride) 40 mg MR capsule (as hydrochloride)
Calcium channel blockers		
DILTIAZEM		Oral: 30 mg and 60 mg tablet (as hydrochloride) 60 mg, 90 mg, 120 mg and 180 mg MR capsule (as hydrochloride) 90 mg, 120 mg and 180 mg MR tablet (as hydrochloride)
	verapamil	Oral: 40 mg and 80 mg tablet (as hydrochloride) **(B)** 120 mg and 240 mg MR capsule (as hydrochloride) 180 mg and 240 mg MR tablet (as hydrochloride)

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
Fatty acid oxidation (pFOX) inhibitor		
	trimetazidine	Oral: 20 mg and 35 mg tablet (as hydrochloride)
5.1.3 Medicines for acute coronary syndrome		
Nitrates (see under Section 5.1.2)		
Anticoagulants		
HEPARIN		
LOW MOLECULAR WEIGHT HEPARIN		
▼ *ENOXAPARIN* (1, 2)		Inj.: 100 mg/mL, 0.2 mL, 0.4 mL, 0.6 mL and 0.8 mL pre-filled syringe (SC) (as sodium salt) 100 mg/mL, 1 mL vial (SC) (as sodium salt)
UNFRACTIONATED HEPARIN (1, 2)		Inj.: 1000 IU/mL and 5000 IU/mL, 5 mL vial (IV, SC) (as sodium salt)
WARFARIN (1, 2)		Oral: 1 mg, 2.5 mg and 5 mg tablet
Antithrombotics		
ASPIRIN		Oral: 80 mg tablet
	clopidogrel	Oral: 75 mg tablet
	▼ *fondaparinux*	Inj.: 2.5 mg/0.5 mL solution (as sodium salt)
Thrombolytic (Fibrinolytic)		
STREPTOKINASE (1, 2)		Inj.: 750,000 IU and 1,500,000 IU vial (IV infusion)
Angiotensin-converting enzyme (ACE) inhibitors		
CAPTOPRIL		Oral: 25 mg and 50 mg tablet
ENALAPRIL		Oral: 5 mg, 10 mg and 20 mg tablet (as maleate)

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
Beta-adrenoceptor blockers		
ATENOLOL (cardioselective/no ISA)		Oral: 50 mg and 100 mg tablet
METOPROLOL (cardioselective/no ISA)		Oral: 50 mg and 100 mg tablet (as tartrate)
PROPRANOLOL (non-cardioselective/no ISA)		Oral: 10 mg and 40 mg tablet (as hydrochloride)
Opioid analgesic		
MORPHINE (A1)		Inj.: 10 mg/mL, 1 mL ampul (IM, IV, SC) (as sulfate) 15 mg/mL, 1 mL ampul (IM, IV, SC) (as sulfate)
5.1.4 Post-myocardial infarction maintenance medicines		
Antithrombotic		
ASPIRIN		Oral: 80 mg tablet
Beta-adrenoceptor blockers		
ATENOLOL (cardioselective/no ISA)		Oral: 50 mg and 100 mg tablet
METOPROLOL (cardioselective/no ISA)		Oral: 50 mg and 100 mg tablet (as tartrate)
PROPRANOLOL (non-cardioselective/no ISA)		Oral: 10 mg and 40 mg tablet (as hydrochloride) 40 mg MR capsule (as hydrochloride)
Angiotensin-converting enzyme (ACE) inhibitors		
CAPTOPRIL		Oral: 25 mg and 50 mg tablet
ENALAPRIL		Oral: 5 mg, 10 mg and 20 mg tablet (as maleate)
Angiotensin-2-receptor blockers (ARBs)		
	irbesartan	Oral: 75 mg, 150 mg and 300 mg tablet

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
	losartan	Oral: 50 mg and 100 mg tablet (as potassium salt)
	telmisartan	Oral: 40 mg and 80 mg tablet
	valsartan	Oral: 80 mg and 160 mg tablet/film coated tablet
5.1.5 Antiarrhythmic agents		
Ventricular		
AMIODARONE (2)		Oral: 200 mg tablet (as hydrochloride) Inj.: 50 mg/mL, 3 mL ampul (IV) (as hydrochloride)
LIDOCAINE (1, 2)		Inj.: 20 mg/mL, 5 mL ampul/vial (IM, IV) (as hydrochloride) 100 mg/mL, 5 mL ampul (IV infusion) (as hydrochloride) 4 mg/mL, 250 mL D5W (pre-mixed) (IV) (as hydrochloride)
	magnesium sulfate (1, 2)	Inj.: 250 mg/mL, 2 mL and 10 mL ampul (IV) (as heptahydrate) 250 mg/mL, 20 mL and 50 mL vial (IV) (as heptahydrate) 500 mg/mL, 2 mL and 10 mL ampul (IV) (as heptahydrate)
Supraventricular		
AMIODARONE (2)		Oral: 200 mg tablet (as hydrochloride) Inj.: 50 mg/mL, 3 mL ampul (IV) (as hydrochloride) (2)
ATENOLOL (cardioselective/no ISA)		Oral: 50 mg and 100 mg tablet
METOPROLOL (cardioselective/no ISA)		Oral: 50 mg and 100 mg tablet (as tartrate)
PROPRANOLOL (non-cardioselective/no ISA)		Oral: 10 mg and 40 mg tablet (as hydrochloride) 40 mg MR capsule (as hydrochloride) (for maintenance therapy)

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
DIGOXIN (2)		Oral: 250 microgram tablet 50 mg/mL elixir, 60 mL Inj.: 250 micrograms/mL, 2 mL ampul (IM, IV)
	adenosine (1, 2)	Inj.: 3 mg/mL, 2 mL vial (IV) (For SVT)
	diltiazem	Oral: 30 mg and 60 mg tablet (as hydrochloride) 90 mg, 120 mg, 180 mg and 240 mg MR capsule (as hydrochloride) (for maintenance therapy) 90 mg, 120 mg and 180 mg MR tablet (as hydrochloride) (for maintenance therapy)
	★ *esmolol* (1, 2)	Inj.: 10 mg/mL, 10 mL vial (IV) (as hydrochloride)
	verapamil	Oral: 40 mg and 80 mg tablet (as hydrochloride) **(B)** 120 mg and 240 mg MR capsule (as hydrochloride) (for maintenance therapy) 180 mg and 240 mg MR tablet (as hydrochloride) (for maintenance therapy) Inj.: 2.5 mg/mL, 2 mL ampul (IV) (as hydrochloride) (1, 2)

5.1.6 Anticongestive heart failure

Antialdosterone / renin angiotensin aldosterone (RAA) modulator

SPIRONOLACTONE **(B)**		Oral: 25 mg, 50 mg and 100 mg tablet

Diuretics

FUROSEMIDE		Oral: 20 mg, 40 mg and 80 mg tablet **(B)** Inj.: 10 mg/mL, 2 mL ampul (IM, IV) 10 mg/mL, 25 mL ampul (IV infusion)
	bumetanide	Oral: 1 mg tablet Inj.: 500 micrograms/mL, 4 mL ampul (IM, IV)

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
Cardiac glycoside		
DIGOXIN (2)		Oral: 250 microgram tablet 50 micrograms/mL elixir, 60 mL Inj.: 250 micrograms/mL, 2 mL ampul (IM, IV)
Angiotensin-converting enzyme (ACE) inhibitors		
CAPTOPRIL		Oral: 25 mg and 50 mg tablet
ENALAPRIL		Oral: 5 mg, 10 mg and 20 mg tablet (as maleate)
Combined alpha and beta-adrenoceptor blocker		
CARVEDILOL		Oral: 6.25 mg tablet 25 mg tablet
Beta-adrenoceptor blockers		
METOPROLOL (cardioselective/no ISA)		Oral: 50 mg and 100 mg tablet (as tartrate)
	bisoprolol	Oral: 2.5 mg and 5 mg tablet (as fumarate)
5.2 ANTIHYPERTENSIVES		
5.2.1 Diuretics		
HYDROCHLOROTHIAZIDE		Oral: 25 mg and 50 mg tablet
	indapamide	Oral: 1.5 mg MR tablet
5.2.2 Antiadrenergics		
Beta-adrenoceptor blockers		
ATENOLOL (cardioselective/no ISA)		Oral: 50 mg and 100 mg tablet
METOPROLOL (cardioselective/no ISA)		Oral: 50 mg and 100 mg tablet (as tartrate)
PROPRANOLOL (non-cardioselective/no ISA)		Oral: 10 mg and 40 mg tablet (as hydochloride) 40 mg MR capsule (as hydrochloride)

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
Centrally acting antihypertensives (alpha-2 adrenoceptor agonists)		
	clonidine	Oral: 75 microgram and 150 microgram tablet (as hydrochloride) Inj.: 150 micrograms/mL, 1 mL ampul (IV) (as hydrochloride)
	methyldopa	Oral: 125 mg and 250 mg tablet
5.2.3 Direct vasodilators		
GLYCERYL TRINITRATE (1) *(nitroglycerin)*		Inj.: 1 mg/mL, 5 mL, 10 mL and 25 mL ampul (IV) 1 mg/mL, 50 mL vial (IV infusion) (especially with unstable angina)
HYDRALAZINE		Oral: 10 mg, 25 mg and 50 mg tablet (as hydrochloride) Inj.: 20 mg/mL, 1 mL ampul (IM, IV) (as hydrochloride)
★ *SODIUM NITROPRUSSIDE* (1, 2)		Inj.: 50 mg powder ampul (IV infusion)
5.2.4 Calcium channel blockers		
NIFEDIPINE		Oral: 20 mg and 30 mg MR tablet
	amlodipine	Oral: 5 mg and 10 mg tablet (as besilate/ camsylate)
	felodipine	Oral: 2.5 mg, 5 mg and 10 mg MR tablet
	nicardipine	Oral: 10 mg and 20 mg tablet (as hydrochloride) ▼ Inj.: 1 mg/mL, 2 mL and 10 mL ampul (IV) (as hydrochloride) (1)
	nifedipine	Oral: 5 mg and 10 mg capsule **(B)** (restricted use for acute hypertensive emergencies in patients less than 18 years old with extreme caution due to rapid and prolonged fall in blood pressure)
	nimodipine	▼ Oral: 30 mg tablet Inj.: 200 micrograms/mL, 50 mL vial (IV infusion)

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
		10 mg solution, 50 mL vial (IV infusion) (1, 2)
5.2.5 Angiotensin-converting enzyme (ACE) inhibitors		
CAPTOPRIL		Oral: 25 mg and 50 mg tablet
ENALAPRIL		Oral: 5 mg, 10 mg and 20 mg tablet (as maleate)
5.2.6 Angiotensin-2-receptor blockers (ARBs)		
	candesartan	Oral: 8 mg and 16 mg tablet (as cilexetil)
	eprosartan	Oral: 600 mg tablet (as mesilate)
	irbesartan	Oral: 75 mg, 150 mg and 300 mg tablet
	losartan	Oral: 50 mg and 100 mg tablet (as potassium salt)
	telmisartan	Oral: 40 mg and 80 mg tablet
	valsartan	Oral: 80 mg and 160 mg tablet/film coated tablet
Fixed-dose combinations		
	enalapril + hydrochlorothiazide	Oral: 20 mg enalapril + 12.5 mg hydrochlorothiazide tablet
	irbesartan + hydrochlorothiazide	Oral: 150 mg irbesartan + 12.5 mg hydrochlorothiazide tablet 300 mg irbesartan + 12.5 mg hydrochlorothiazide tablet
	losartan + hydrochlorothiazide	Oral: 50 mg losartan + 12.5 mg hydrochlorothiazide tablet 100 mg losartan + 25 mg hydrochlorothiazide tablet
	▼ *telmisartan + hydrochlorothiazide*	Oral: 40 mg telmisartan + 12.5 mg hydrochlorothiazide tablet 80 mg telmisartan + 12.5 mg hydrochlorothiazide tablet
	▼ *valsartan + hydrochlorothiazide*	Oral: 80 mg valsartan + 12.5 mg hydrochlorothiazide tablet

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
		160 mg valsartan + 12.5 mg hydrochlorothiazide tablet
5.3 MEDICINES FOR BLOOD LIPID DISORDERS		
Hypercholesterolemia		
SIMVASTATIN (1)		Oral: 10 mg, 20 mg and 40 mg tablet
▼ *rosuvastatin*		Oral: 10 mg and 20 mg tablet (as calcium salt)
Hypertriglyceridemia		
fenofibrate (1)		Oral: 67 mg, 100 mg and 200 mg capsule 160 mg tablet
5.4 MEDICINES FOR SHOCK		
5.4.1 Anaphylactic shock		
CORTICOSTEROIDS (parenteral) (See Section 8.3)		
EPINEPHRINE (1, 2) *(adrenaline)*		Inj.: 1 mg/mL, 1 mL ampul (IM, SC) (as hydrochloride)
H1-RECEPTOR ANTAGONISTS (ANTIHISTAMINES) (parenteral) (See Section 8.1)		
H2-RECEPTOR ANTAGONISTS (See Section 8.2)		
5.4.2 Cardiogenic / Vascular shock		
DOBUTAMINE (1, 2)		Inj.: 12.5 mg/mL, 20 mL vial (IV) (as hydrochloride) 50 mg/mL, 5 mL ampul (concentrate) (IV infusion) (as hydrochloride) 1 mg/mL, 250 mL D5W (pre-mixed) (IV) (as hydrochloride) 2 mg/mL, 250 mL D5W (pre-mixed) (IV) (as hydrochloride) 4 mg/mL, 250 mL D5W (pre-mixed) (IV) (as hydrochloride)

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
DOPAMINE	(1, 2)	Inj.: 20 mg/mL, 5 mL and 10 mL ampul (IV) (as hydrochloride) 40 mg/mL, 5 mL vial/ampul (IV) (as hydrochloride) 80 mg/mL, 5 mL vial (IV) (as hydrochloride) 800 micrograms/mL, 250 mL D5W (pre-mixed) (IV) (as hydrochloride) 1.6 mg/mL, 250 mL D5W (pre-mixed) (IV) (as hydrochloride) 3.2 mg/mL, 250 mL D5W (pre-mixed) (IV) (as hydrochloride)
EPINEPHRINE *(adrenaline)*	(1, 2)	Inj.: 1 mg/mL, 1 mL ampul (IM, SC) (as hydrochloride)
NOREPINEPHRINE	(1, 2)	Inj.: 1 mg/mL, 2 mL ampul (IV infusion) (as bitartrate)

5.4.3 Hemorrhagic / Hypovolemic shock

BLOOD PRODUCTS AND BLOOD SUBSTITUTES
(See Section 11)

IV FLUIDS
(also used in other forms of shock)
(See Section 16)

PLASMA EXPANDERS
(See Section 11.1)

5.4.4 Septic shock

ANTIMICROBIALS
(See Section 3)

5.5 CHRONOTROPIC AGENT

ATROPINE	(1, 2)	Inj.: 1 mg/mL, 1 mL ampul (IM, IV, SC) (as sulfate)

5.6 MEDICINES FOR PERIPHERAL ARTERY OCCLUSIVE DISEASE

ASPIRIN		Oral: 80 mg tablet

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
CILOSTAZOL		Oral: 50 mg and 100 mg tablet
HEPARIN		
LOW MOLECULAR WEIGHT HEPARIN		
▼ *ENOXAPARIN* (1, 2)		Inj.: 100 mg/mL, 0.2 mL, 0.4 mL, 0.6 mL and 0.8 mL, pre-filled syringe (SC) (as sodium salt)
UNFRACTIONATED HEPARIN (1, 2)		Inj.: 1000 IU/mL, 5000 IU/mL, 5 mL vial (IV, IV infusion, SC) (as sodium salt)
WARFARIN (1, 2)		Oral: 2.5 mg and 5 mg tablet
	clopidogrel	Oral: 75 mg tablet

5.7 MEDICINES FOR VENOUS THROMBOSIS / THROMBOEMBOLISM (ANTICOAGULANT)

LOW MOLECULAR WEIGHT HEPARIN		
▼ *ENOXAPARIN* (1, 2)		Inj.: 100 mg/mL, 0.2 mL, 0.4 mL, 0.6 mL and 0.8 mL pre-filled syringe (SC) (as sodium salt)
UNFRACTIONATED HEPARIN (1, 2)		Inj.: 1,000 IU/mL; 5,000 IU/mL, 5 mL vial (IV, IV infusion, SC) (as sodium salt)
WARFARIN (1, 2)		Oral: 2.5 mg and 5 mg tablet

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
6 DIURETICS		
FUROSEMIDE		Oral: 20 mg and 40 mg tablet **(B)** Inj.: 10 mg/mL, 2 mL ampul (IM, IV, IV infusion)
HYDROCHLOROTHIAZIDE		Oral: 25 mg and 50 mg tablet
MANNITOL		Inj.: 20%, 250 mL and 500 mL bottle (IV)
	bumetanide	Oral: 1 mg tablet Inj.: 500 micrograms/mL, 4 mL ampul (IM, IV)
	● *sambong [Blumea balsamifera (L) DC (* Fam. Compositae*)]*	Oral: 250 mg and 500 mg tablet
	spironolactone (2, **B**) (K-sparer)	Oral: 25 mg, 50 mg and 100 mg tablet

7 RESPIRATORY MEDICINES

7.1 ANTIASTHMA

7.1.1 Relievers (quick relief / rescue medications)

Bronchodilators

SALBUTAMOL

Oral: 2 mg tablet (as sulfate)
2 mg/5 mL syrup, 30 mL, 60 mL and 120 mL (as sulfate)

Inhalation:
Dry Powder Inhaler (DPI):
200 micrograms/dose (as sulfate) with appropriate accompanying dispenser
400 micrograms/dose (as sulfate) with appropriate accompanying dispenser
Metered Dose Inhaler (MDI):
100 micrograms/dose x 200 and 300 doses (as sulfate)
Breath Actuated MDI:
100 micrograms/dose x 200 doses (as sulfate)
100 micrograms/dose x 400 doses (as sulfate)
Resp. Soln.: (for nebulization)
1 mg/mL, 2.5 mL (unit dose) (as sulfate)
1 mg/mL, 30 mL bottle (as sulfate)
2 mg/mL, 2.5 mL (unit dose) (as sulfate)
5 mg/mL, 10 mL and 20 mL (multidose) (as sulfate)

TERBUTALINE

Oral: 2 mg and 2.5 mg tablet (as sulfate)
1.5 mg/5 mL syrup, 60 mL and 120 mL (as sulfate)
Inhalation:
DPI: 500 micrograms/dose x 100 doses (as sulfate) with appropriate accompanying dispenser

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
		Resp. Soln.: (for nebulization) 2.5 mg/mL, 2 mL (unit dose) (as sulfate) 2.5 mg/mL, 15 mL and 30 mL (multidose) (as sulfate) Inj.: 500 micrograms/mL, 1 mL ampul (IM, IV, SC) (as sulfate)
	aminophylline (theophylline ethylenediamine) (1)	Inj.: 25 mg/mL, 10 mL ampul (IV)
	epinephrine (adrenaline)	Inj.: 1 mg/mL, 1 mL ampul (IM, SC) (as hydrochloride)
	ipratropium	Inhalation: MDI: 20 micrograms/dose x 200 doses (as bromide) Resp. Soln.: (for nebulization) 250 micrograms/mL, 1 mL and 2 mL (unit dose) (as bromide) 250 micrograms/mL, 20 mL (multidose) (as bromide)
	● *lagundi [Vitex negundo L. (* Fam. Verbenaceae*)]*	Oral: 300 mg and 600 mg tablet 300 mg/5 mL syrup, 60 mL and 120 mL bottle
	theophylline (anhydrous)	Oral: 125 mg, 150 mg, 200 mg and 300 mg tablet **(B)** 25 mg/5 mL (26.7 mg/5 mL) syrup, 60 mL and 120 mL
Corticosteroids		
HYDROCORTISONE		Inj.: 50 mg/mL, 2 mL vial (IM, IV) (as sodium succinate) 125 mg/mL, 2 mL and 4 mL vial (IV) (as sodium succinate) powder, 100 mg, 250 mg and 500 mg vial (IV) (as sodium succinate)
PREDNISOLONE		Oral: 5 mg and 20 mg tablet 15 mg/5 mL syrup, 20 mL, 30 mL and 60 mL (as sodium phosphate) 20 mg/5 mL syrup, 30 and 60 mL (as sodium phosphate)

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
PREDNISONE		Oral: 5 mg, 10 mg and 20 mg tablet 30 mg film coated tablet 10 mg/5 mL suspension, 30 mL and 60 mL
	methylprednisolone	Oral: 4 mg and 16 mg tablet Inj.: 40 mg/mL, 1 mL suspension vial (IM) (as acetate) powder, 125 mg/mL, 2 mL vial + diluent vial (IM, IV, IV infusion) (as sodium succinate) powder, 500 mg, 7.7 mL vial (IV) + diluent vial (IM, IV, IV infusion) (as sodium succinate) powder, 1 g/16 mL vial + diluent vial (IM, IV, IV infusion) (as sodium succinate)

7.1.2 Controllers (prophylactic / maintenance medications)

Bronchodilators (symptom controllers)

●	*lagundi* *[Vitex negundo L.* *(* Fam. Verbenaceae*)]*	Oral: 300 mg and 600 mg tablet 300 mg/5 mL syrup, 60 mL and 120 mL bottle
	salbutamol	Oral: 4 mg and 8 mg MR tablet (as sulfate)
	terbutaline	Oral: 5 mg MR tablet (as sulfate)
	theophylline (anhydrous)	Oral: 125 mg, 200 mg, 250 mg and 300 mg MR tablet 400 mg MR tablet/capsule

Corticosteroids (inflammation controllers)

BUDESONIDE	Inhalation: DPI: 100 micrograms/dose x 200 doses with appropriate accompanying dispenser 200 micrograms/dose x 100 doses and 300 doses with appropriate accompanying dispenser 400 micrograms/dose x 50 doses with appropriate accompanying dispenser

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
		MDI: 200 micrograms/dose x 100 doses Resp. Soln.: (for nebulization) 250 micrograms/mL, 2 mL (unit dose) 500 micrograms/mL, 2 mL (unit dose)
FLUTICASONE		Inhalation: DPI: 50 micrograms/dose (as propionate) with appropriate accompanying dispenser 250 micrograms/dose (as propionate) with appropriate accompanying dispenser MDI: 50 micrograms/dose x 60 doses and 120 doses (as propionate) 125 micrograms/dose x 60 doses and 120 doses (as propionate) Resp. Soln.: (for nebulization) 250 micrograms/mL, 2 mL (unit dose) (as propionate)
	beclometasone	Inhalation: DPI: 100 micrograms/dose (as dipropionate) with appropriate accompanying dispenser 200 micrograms/dose (as dipropionate) with appropriate accompanying dispenser 400 micrograms/dose (as dipropionate) with appropriate accompanying dispenser MDI: 50 micrograms/dose x 100 and 200 doses (as dipropionate) 250 micrograms/dose x 200 doses (as dipropionate) Breath Actuated MDI: 50 micrograms/dose x 200 doses (as dipropionate) 100 micrograms/dose x 200 doses (as dipropionate)

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
		250 micrograms/dose x 200 doses (as dipropionate)
	methylprednisolone	Oral: 4 mg and 16 mg tablet
	prednisolone	Oral: 5 mg and 20 mg tablet 15 mg/5 mL syrup, 20 mL, 30 mL and 60 mL (as sodium phosphate) 20 mg/5 mL syrup, 30 mL and 60 mL (as sodium phosphate)
	prednisone	Oral: 5 mg, 10 mg and 20 mg tablet 30 mg film coated tablet 10 mg/5 mL suspension, 30 mL and 60 mL
Fixed dose combination inhalation corticosteroid and beta-2 adrenoceptor agonists		
	budesonide + formoterol	Inhalation: DPI: 80 micrograms budesonide + 4.5 micrograms formoterol (as fumarate dihydrate) x 60 doses and 120 doses with appropriate accompanying dispenser 160 micrograms budesonide + 4.5 micrograms formoterol (as fumarate dihydrate) x 60 doses and 120 doses with approriate accompanying dispenser
	fluticasone + salmeterol	Inhalation: DPI: 100 micrograms fluticasone (as propionate) + 50 micrograms salmeterol (as xinafoate) x 28 doses and 60 doses with appropriate accompanying dispenser 250 micrograms fluticasone (as propionate) + 50 micrograms salmeterol (as xinafoate) x 28 doses and 60 doses with appropriate accompanying dispenser

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
		500 micrograms fluticasone (as propionate) + 50 micrograms salmeterol (as xinafoate) x 28 doses and 60 doses with appropriate accompanying dispenser
		MDI: 50 micrograms fluticasone (as propionate) + 25 micrograms salmeterol (as xinafoate) x 120 doses
		125 micrograms fluticasone (as propionate) + 25 micrograms salmeterol (as xinafoate) x 120 doses
		250 micrograms fluticasone (as propionate) + 25 micrograms salmeterol (as xinafoate) x 120 doses
Leukotriene receptor antagonist		
	montelukast (1)	Oral: 4 mg granules (as sodium salt), sachet 4 mg and 5 mg chewable tablet (as sodium salt) 10 mg tablet (as sodium salt)
7.2 MEDICINES FOR CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)		
7.2.1 Relievers (quick relief/rescue medications) see under Bronchodilators (See Section 7.1.1)		
	ipratropium + fenoterol	Inhalation: MDI: 20 micrograms ipratropium (as bromide) + 50 micrograms fenoterol (as hydrobromide) x 10 mL doses Resp. Soln.: (for nebulization) 250 micrograms ipratropium (as bromide) + 500 micrograms fenoterol (as hydrobromide) per mL, 20 mL (multidose) 500 micrograms ipratropium (as bromide) + 1.25 mg fenoterol (as hydrobromide) per 4 mL, (unit dose)

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
	ipratropium + salbutamol	Inhalation: MDI: 21 micrograms ipratropium (as bromide) + 120 micrograms salbutamol x 200 doses x 10 mL Resp. Soln.: (for nebulization) 500 micrograms ipratropium (as bromide anhydrous) + 2.5 mg salbutamol (as base) x 2.5 mL (unit dose)
7.2.2 Maintenance medication		
	budesonide + formoterol	Inhalation: DPI: 320 micrograms budesonide + 9 micrograms formoterol (as fumarate) x 60 doses with appropriate accompanying dispenser
	fluticasone + salmeterol	Inhalation: DPI: 50 micrograms fluticasone (as propionate) + 500 micrograms salmeterol (as xinafoate) x 60 doses with appropriate accompanying dispenser
	theophylline (anhydrous)	Oral: 125 mg, 200 mg, 250 mg and 300 mg MR tablet 400 mg MR tablet/capsule
	▼ *tiotropium*	Inhalation: DPI: 18 micrograms/dose (as bromide) with appropriate accompanying dispenser
7.3 CENTRALLY ACTING ANTITUSSIVES		
	butamirate (2)	Oral: 50 mg MR tablet (as citrate) 7.5 mg/5 mL syrup, 60 mL and 120 mL (as citrate)
	dextromethorphan (2)	Oral: 10 mg tablet (as hydrobromide) 5 mg/5 mL syrup, 30 mL, 60 mL and 120 mL (alcohol-free) (as hydrobromide)

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
		10 mg/5 mL syrup, 60 mL (alcohol-free) (as hydrobromide) 15 mg/5 mL syrup, 30 mL, 60 mL and 120 mL (alcohol-free) (as hydrobromide)
7.4 RESPIRATORY STIMULANT		
	aminophylline (1) *(theophylline ethylenediamine)*	Inj.: 25 mg/mL, 10 mL ampul (IV)
7.5 SURFACTANT		
	▼ *beractant*	Inj.: 25 mg/mL suspension, 1 mL vial, Intratracheal administration (restricted to tertiary hospitals with adequately trained neonatologist and facilities for neonatal intensive care)

8 ANTIALLERGICS

8.1 H1-RECEPTOR ANTAGONISTS (ANTIHISTAMINES)

DIPHENHYDRAMINE	Oral:	25 mg and 50 mg capsule (as hydrochloride) 12.5 mg/5 mL syrup, 30 mL, 60 mL and 120 mL (alcohol-free) (as hydrochloride)
	Inj.:	50 mg/mL, 1 mL ampul and 10 mL vial (IM, IV) (as hydrochloride)
HYDROXYZINE	Oral:	10 mg and 25 mg tablet (as dihydrochloride) 2 mg/mL syrup, 60 mL (as dihydrochloride or as hydrochloride)
	Inj.:	50 mg/mL, 1 mL vial (IM, IV)
cetirizine	Oral:	10 mg tablet (as dihydrochloride) 10 mg/mL drops, 10 mL (as dihydrochloride) 1 mg/mL solution, 30 mL and 60 mL (as dihydrochloride) 5 mg/5 mL syrup, 30 mL (as dihydrochloride)
chlorphenamine (chlorpheniramine)	Oral:	4 mg tablet (as maleate) 2 mg/5 mL syrup, 60 mL (as maleate) 2.5 mg/5 mL syrup, 60 mL (as maleate)
	Inj.:	10 mg/mL, 1 mL ampul/vial (IM, IV) (as maleate) 10 mg/mL, 10 mL vial (IM, IV) (as maleate)
loratadine	Oral:	10 mg tablet and 10 mg film coated tablet 5 mg/5 mL syrup, 30 mL

8.2 H2-RECEPTOR ANTAGONISTS

famotidine	Oral:	20 mg and 40 mg tablet 20 mg film coated tablet

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
		Inj.: 10 mg/mL, 2 mL ampul (IM, IV) lyophilized powder, 20 mg vial (IM, IV)
	ranitidine	Oral: 150 mg and 300 mg tablet (as hydrochloride) 150 mg and 300 mg dispersable/ effervescent tablet (as hydrochloride) 75 mg/5 mL syrup, 60 mL and 150 mL (as hydrochloride) Inj.: 25 mg/mL, 2 mL ampul/vial (IM, IV, IV infusion) (as hydrochloride)
8.3 CORTICOSTEROIDS (See also Section 14.1)		
HYDROCORTISONE		Inj.: 50 mg/mL, 2 mL vial (IM, IV) (as sodium succinate) 125 mg/mL, 2 mL and 4 mL vial (IV) (as sodium succinate) powder, 100 mg, 250 mg and 500 mg vial (IV) (as sodium succinate)
PREDNISOLONE		Oral: 5 mg and 20 mg tablet 15 mg/5 mL syrup, 20 mL, 30 mL and 60 mL (as sodium phosphate) 20 mg/5 mL syrup, 30 mL and 60 mL (as sodium phosphate)
PREDNISONE		Oral: 5 mg, 10 mg, and 20 mg tablet 30 mg film coated tablet 10 mg/5 mL suspension, 30 mL and 60 mL
	methylprednisolone	Oral: 4 mg and 16 mg tablet Inj.: 40 mg/mL, 1 mL suspension vial (IM) (as acetate) powder, 125 mg/mL, 2 mL vial + diluent vial (IM, IV) (as sodium succinate) powder, 500 mg/7.7 mL vial + diluent vial (IM, IV) (as sodium succinate) powder, 1 g/16 mL vial + diluent vial (IM, IV) (as sodium succinate)

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
8.4 ADRENERGIC AGENT		
EPINEPHRINE *(adrenaline)*		Inj.: 1 mg/mL, 1 mL ampul (IM, SC) (as hydrochloride)

9 ANTINEOPLASTICS AND IMMUNOSUPPRESSIVES

9.1 ANTINEOPLASTICS

9.1.1 Cell cycle-specific agents

BLEOMYCIN (1, 2)	Inj.:	powder, 15 mg ampul/vial (IM, IV, SC) (as sulfate)
CYTARABINE (1, 2)	Inj.:	powder, 100 mg vial (IM, SC, Intrathecal) 20 mg/mL, 5 mL ampul (IM, SC, Intrathecal)
DOXORUBICIN (1, 2)	Inj.:	powder, 10 mg and 50 mg vial (IV) (as hydrochloride) 2 mg/mL, 5 mL and 25 mL vial (IV) (as hydrochloride)
ETOPOSIDE (1, 2)	Oral: Inj.:	25 mg, 50 mg and 100 mg capsule **(B)** 20 mg/mL, 5 mL ampul/vial (IV) 20 mg/mL, 2.5 mL and 10 mL vial (IV) powder 100 mg vial (IV)
FLUOROURACIL (1, 2)	Inj.:	25 mg/mL, 10 mL vial (IV, IV infusion) 50 mg/mL, 5 mL, 10 mL, 20 mL and 100 mL ampul/vial (IV, IV infusion)
MERCAPTOPURINE (1, 2, **B**)	Oral:	50 mg tablet
METHOTREXATE	Oral: Inj.:	2.5 mg, 5 mg and 10 mg tablet (as sodium salt) 2.5 mg/mL, 2 mL and 8 mL vial (IM, IV, Intrathecal) (as sodium salt, preservative-free) 5 mg/mL, 2 mL vial (IM, IV, Intrathecal) (as sodium salt, preservative-free) 10 mg/mL, 1 mL and 5 mL vial (IM) (as sodium salt, preservative-free)

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
		25 mg/mL, 2 mL, 4 mL, 8 mL and 20 mL vial (IM, IV, Intrathecal) (as sodium salt, preservative-free) 100 mg/mL, 5 mL, 10 mL and 50 mL vial (IM, IV, Intrathecal) (as sodium salt, preservative-free)
PACLITAXEL (1, 2)		Inj.: 6 mg/mL, 5 mL, 17 mL, 25 mL and 43.4 mL vial (IV, IV infusion) 100 mg/15 mL, 15 mL multidose vial (IV)
VINBLASTINE (1, 2)		Inj.: powder, 10 mg vial for reconstitution (IV) (as sulfate) 1 mg/mL, 10 mL vial (IV) (as sulfate)
VINCRISTINE (1, 2)		Inj.: 1 mg/mL, 1 mL, 2 mL, 5 mL and 10 mL vial (IV) (as sulfate) powder, 1 mg and 2 mg vial + diluent (IV) (as sulfate)
	capecitabine (1, 2)	Oral: 150 mg and 500 mg tablet
	▼ *docetaxel* (1, 2)	Inj.: 20 mg/0.5 mL, 0.5 mL vial (IV infusion) (anhydrous) 40 mg/mL, 2 mL vial (IV infusion) (anhydrous)
	▼ *gemcitabine* (1, 2)	Inj.: 200 mg vial (IV infusion) (as hydrochloride) 1 g vial (IV infusion) (as hydrochloride)
	▼ *irinotecan* (1, 2)	Inj.: 40 mg/2 mL concentrate, vial (IV infusion) (as hydrochloride) 100 mg/5 mL concentrate, vial (IV infusion) (as hydrochloride)
	tegafur + uracil (1, 2)	Oral: 100 mg + 224 mg capsule
9.1.2 Cell cycle-nonspecific agents		
CHLORAMBUCIL (1, 2)		Oral: 2 mg tablet

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
CISPLATIN (1, 2)		Inj.: powder, 10 mg, 50 mg and 100 mg vial (IV) 500 micrograms/mL, 20 mL, 50 mL and 100 mL vial (IV) 1 mg/mL, 10 mL, 20 mL and 50 mL vial (IV)
CYCLOPHOSPHAMIDE (1, 2)		Oral: 50 mg tablet (as anhydrous) Inj.: powder, 100 mg, 200 mg, 500 mg and 1 g vial (IV)
DACARBAZINE (1, 2)		Inj.: powder, 100 mg and 200 mg vial (IV, IV infusion)
DACTINOMYCIN (actinomycin D) (1, 2)		Inj.: powder, 500 micrograms vial (IV)
IFOSFAMIDE (1, 2)		Inj.: powder, 1 g and 2 g vial (IV infusion)
★ *LOMUSTINE* (1, 2)		Oral: 300 mg combo-pack capsule
MELPHALAN (1, 2)		Oral: 2 mg tablet
	basiliximab (1, 2)	Inj.: 20 mg vial (IV infusion)
	carboplatin (1, 2)	Inj.: powder, 150 mg and 450 mg vial (IV) 10 mg/mL, 5 mL, 15 mL, 45 mL and 50 mL vial (IV)
	carmustine (1, 2)	Inj.: powder, 100 mg vial + 3 mL vial diluent (IV)
	★ *daunorubicin* (1, 2)	Inj.: 2 mg/mL, 10 mL and 25 mL vial (IV)
	epirubicin (1, 2)	Inj.: powder, 10 mg and 50 mg vial (IV) (as hydrochloride)
	idarubicin (1, 2)	Inj.: powder, 5 mg vial (IV) (as hydrochloride)
	mitoxantrone (1,2)	Inj.: 2 mg/mL solution, 5 mL and 10 mL
	oxiplatin (1, 2)	Inj.: 2 mg/mL, 25 mL and 50 mL vial (IV infusion)

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
		5 mg/mL Concentrate Solution 10 mL, 20 mL and 40 mL vial (IV infusion) powder, 50 mg vial (IV infusion)
	★ *procarbazine* (1, 2)	Oral: 50 mg capsule (as hydrochloride)

9.2 HORMONES AND ANTIHORMONES IN MALIGNANT DISEASES

FLUTAMIDE (1, 2)		Oral: 250 mg tablet
MEGESTROL (1, 2)		Oral: 40 mg and 160 mg tablet (as acetate)
TAMOXIFEN (1, 2)		Oral: 10 mg, 20 mg, 30 mg and 40 mg tablet (as citrate)
	cyproterone (1, 2)	Oral: 50 mg tablet (as acetate) Inj.: 100 mg/mL, 3 mL ampul, depot (IM) (as acetate)
	leuproreline (1, 2)	Inj.: 3.75 mg/ 2 mL vial with syringe (IM, SC) (as acetate) powder (depot), 11.25 mg vial with syringe (IM, SC) (as acetate) powder, 1.88 mg vial with syringe (IM, SC) (as acetate)

9.3 IMMUNOTHERAPEUTICS

9.3.1 Immunomodulators

INTERFERON ALFA 2A (human) (1, 2)		Oral: 200 IU sublingual tablet Inj.: 3 million IU, pre-filled syringe (IM, SC) 3 million IU, 4.5 million IU and 9 million IU per 1 mL vial (SC, IM) 4.5 million IU/0.5 mL pre-filled syringe (SC) 6 million IU/0.5 mL pre-filled syringe (SC)
INTERFERON ALFA 2B (human) (1, 2)		Inj.: 3 million IU, 5 million IU and 10 million IU per mL vial + diluent (IM, SC)

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
PEGINTERFERON ALFA 2A (1, 2)		Inj.: 135 micrograms/ 0.5 mL and 180 micrograms/ 0.5 mL pre-filled syringe (SC)
9.3.2 Immunosuppressives		
Corticosteroids (See Section 8.3)		
AZATHIOPRINE (1, 2)		Oral: 50 mg tablet **(B)** ★ Inj.: freeze-dried powder, 50 mg vial (IV, IV infusion) (as sodium salt)
CICLOSPORIN (1, 2)		Oral: 25 mg, 50 mg and 100 mg capsule **(B)** 100 mg/mL solution, 50 mL ★ Inj.: 50 mg/mL, 5 mL ampul (concentrate) (IV infusion) (for organ transplant)
TACROLIMUS (1, 2)		Oral: 1 mg capsule ▼ 5 mg capsule Inj.:▼ 5 mg/mL, 1 mL ampul (concentrate) (IM, IV infusion)
	★ *antilymphocyte immunoglobulin (ALG) (equine)* (1, 2)	Inj.: 100 mg/5 mL vial (IV)
	★ *antithymocyte immunoglobulin (ATG) (rabbit)* (1, 2)	Inj.: 25 mg/5 mL vial (IV)
	▼ *everolimus*	Oral: 500 microgram and 750 microgram tablet
	mycophenolate mofetil (1, 2)	Oral: 500 mg tablet
	▼ *mycophenolic acid (as mycophenolate sodium)* (1, 2)	Oral: 180 mg and 360 mg tablet
	sirolimus (1, 2)	Oral: 1 mg tablet 1 mg/mL solution, 60 mL

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
9.4 RADIOPHARMACEUTICAL		
★ *SODIUM IODIDE* ^{1311}	(1, 2)	Oral: capsule with radioactivity range of 0.8 to 100 mCi per capsule solution with radioactivity range of 3.5 to 150 mCi per vial
9.5 MISCELLANEOUS ANTI-CANCER AGENTS		
ASPARAGINASE	(1, 2)	Inj.: lyophilized powder, 10,000 IU vial (IV)
HYDROXYUREA	(1, 2)	Oral: 500 mg capsule
imatinib	(1, 2)	Inj.: 100 mg and 400 mg tablet (as mesilate)
rituximab	(1, 2)	Inj.: 10 mg/mL, 10 mL and 50 mL vial (IV)
trastuzumab	(1, 2)	Inj.: 150 mg lyophilized powder (IV infusion)
9.6 ADJUNCTS TO ANTINEOPLASTIC CHEMOTHERAPY		
calcium folinate (leucovorin calcium)	(1, 2)	Oral: 15 mg capsule/tablet and 25 mg tablet (as anhydrous) (equiv. to 25 mg folinic acid) Inj.: 3 mg/mL, 1 mL and 10 mL ampul (IM, IV) 7.5 mg/mL, 2 mL ampul (IM, IV) 10 mg/mL, 3mL, 5 mL and 10 mL ampul/vial (IM, IV) 50 mg and 100 mg vial (IM, IV)
mesna (sodium -2- mercapto ethanesulphonate)	(1, 2)	Inj.: 100 mg/mL, 4 mL, 5 mL and 10 mL ampul (IV)
ondansetron (for antineoplastic-induced emesis)	(1, 2)	Oral: 8 mg tablet (as hydrochloride dihydrate) Inj.: 2 mg/mL, 2 mL and 4 mL ampul (IM, IV)

10 BLOOD, MEDICINES AFFECTING THE

10.1 HEMATINICS

FERROUS SALT

Oral: tablet, (equiv. to 60 mg elemental iron)
solution, (equiv. to 15 mg elemental iron/0.6 mL) drops, 15 mL and 30 mL
solution, (equiv. to 30 mg elemental iron/5 mL) syrup, 60 mL

N.B.: The elemental iron content of a ferrous salt depends on the type of preparation as follows:

Ferrous fumarate	–	33%
Ferrous gluconate	–	12%
Ferrous lactate	–	19%
Ferrous sulfate, hydrated	–	20%
Ferrous sulfate, dessicated	–	32%

FOLIC ACID

Oral: 1 mg and 5 mg tablet
Inj.: 1 mg/mL, 1 mL ampul (IM) (as sodium salt)

★ *HYDROXOCOBALAMIN (vitamin B12)*

Oral: 100 microgram and 250 microgram tablet
Inj.: 1 mg/mL, 1 mL ampul/vial (IM)

mecobalamin

Oral: 500 microgram tablet
Inj.: 500 micrograms/mL ampul (IM, IV)

10.2 HEMATOPOIETIC GROWTH FACTORS

epoetin alfa (recombinant human erythropoietin) (1, 2)

Inj.: 2000 IU/0.5 mL, pre-filled syringe (IV, SC)
4000 IU/0.4 mL, pre-filled syringe (IV, SC)
▼ 10,000 IU/mL, pre-filled syringe (IV, SC)
2000 IU/0.5 mL, pre-filled syringe (HSA-free) (IV, SC)
4000 IU/0.4 mL, pre-filled syringe (HSA-free) (IV, SC)
10,000 IU/mL, pre-filled syringe (HSA-free) (IV, SC)

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
		40,000 IU/mL, pre-filled syringe (HSA-free) (IV, SC) ▼ 2000 IU/mL, 1 mL vial (IV, SC) ▼ 4000 IU/mL, 1 mL vial (IV, SC)
	epoetin beta (recombinant erythropoietin) (1, 2)	Inj.: 2000 IU/0.3 mL, pre-filled syringe with needle (IV, SC) 4000 IU/0.3 mL, pre-filled syringe with needle (IV, SC) 5000 IU/0.3 mL, pre-filled syringe with needle (IV, SC) 10,000 IU/0.6 mL, pre-filled syringe (IV, SC) 20, 000 IU/mL, 1 mL pre-filled syringe (IV, SC) 30, 000 IU/0.6 mL, 1 mL pre-filled syringe (IM, SC)
	filgrastim (G-CSF) (1, 2)	Inj.: 150 micrograms/0.6 mL, vial (IV, SC) 300 micrograms/mL, vial (IV, SC) 300 micrograms/1.2 mL, vial (IV, SC)
	★ *molgramostim (Gm-CSF)* (1, 2)	Inj.: 150 microgram and 400 microgram vial (IV, SC)
10.3 ANTICOAGULANTS		
Low Molecular Weight Heparin (LMWH)		
	dalteparin (1, 2)	Inj.: 2500 IU/0.2 mL and 5000 IU/0.2 mL, pre-filled syringe (SC) (as sodium) 10,000 IU/1 mL, 1 mL ampul (SC) (as sodium)
	nadroparin (1, 2)	Inj.: 950 IU/0.1 mL, 0.2 mL, 0.3 mL, 0.4 mL, 0.6 mL, 0.8 mL, and 1 mL pre-filled syringe (SC) (as calcium)
	▼ *tinzaparin* (1, 2)	Inj.: 10,000 anti-Xa IU/mL, 0.35 mL and 0.45 mL pre-filled syringe (SC) (as sodium) 10,000 anti-Xa IU/mL, 2 mL vial (SC) (as sodium)

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
UNFRACTIONATED HEPARIN (UFH)	(1, 2)	Inj.: 1000 IU/mL and 5000 IU/mL, 5 mL vial (IV, IV infusion, SC) (as sodium salt) (bovine origin)
WARFARIN	(1, 2)	Oral: 1 mg, 2.5 mg and 5 mg tablet (as sodium salt)
10.4 ANTITHROMBOTICS (ANTIPLATELETS)		
ASPIRIN		Oral: 80 mg and 325 mg tablet
▼ *clopidogrel*		Oral: 75 mg tablet
dipyridamole	(2)	Oral: 25 mg, 50 mg and 75 mg tablet (preferably used in combination with aspirin)
10.5 THROMBOLYTIC (FIBRINOLYTIC)		
STREPTOKINASE	(1, 2)	Inj.: powder, 750,000 IU and 1,500,000 IU vial (IV infusion)
10.6 ANTI-FIBRINOLYTIC		
tranexamic acid		Oral: 250 mg and 500 mg capsule 500 mg tablet Inj.: 100 mg/mL, 2.5 mL and 5 mL ampul (IM, IV)

11 BLOOD PRODUCTS AND BLOOD SUBSTITUTES

11.1 PLASMA EXPANDERS / SUBSTITUTES (COLLOIDS)

DEXTRAN, LOW MOLECULAR WEIGHT (dextran 40)	Inj.:	10% dextran 40 in 0.9% sodium chloride, 500 mL bottle (IV infusion) 10% dextran 40 in 5% dextrose, 500 mL bottle (IV infusion)
dextran, high molecular weight (dextran 70)	Inj.:	6% dextran 70 in 0.9% sodium chloride, 500 mL bottle (IV infusion) 6% dextran 70 in 5% dextrose, 500 mL bottle (IV infusion)
hydroxyethyl starch	Inj.:	6% solution, 250 mL and 500 mL bottle (IV infusion) 10% solution, 250 mL and 500 mL bottle (IV infusion)
modified fluid gelatin (polymerisate of degraded succinylated gelatin)	Inj.:	3% and 4% solution, 500 mL bottle (IV infusion)
polygeline	Inj.:	3.5% colloidal solution, 500 mL bottle (IV infusion)

11.2 PLASMA FRACTIONS FOR SPECIFIC USES

(All plasma fractions should comply with the WHO requirements for the Collection, Processing and Quality Control of Human Blood and Blood Products)

ALBUMIN, HUMAN (1, 2)	Inj.:	20%, 50 mL and 100 mL bottle (IV, IV infusion) 25%, 50 mL and 100 mL bottle (IV, IV infusion)
★ *FACTOR VIII CONCENTRATE* (1, 2)	Inj.:	lyophilized powder, 100 IU/g vial + diluent (IV)
★ *FACTOR IX COMPLEX CONCENTRATE (coagulation factors* II, VII, IX, X) (1, 2)	Inj.:	100 IU/mL, 5 mL and 10 mL vial (IV) lyophilized powder, 500 IU vial + diluent (IV)

12 ANTIDOTES

12.1 GENERAL ANTIDOTES

ACTIVATED CHARCOAL, USP		Oral:	powder, USP grade given as slurry
★ *LORAZEPAM* (A1, 2) (for drug-induced seizures)		Inj.:	4 mg/mL, 1 mL ampul (IM, IV)
SODIUM SULFATE		Oral:	powder, USP grade

12.2 SPECIFIC ANTIDOTES / ANTAGONISTS

ACETYLCYSTEINE (for paracetamol, white/yellow phosphorus "watusi", zinc phosphide and carbon tetra-chloride (CCl4) poisoning and cyclophosphamide-induced hemorrhagic cystitis)	★ (1, 2)	Oral: Inj.:	600 mg effervescent tablet 100 mg and 200 mg sachet 100 mg/5 mL granules for suspension, 150 mL 200 mg/mL, 10 mL ampul (IV infusion) 200 mg/mL, 25 mL bottle (IV infusion)
ALCOHOL, ETHYL (1, 2) (for methyl alcohol poisoning)		Oral: Inj.:	95%, USP grade absolute, 1 mL ampul (IV)
ASCORBIC ACID (vitamin C) (1, 2) (for methemoglobinemia and urine acidification)	★	Inj.:	250 mg/mL, 2 mL ampul (IV)
ATROPINE (for organophosphate and carbamate insecticide poisoning, anticholinesterase and muscarinic symptoms)	(1, 2)	Oral: Inj.:	600 microgram tablet (as sulfate) 1 mg/mL, 1 mL ampul (IM, IV) (as sulfate)
BROMOCRIPTINE (1, 2) (for neuroleptic malignant syndrome)		Oral:	2.5 mg tablet (as mesilate)
CALCIUM FOLINATE *(leucovorin calcium)* (for formaldehyde and methyl alcohol poisoning and methotrexate toxicity drug-induced megaloblastic anemia)	(1, 2)	Oral: Inj.:	15 mg capsule/tablet and 25 mg tablet (as anhydrous) (equiv. to 25 mg folinic acid) 3 mg/mL, 1 mL ampul (IM, IV) 7.5 mg/mL, 2 mL ampul (IM, IV) 10 mg/mL, 3 mL, 5 mL ampul and 10 mL vial (IM, IV)

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
		15 mg/mL, 1 mL ampul (IM, IV) 50 mg and 100 mg vial (IM, IV infusion)
CALCIUM SALT (for poisoning with white/yellow phosphorus "watusi", organochlorines, and severe jellyfish bites)		Oral: powder, USP grade (as chloride) Inj.: 10% solution, 10 mL ampul (IV) (as gluconate)
COBRA ANTIVENIN	(1, 2)	Inj.: 800 IU/mL, 5 mL ampul (IV infusion)
★ *DANTROLENE* (for malignant hyperthermia and neuroleptic malignant syndrome)		Oral: 25 mg and 50 mg capsule (as sodium salt) Inj.: 20 mg (with mannitol 3 g)/vial (1, 2) (for reconstitution with 60 mL sterile water for injection) (IV) (as sodium salt)
DEFEROXAMINE (for acute iron poisoning)	(1, 2)	Inj.: powder, 500 mg vial (IM, IV infusion, SC) (as mesilate) powder, 2 g vial (IM, IV, SC) (as mesilate)
★ *DIMERCAPROL* (for mercury, lead and arsenic poisoning)	(1, 2)	Inj.: (in oil) 50 mg/mL, 2 mL ampul (IM)
DIPHENHYDRAMINE (for phenothiazine extrapyramidal side effects)		Inj.: 50 mg/mL, 1 mL ampul and 10 mL vial (IM, IV) (as hydrochloride)
★ *EDROPHONIUM* (as adjunct for cobra bite)	(1, 2)	Inj.: 10 mg/mL, 1 mL ampul (IM, IV) (as chloride)
FLUMAZENIL (for benzodiazepine, zolpidem and zopiclone poisoning)	(1, 2)	Inj.: 100 micrograms/mL, 5 mL and 10 mL ampul (slow IV, IV infusion)
GLUCAGON (for toxicity of calcium channel blockers and beta blockers)	(1, 2)	Inj.: lyophilized powder, 1 mg + solvent (IM, IV, SC) (as hydrochloride)
★ *HYDROXOCOBALAMIN* (vitamin B12) (for cyanide poisoning)	(1, 2)	Inj: 1 mg/mL ampul/vial (IM)

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
★	*METHYLENE BLUE* (1, 2) (for severe methemoglobinemia)	Oral: 1% solution 55 mg and 65 mg tablet Inj.: 10 mg/mL, 1 mL and 10 mL ampul/vial
	N-ACETYL PENICILLAMINE (1, 2) (for copper, lead and mercury poisoning)	Oral: crystals, 25 g/bottle
	NALOXONE (1, 2) (for opioid poisoning)	Inj.: 20 micrograms/mL, 2 mL ampul (IM, IV, SC) (as hydrochloride) 400 micrograms/mL, 1 mL ampul (IM, IV, SC) (as hydrochloride)
★	*NALTREXONE* (for narcotic addiction and alcoholism)	Oral: 50 mg tablet (as hydrochloride)
	PENICILLIN G CRYSTALLINE (1, 2) *(benzylpenicillin)* (for amanita mushroom poisoning)	Inj.: 1 MU and 5 MU (IM, IV) (as sodium salt)
★	*PHYSOSTIGMINE* (1, 2) (for atropine poisoning and as adjunct to cobra bite)	Inj.: 1 mg/mL, 2 mL ampul (IM, IV) (as salicylate)
	PHYTOMENADIONE (for warfarin and white or yellow phosphorus "watusi" poisoning)	Oral/Inj.: 2 mg/0.2 mL pediatric ampul (IM, IV, PO) (as mixed micelle) Inj.: 10 mg/mL, 1 mL ampul (IM, IV) (as aqueous colloidal solution with benzyl alcohol) 10 mg/mL, 1 mL ampul (IM, IV) (as mixed micelle)
★	*PRALIDOXIME CHLORIDE* (1, 2) (for organophosphate insecticide poisoning)	Inj: 50 mg/mL, 20 mL vial (IV)
	PROTAMINE SULFATE (1, 2) (for heparin overdosage)	Inj.: 10 mg/mL, 5 mL and 25 mL ampul (IV)
	PYRIDOXINE (vitamin B6) (1, 2) (for isoniazid, hydrazine, hydrogen sulfide, gynomethrin mushroom and theophylline poisoning)	Oral: 50 mg tablet (as hydrochloride) Inj.: 100 mg/mL, 10 mL ampul (IM, IV) (as hydrochloride)

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
★ *SODIUM CALCIUM EDETATE* (1, 2) (for lead poisoning)		Inj.: 200 mg/mL, 5 mL ampul (IM)
★ *SODIUM NITRITE* (1, 2) (for cyanide poisoning)		Inj.: 30 mg/mL, 10 mL ampul/vial (IV)
★ *SODIUM THIOSULFATE* (1, 2) (for cyanide and cisplatin poisoning)		Inj.: 250 mg/mL, 50 mL ampul (IV)
★ *SUCCIMER* (1, 2) *(dimercapto succinic acid, DMSA)* (for lead, mercury, arsenic and other heavy metal poisoning)		Oral: 100 mg capsule
★ *THIAMINE* (for alcohol intoxication)		Inj.: 100 mg/mL, 10 mL vial (as hydrochloride) (IM, IV)
	deferiprone (for chronic iron poisoning) (1, 2)	Oral: 500 mg tablet
	★ *dimercaptopropane-sulphonate (DMPS)* (for arsenic and methyl mercury poisoning) (1, 2)	Inj.: 100 mg/mL, 1 mL ampul 10 mL vial (IM)
	★ *fomepizole* (4-methylprazole) (for methanol and ethylene glycol poisoning) (1, 2)	Inj.: 1 g/mL, 1.5 mL vial (IV)
	★ *fosphenytoin* (for drug-induced seizures)	Inj.: 30 mg/mL, 5 mL (IM, IV) 75 mg/mL, 10 mL (IM, IV)
	glyceryl trinitrate *(nitroglycerin)* (for cyanide and hydrogen sulfide poisoning)	Patch: 5 mg and 10 mg

13 GASTROINTESTINAL MEDICINES

13.1 ANTICHOLINERGICS

ATROPINE	Oral:	600 microgram (equiv. to 500 microgram atropine) tablet (as sulfate)
	Inj.:	600 micrograms/mL, 500 micrograms/mL and 1 mg/mL, 1 mL ampul (IM, IV, SC) (as sulfate)
DICYCLOVERINE (dicyclomine)	Oral:	10 mg tablet (as hydrochloride) 10 mg/5 mL syrup, 30 mL, 60 mL and 120 mL (as hydrochloride)
hyoscine	Oral:	10 mg tablet (as N-butyl bromide) 5 mg/5 mL syrup, 60 mL (as N-butyl bromide)
	Inj.:	20 mg/mL, 1 mL ampul (IM, IV, SC) (as N-butyl bromide) 500 micrograms/mL, 1 mL ampul (IM, IV) (as hydrobromide) 200 micrograms/mL, 1 mL ampul (IM, IV) (as hydrobromide)

13.2 ANTIEMETICS (See also Sec. 13.10 Gastrokinetic and Sec. 1.6 Anti-vertigo)

ondansetron (prevention and treatment of nausea and vomiting from antineoplastics, postoperative and postradiotherapy)	Oral:	8 mg tablet (as hydrochloride dihydrate)
	Inj.:	2 mg/mL, 2 mL and 4 mL ampul (IM, IV) (as hydrochloride)

13.3 ANTIMOTILITY

loperamide	Oral:	2 mg capsule (as hydrochloride) (N.B.: Not for infants and children less than 12 years old)
● *tsaang gubat [Carmona retusa (Vahl) Masam (* Fam. *Boraginaceae)]*	Oral:	250 mg tablet

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
13.4 ANTIPEPTIC ULCER MEDICINES		
Antacids		
	aluminum hydroxide + magnesium hydroxide	Oral: 225 mg aluminum hydroxide + 200 mg magnesium hydroxide per 5 mL suspension, 60 mL, 120 mL, 180 mL, 250 mL and 355 mL
	aluminum hydroxide	Oral: 600 mg/5 mL gel, 240 mL (for use of not more than 15 days)
Anti - *H. pylori* (in conjunction with proton pump inhibitor) (See Section 3.1.14)		
Cytoprotector		
SUCRALFATE		Oral: 500 mg and 1 g tablet 1 g/5 mL gel, sachet
H2-Receptor Antagonists		
RANITIDINE		Oral: 75 mg tablet (as base and as hydrochloride) 150 mg and 300 mg tablet (as base and as hydrochloride) 150 mg and 300 mg effervescent tablet (as hydrochloride) Inj.: 25 mg/mL, 2 mL ampul (IM, IV, IV infusion) (as hydrochloride)
	famotidine	Oral: 10 mg, 20 mg and 40 mg tablet Inj.: 10 mg/mL, 2 mL ampul/vial (IM, IV) lyophilized powder, 20 mg vial (IV)
Proton Pump (H+K+ ATPase) Inhibitors		
OMEPRAZOLE		Oral: 10 mg, 20 mg and 40 mg capsule Inj.: powder, 40 mg vial + 10 mL solvent ampul (IV)
	lansoprazole	Oral: 15 mg and 30 mg capsule 15 mg and 30 mg MR tablet

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
13.5 BILE ACID MALABSORPTION		
	★ *colestyramine*	Oral: powder, 4 g sachet
13.6 BILE SALT		
	URSODEOXYCHOLIC ACID (for primary biliary cirrhosis)	Oral: 250 mg capsule 100 mg and 200 mg tablet
13.7 BOWEL ANTI-INFLAMMATORY		
	mesalazine (1)	Oral: 250 mg tablet 250 mg and 500 mg enteric coated tablet 500 mg enteric MR tablet Rectal: 250 mg and 1 g suppository
13.8 DIRECT SMOOTH MUSCLE RELAXANT		
	mebeverine	Oral: 100 mg tablet (as hydrochloride)
13.9 LAXATIVES / CATHARTICS		
	bisacodyl	Oral: 5 mg tablet 5 mg MR tablet Rectal: 5 mg (children) and 10 mg (adult) suppository
	castor oil	Oral: USP grade
	glycerol (glycerin)	Rectal: 2 g and 2.5 g suppository
	lactulose (for hepatic encephalopathy)	Oral: 3.3 g/5 mL (66%) syrup, 120 mL and 200 mL
	monobasic/dibasic sodium phosphate	Oral: 48 g/18 g per 100 mL solution, 45 mL bottle Rectal: 19 g/7 g solution per 133 mL and 66 mL bottle (enema)
	standard senna concentrate	Oral: 187 mg tablet and 374 mg tablet 337 microgram/3 g granules, 30 g bottle

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
13.10 GASTROKINETICS (PROKINETICS)		
	domperidone	Oral: 10 mg tablet 1 mg/mL suspension, 30 mL and 60 mL
	metoclopramide	Oral: 10 mg tablet (as hydrochloride) 5 mg/5 mL syrup, 60 mL (as base and as hydrochloride) Inj.: 5 mg/mL, 2 mL and 3 mL ampul (IM, IV) (as base and as hydrochloride)
13.11 HEMOSTATIC MEDICINES FOR ESOPHAGEAL VARICES		
	octreotide (1, 2)	Inj.: 100 micrograms/mL and 500 micrograms/mL, 1 mL ampul (IV infusion) (as acetate)
	somatostatin (1, 2)	Inj.: 250 microgram and 3 mg ampul/vial (IV, IV infusion)

14 HORMONES AND HORMONE ANTAGONISTS

14.1 CORTICOSTEROIDS

DEXAMETHASONE

Oral: 500 microgram, 750 microgram, 3 mg and 4 mg tablet
Inj.: 4 mg/mL, 2 mL ampul/vial (IM, IV) (as sodium phosphate)
5 mg/mL, 1 mL ampul (IM, IV) (as sodium phosphate)

HYDROCORTISONE

Oral ★ 5 mg and 20 mg tablet
Inj.: 50 mg/mL, 2 mL vial (IM, IV) (as sodium succinate)
125 mg/mL, 2 mL and 4 mL vial (IV) (as sodium succinate)
powder, 100 mg, 250 mg and 500 mg vial (IV) (as sodium succinate)

PREDNISOLONE

Oral: 5 mg and 20 mg tablet
15 mg/5 mL syrup, 30 mL and 60 mL (as sodium phosphate)
20 mg/5 mL syrup, 30 mL and 60 mL (as sodium phosphate)

PREDNISONE

Oral: 5 mg, 10 mg and 20 mg tablet
30 mg film coated tablet
10 mg/5 mL suspension, 30 mL and 60 mL

betamethasone

Oral: 500 microgram tablet (as base)
Inj.: 5 mg (as dipropionate) + 2 mg (as sodium phosphate) per mL, 1 mL ampul and 2 mL vial (IM, ID, intraarticular, intralesional) (not for IV or SC use)

methylprednisolone

Oral: 4 mg and 16 mg tablet
Inj.: 40 mg/mL, 1 mL suspension vial (IM, intralesional) (as sodium acetate)
lyophilized powder,125 mg vial (IM, IV) (as sodium succinate)
lyophilized powder, 500 mg vial (IM, IV) (as sodium succinate)

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
		lyophilized powder, 1 g vial (IM, IV) (as sodium succinate) powder, 62.5 mg/mL, 4 mL vial (as sodium succinate) powder, 62.5 mg/mL, 2 mL vial + diluent vial (IM, IV, IV infusion) (as sodium succinate) powder, 500 mg/8.0 mL vial + diluent vial (IM, IV, IV infusion) (as sodium succinate) powder, 1 g/16 mL vial + diluent vial (IM, IV, IV infusion) (as sodium succinate)
	triamcinolone	Inj.: 10 mg/mL, 1 mL and 5 mL vial (as acetonide) (intraarticular, intradermal) 40 mg/mL, 1 mL ampul (as acetonide) (intraarticular, intralesional, intradermal)
14.2 ANTERIOR PITUITARY HORMONES AND ANTERIOR PITUITARY-LIKE HORMONES		
	human chorionic gonadotrophin (HCG) (1, 2)	Inj.: ★ lyophilized powder, 500 IU ampul + 1 mL solvent (IM) ★ lyophilized powder, 1,000 IU ampul/ vial + 1 mL solvent (IM) lyophilized powder, 5,000 IU ampul/ vial + 1 mL solvent (IM)
★	*human growth hormone (biosynthetic)* (1, 2)	Inj.: lyophilized powder, 5 mg vial + 5 mL diluent (IM, SC) lyophilized powder, 4 mg vial + 2 mL diluent (SC)
★	*human menopausal gonadotrophin (HMG, menotropin)* (1, 2)	Inj.: freeze-dried powder, 75 IU FSH + 75 IU LH per ampul + 1 mL solvent (IM)
★	*tetracosactide (cosyntropin)*	Inj.: 250 micrograms/mL, 1 mL ampul (IM) (as acetate) 1 mg/mL, 1 mL ampul (IM) (as hexaacetate)

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
14.3 POSTERIOR PITUITARY HORMONES		
DESMOPRESSIN		Oral: 100 microgram and 200 microgram tablet (as acetate) ★ Inj.: 15 micrograms/mL, 1 mL ampul (IM, SC) (as acetate)
OXYTOCIN (synthetic) (2)		Inj.: 5 IU/mL and 10 IU/mL, 1 mL ampul (IM, IV)
	★ *vasopressin* (2) *(antidiuretic hormone, ADH)*	Inj.: 20 pressor units/mL, 1 mL ampul (IM, IV)
14.4 HYPOTHALAMIC HORMONES		
	goserelin	Inj.: 3.6 mg depot solution, pre-filled syringe (SC) (as acetate) 10.8 mg depot solution, pre-filled syringe (SC) (as acetate)
	leuproreline	Inj.: powder, 1.88 mg single dose with syringe (IM, SC) (as acetate) ▼ powder, 3.75 mg single dose with syringe (IM, SC) (as acetate) powder, 11.25 mg depot solution, vial + syringe (IM, SC) (as acetate)
14.5 SEX HORMONES AND ANTAGONISTS		
Androgens		
DANAZOL (1)		★ Oral: 100 mg and 200 mg capsule
TESTOSTERONE (1)		Oral: 40 mg capsule (as undecanoate)
Anti-androgens		
	cyproterone (1)	Oral: 50 mg tablet (as acetate) Inj.: ★ 100 mg/mL, 3 mL ampul, depot (IM) (as acetate)
	flutamide (1)	Oral: 250 mg tablet

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
Estrogen		
CONJUGATED ESTROGENS		Oral: 300 microgram, 625 microgram and 1.25 mg tablet ★ Inj.: powder, 25 mg vial + 5 mL diluent (IM, IV)
Dopamine agonist (for hyperprolactinemia)		
	bromocriptine (2)	Oral: 2.5 mg tablet (as mesilate)
Ovulation inducing medicines		
	clomifene (1, 2)	Oral: 50 mg tablet (as citrate)
★	*human menopausal gonadotrophin (HMG, menotropin)* (1, 2)	Inj.: freeze-dried powder, 75 IU FSH + 75 IU LH per ampul + 1 mL solvent (IM)
Progestins (Progestogens)		
	dydrogesterone	Oral: 10 mg tablet
	lynestrenol	Oral: 500 microgram tablet
	medroxy-progesterone (2)	Oral: 2.5 mg, 5 mg, 10 mg, 100 mg, 250 mg, 400 mg and 500 mg tablet (as acetate) Inj.: 50 mg/mL, 3 mL vial + syringe (IM) (as acetate) (N.B.: Use one (1) inch long needle) 150 mg/mL, 1 mL vial (IM) (as acetate)
	norethisterone (2)	Oral: 5 mg tablet (as acetate and as base) Inj.: 200 mg/mL, 1 mL ampul (IM) (as enanthate)
Hormonal contraceptives		
ETHINYLESTRADIOL + LEVONORGESTREL		Oral: 30 microgram ethinylestradiol + 150 microgram levonorgestrel per tablet
	ethinylestradiol + desogestrel	Oral: 30 microgram ethinylestradiol + 150 microgram desogestrel per tablet

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
	ethinylestradiol + norgestrel	Oral: 30 microgram ethinylestradiol + 300 microgram norgestrel per tablet
	ethinylestradiol + norethisterone	Oral: 35 microgram ethinylestradiol + 400 microgram norethisterone acetate per tablet
	medroxyprogesterone	Inj.: 50 mg/mL, 3 mL vial + syringe (IM) (as acetate) (N.B. Use one (1) inch long needle) 150 mg/mL, 1 mL vial (IM) (as enanthate)
Hormonal replacement therapy		
	conjugated equine estrogen	Oral: 300 microgram, 625 microgram and 1.25 mg tablet
	conjugated equine estrogen + medroxy-progesterone acetate	Oral: 625 microgram + 2.5 mg tablet 625 microgram + 5 mg tablet
14.6 MEDICINES FOR BENIGN PROSTATIC HYPERTROPHY (BPH)		
	alfuzosin	Oral: 2.5 mg film coated tablet (as hydrochloride) 5 mg film coated tablet (MR) (as hydrochloride) 10 mg tablet (once a day) (as hydrochloride)
	finasteride	Oral: 5 mg tablet
	tamsulosin	Oral: 200 microgram capsule (as hydrochloride)
14.7 THYROID HORMONES AND ANTITHYROID MEDICINES		
14.7.1 Thyroid hormone replacement		
	LEVOTHYROXINE	Oral: 25, 50, 75, 100, 125 and 150 microgram tablet (as anhydrous sodium)

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths

14.7.2 Antithyroid medicines

Thioamides

THIAMAZOLE *(methimazole)*	Oral:	5 mg and 10 mg tablet
PROPYLTHIOURACIL	Oral:	50 mg tablet
carbimazole	Oral:	5 mg and 20 mg tablet

Iodides and Radioactive Iodine (Therapeutic)

★ *IODINE*	Oral:	aqueous iodine solution (Lugol's solution) 5% iodine, 10 % potassium iodide (total iodine - 130 mg/mL), 30 mL
★ *SODIUM IODIDE* ^{1311} (1)	Oral:	capsule with radioactivity range of 1.0 to 250 mCi per capsule solution with radioactivity range of 3.5 to 150 mCi per vial

Adjunct for Crisis States

PROPRANOLOL	Oral:	10 mg and 40 mg tablet (as hydrochloride) 40 mg MR capsule (as hydrochloride)

14.8 INSULINS AND OTHER ANTIDIABETIC MEDICINES

14.8.1 Insulins

Short Acting

REGULAR, INSULIN *(recombinant DNA, human)*	Inj.:	100 IU/mL, 3 mL pre-filled syringe (IM, IV, SC) 100 IU/mL, 10 mL vial (IM, IV, SC)

Intermediate Acting

ISOPHANE INSULIN HUMAN *(recombinant DNA)*	Inj.:	100 IU/mL, 3 mL pre-filled syringe (IM, SC) 100 IU/mL, 10 mL vial (IM, SC)

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
	biphasic isophane human insulin 70/30 (recombinant DNA)	Inj.: 70% isophane suspension + 30% soluble insulin in 100 IU/mL, 10 mL vial (IM, SC) and 100 IU/mL, 3 mL disposable syringe (IM, SC)
	insulin zinc suspension human	Inj.: 100 IU/mL, 10 mL vial (IM, SC)
14.8.2 Oral hypoglycemics		
Sulfonylureas		
GLIBENCLAMIDE **(B)**		Oral: 2.5 mg and 5 mg tablet
GLICLAZIDE		Oral: 30 mg MR tablet 80 mg tablet
GLIPIZIDE		Oral: 2.5 mg and 5 mg tablet
	chlorpropamide	Oral: 250 mg tablet
Biguanide		
METFORMIN		Oral: 500 mg tablet/film coated tablet (as hydrochloride) 850 mg and 1 g tablet (as hydrochloride)
Thiazolidinedione		
	rosiglitazone	Oral: 4 mg and 8 mg tablet (as maleate)
Alpha Glucosidase Inhibitor		
	acarbose	Oral: 50 mg and 100 mg tablet
14.9 ANTI-HYPOGLYCEMICS		
GLUCOSE (dextrose)		Inj.: 50%, 50 mL vial (IV)
	glucagon	Inj.: lyophilized powder, 1 mg + solvent (IM, IV, SC) (as hydrochloride)

15 MEDICINES ACTING ON THE UTERUS

15.1 OXYTOCICS (UTERINE STIMULANTS)

METHYLERGOMETRINE (A2) *(methylergonovine)*	Oral: 125 microgram tablet (as hydrogen maleate or maleate) Inj.: 200 micrograms/mL, 1 mL ampul (IM, IV) (as hydrogen maleate or maleate)
OXYTOCIN *(synthetic)* (2)	Inj.: 5 IU/mL and 10 IU/mL, 1 mL ampul (IM, IV)

15.2 TOCOLYTICS (UTERINE RELAXANTS)

TERBUTALINE	Oral: 2.5 mg and 5 mg tablet (as sulfate) Inj.: 500 micrograms/mL, 1 mL ampul (IV infusion) (as sulfate)
isoxsuprine	Oral: 10 mg and 40 mg tablet (as hydrochloride) Inj.: 5 mg/mL, 2 mL ampul (IM, IV infusion) (as hydrochloride)
magnesium sulfate (1)	Inj.: 250 mg/mL, 2 mL and 10 mL ampul and 10 mL and 20 mL vial (IM, IV) (as heptahydrate) 500 mg/mL, 2 mL and 10 mL ampul (IM, IV) (as heptahydrate)

16 MEDICINES CORRECTING WATER ELECTROLYTE ACID-BASE, AND CALORIC DISTURBANCES

16.1 REHYDRATION SOLUTIONS

16.1.1 Oral rehydration salts

ORAL REHYDRATION SALTS (ORS 75-replacement)

Oral: Composition of reduced osmolarity ORS per liter of water (WHO recommended):

Sodium chloride	—	2.6 g
Trisodium citrate dihydrate	—	2.9 g
Potassium chloride	—	1.5 g
Glucose anhydrous	—	13.5 g
Total Weight	—	20.5 g

Reduced osmolarity ORS Equivalent in mmol/L:

Sodium	—	75
Chloride	—	65
Potassium	—	20
Citrate	—	10
Glucose anhydrous	—	75
Total osmolarity	—	245

N.B.: Reconstitute with clean potable water. Unused reconstituted solution shall be discarded after 24 hours.

POTASSIUM

Oral: 750 mg durules (as chloride) equiv. to approximately 10 mEq
10 mEq tablet (as citrate)
★ 1 mmol/mL syrup, 30 mL and and 60 mL (as chloride)

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths

16.1.2 Parenteral

★ *ACETATED RINGER'S SOLUTION*

Inj.: 500 mL and 1 L bottle/bag (IV infusion)

Composition:

Na^+	—	130 mmol/L
K^+	—	4 mmol/L
Ca^{++}	—	3 mmol/L
Cl^-	—	109 mmol/L
Acetate	—	28 mmol/L

BALANCED MULTIPLE MAINTENANCE SOLUTION

Inj.: with 5% dextrose, 250 mL and 500 mL (infants) and 1 L (children and adults) bottle/bag (IV infusion)

Composition:

	Infants	Children & Adults
Dextrose	50 g/L	50 g/L
Na^+	25-30 mmol/L	40-50 mmol/L
K^+	20-25 mmol/L	13-30 mmol/L
Mg^{++}	3 mmol/L	3 mmol/L
Cl^-	22 mmol/L	40 mmol/L
Acetate	23 mmol/L	16 mmol/L

BALANCED MULTIPLE REPLACEMENT SOLUTION

Inj.: 500 mL and 1 L bottle/bag (IV infusion)

Composition:

Na^+	—	140 mmol/L
K^+	—	5 mmol/L
Mg^{++}	—	3 mmol/L
Cl^-	—	98 mmol/L
Acetate	—	50 mmol/L

plus 5% dextrose (50 g/L)

BALANCED MULTIPLE REPLACEMENT SOLUTION WITH pH 7.4

Inj.: 500 mL and 1 L bottle/bag (IV infusion)

Composition:

Na^+	—	140 mmol/L
K^+	—	5 mmol/L
Mg^{++}	—	3 mmol/L
Cl^-	—	98 mmol/L
Acetate	—	50 mmol/L

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
5% DEXTROSE IN 0.3% SODIUM CHLORIDE		Inj.: 250 mL, 500 mL and 1 L bottle/bag (IV infusion) Composition: Dextrose — 50 g/L Na^+ — 51 mmol/L Cl^- — 51 mmol/L
5% DEXTROSE IN 0.45% SODIUM CHLORIDE		Inj.: 250 mL, 500 mL and 1 L bottle/bag (IV infusion) Composition: Dextrose — 50 g/L Na^+ — 77 mmol/L Cl^- — 77 mmol/L
5% DEXTROSE IN 0.9% SODIUM CHLORIDE		Inj.: 250 mL, 500 mL and 1 L bottle/bag (IV infusion) Composition: Dextrose — 50 g/L Na^+ — 154 mmol/L Cl^- — 154 mmol/L
5% DEXTROSE IN LACTATED RINGER'S		Inj.: 250 mL, 500 mL and 1 L bottle/bag (IV infusion) Composition: Dextrose — 50 g/L Na^+ — 130 mmol/L K^+ — 4 mmol/L Ca^{++} — 3 mmol/L Cl^- — 109 mmol/L Lactate — 28 mmol/L
5% DEXTROSE IN WATER		Inj.: 250 mL, 500 mL and 1 L bottle/bag (IV infusion and as vehicle for IV medications)
10% DEXTROSE IN WATER		Inj.: 250 mL, 500 mL and 1 L bottle/bag (IV infusion) 3 mL ampul (as solvent)

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
LACTATED RINGER'S SOLUTION (Ringer's lactate)		Inj.: 500 mL and 1 L bottle/bag (IV infusion) Composition: Na^+ — 130 mmol/L K^+ — 4 mmol/L Ca^{++} — 3 mmol/L Cl^- — 109 mmol/L Lactate — 28 mmol/L
0.9% SODIUM CHLORIDE		Inj.: 2 mL, 2.5 mL, 5 mL, 10 mL and 20 mL ampul 50 mL, 100 mL, 200 mL, 250 mL, 500 mL and 1 L bottle/bag (IV infusion) Composition: Na^+ — 154 mmol/L Cl^- — 154 mmol/L
STERILE WATER FOR INJECTION		Inj.: 2 mL, 5 mL, 10 mL and 20 mL ampul 50 mL, 100 mL, 500 mL and 1 L bottle/bag (no preservative)

16.2 ELECTROLYTE OR IV ADDITIVE SOLUTIONS

CALCIUM GLUCONATE (1, 2)		Inj.: 10%, 10 mL ampul/vial (IV) 10%, 20 mL and 25 mL bottle (IV)
MAGNESIUM SULFATE (1)	(also for parenteral nutrition)	Inj.: 250 mg/mL, 2 mL and 10 mL ampul and 20 mL and 50 mL vial (IM, IV) (as heptahydrate) 500 mg/mL, 2 mL and 10 mL ampul (IV) (as heptahydrate)
POTASSIUM CHLORIDE	(also for parenteral nutrition)	Inj.: 2 mEq/mL, 2 mL and 5 mL ampul (IV infusion) 2 mEq/mL, 20 mL and 10 mL vial (IV infusion)
★ *POTASSIUM PHOSPHATE*	(also for parenteral nutrition)	Inj.: 224 mg monobasic potassium phosphate equiv. to 3 mmol phosphorus and 4.4 mEq K/236 mg dibasic-potassium phosphate anhydrous per mL in 5 mL vial (IV)

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
SODIUM BICARBONATE (also for parenteral nutrition)		Inj.: 1 mEq/mL, 10 mL vial (pediatric), 50 mL and 100 mL ampul/vial (adult) (IV infusion)
SODIUM CHLORIDE		Inj.: 2.5 mEq/mL, 20 mL and 50 mL vial
TRACE ELEMENTS		Inj.: contains Zn, Cu, Mn, Mg, Mb etc. 10 mL ampul (IV nutrition)
VITAMINS INTRAVENOUS (IV)		
FAT-SOLUBLE		Inj.: contains vitamins A, D, E and K 10 mL ampul (IV)
WATER-SOLUBLE		Inj.: contains vitamin B complex and vitamin C, 1 mL vial and 2 mL ampul (IV)

16.3 ENTERAL NUTRITION

ADULT POLYMERIC	Oral:	Calories	—	100 - 475 Kcal
		Dilution	—	1:1 - 1.5:1
		Carbohydrates	—	13.8 - 59 g
		Protein	—	3.8 - 19.9 g
		Fat	—	3.4 - 21.5 g
		mOsm/kg	—	270 - 730
		Sodium	—	75 - 402 mg
		Potassium	—	370 - 580 mg
		Phosphorous	—	47 - 307 mg
		Volume	—	100 mL - 1 L
DISEASE SPECIFIC	Oral:	Calories	—	100 - 1000 Kcal
		Dilution	—	1:1 - 2:1
		Carbohydrates	—	10.4 - 156 g
		Protein	—	5.5 - 88 g
		Fat	—	3.3 - 108 g
		mOsm/kg	—	230 - 635
		Sodium	—	80 - 2400 mg
		Potassium	—	172 - 5600 mg
		Phosphorous	—	50 - 1789 mg
		Volume	—	50 mL - 500 mL 50 g - 500 g
FIBER CONTAINING	Oral:	Calories	—	100 - 1048 Kcal
		Dilution	—	1:1
		Carbohydrates	—	13.8 - 148 g

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths			
			Protein	—	3.8 - 40 g
			Fat	—	3.4 - 34.7 g
			mOsm/kg	—	270 - 375
			Sodium	—	46.5 - 930 mg
			Potassium	—	78.5 - 1570 mg
			Phosphorous	—	63 - 720 mg
			Fiber	—	2.0 - 10.6 g
			Volume	—	100 g - 400 g 500 mL
	PEDIATRIC POLYMERIC	Oral:	Calories	—	445 - 511 Kcal
			Dilution	—	1:1
			Carbohydrates	—	14.9 - 62.2 g
			Protein	—	13.4 - 54.3 g
			Fat	—	16.2 - 26 g
			mOsm/kg	—	308 - 345
			Sodium	—	120 - 250 mg
			Potassium	—	400 - 750 mg
			Phosphorous	—	150 - 760 mg
			Volume	—	100 g
	SEMI - ELEMENTAL	Oral:	Calories	—	100 - 1300 Kcal
			Dilution	—	1:1 - 1.3:1
			Carbohydrates	—	13.8 - 177.2 g
			Protein	—	3.0 - 66.6 g
			Fat	—	3.9 - 37.4 g
			mOsm/kg	—	375 - 575
			Sodium	—	66 - 1040 mg
			Potassium	—	135 - 1730 mg
			Phosphorous	—	22 - 867 mg
			Volume	—	100 mL - 1 L 76 g - 450 g
	MODULAR	Oral:	Calories	—	9.5 - 380 Kcal
			Dilution	—	0
			Carbohydrates	—	0.67 - 94 g
			Protein	—	5 - 23 g
			Fat	—	0.6 g
			mOsm/kg	—	900
			Sodium	—	15 - 110 mg
			Potassium	—	10 - 66 mg
			Phosphorous	—	5 - 30 mg
			Volume	—	280 g - 400 g

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths

16.4 PARENTERAL NUTRITION

Caloric Medicines

GLUCOSE
(dextrose)
(also for parenteral nutrition)

Inj.: 50%, 10 mL and 20 mL ampul (IV)
50%, 10 mL, 20 mL and 50 mL (85 Kcal) vial (IV)

LIPIDS
(also for parenteral nutrition)

Inj.: 10%, 100 mL, 200 mL and 500 mL bottle (IV infusion)
20%, 100 mL and 500 mL bottle (IV infusion)

Emulsion:

Volume	—	100 - 500 mL
Concentration	—	10 - 20 %
Protein	—	50 - 100 g/100 mL
Lipid	—	10 - 20 g/100 mL (LCT or combined LCT - MCT)
Calories	—	100-200 cal/100 mL
Electrolytes	—	variable

Amino Acids, Crystalline Standard

Inj.: 3.5%, 500 mL bottle (IV infusion)
5%, 100 mL, 250 mL and 500 mL bottle (IV infusion)
6%, 100 mL and 250 mL bottle (IV infusion)
7%, 8.5%, 10%, and 11.4%, 100 mL, 500 mL and 1 L bottle (IV infusion)
8%, 500 mL bottle (IV infusion) (as branched chain)
9.12%, 20 mL ampul and 200 mL bottle (IV infusion)
10%, 100 mL and 500 mL bottle (IV infusion)

Amino Acids, Combined

AMINO ACID SOLUTIONS FOR HEPATIC FAILURE

Volume	—	500 mL
Concentration	—	5 - 8 %
Protein	—	35-50 g; rich in branched-chain amino acids
Calories	—	50 - 200
Electrolytes	—	variable

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
	AMINO ACID SOLUTIONS FOR IMMUNONUTRITION / IMMUNOENHANCEMENT	Volume — 50 mL and 100 mL Protein — 20 g; L-alanyl-L-glutamine Calories — 70 - 90 Electrolytes — none
	AMINO ACID SOLUTIONS FOR INFANTS	Volume — 100 mL Concentration — 5 - 10 % Protein — 20 - 50 g including taurine Calories — 80 - 150 Electrolytes — none
	AMINO ACID SOLUTIONS FOR RENAL CONDITIONS	Volume — 500 mL Concentration — 3.5 - 7 % Protein — 35 - 50 g rich in essential amino acid Calories — 50 - 200 Kcal
	COMBINED GLUCOSE-AMINO ACID SOLUTIONS	Volume — 100 mL and 500 mL Concentration — variable Glucose — 25 - 50 g Protein — 20 - 30 g Calories — 300 - 450 Kcal Electrolytes — variable
	ALL-IN-ONE ADMIXTURES (also called "3 in 1" or "dual energy" solutions)	Volume — 1000 - 2500 mL Concentration — variable CHO — 7 - 15 g/100 mL Protein — 4 - 5 g/100 mL Lipid — 2 - 5 g/100 mL Calories — 50 - 100 Kcal Electrolytes — variable
16.5	**PERITONEAL DIALYSIS SOLUTION**	Solution: Sterile with 1.5%, 2.5% and 4.25% dextrose, 1 L, 1.5 L, 2 L and 5 L bottle Electrolytes composition per 100 mL: Sodium lactate anhydrous — 390 - 448 mg Sodium chloride — 538 - 578.6 mg Calcium chloride dihydrate — 14.7 - 25.73 mg

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
		Magnesium chloride hexahydrate — 5.07 - 15.25 mg May contain hydrochloric acid or sodium hydroxide for pH adjustment. Electrolytes in mEq per liter (excluding ions for pH adjustments): Sodium — 132.6 - 146 mEq Calcium — 1.9 - 3.4 mEq Magnesium — 1.0 - 1.7 mEq Chloride — 97.8 - 109.2 mEq Lactate — 34.8 - 39.98 mEq
16.6 HEMODIALYSIS SOLUTION		Solution: (concentrate) 5 gallon (approx. 20 L), drum, 5 L and 10 L) Composition per liter: Magnesium chloride hexahydrate Calcium chloride dihydrate, USP Sodium acetate trihydrate Sodium chloride
Potassium Free Dialysate		
	ACETATE BASED CONTAINING	Sodium — 135 - 145 mEq/L Potassium — 0 Calcium — 2.5 - 3.8 mEq/L Dextrose — 10 - 15 mEq/L Bicarbonate — 0 Acetate — 30 - 40 mEq/L % daily utilization by dialysis unit: 10%
	BICARBONATE BASED CONTAINING	Sodium — 135 - 145 mEq/L Potassium — 0 Calcium — 2.5 - 3.8 mEq/L Dextrose — 10 - 15 Bicarbonate — 30 - 40 Acetate — 0 % daily utilization by dialysis unit: 9%

Low Calcium Dialysate

Sodium	—	135 - 145 mEq/L
Potassium	—	1.5 - 3.0 mEq/L
Calcium	—	below 2.6 mEq/L
Dextrose	—	10 - 15 mEq/L
Bicarbonate	—	30 - 40 mEq/L
Acetate	—	0

% daily utilization
by dialysis unit: 13.5%

17 DIAGNOSTIC AGENTS

17.1 OPHTHALMIC

FLUORESCEIN
Inj.: 100 mg/mL, 5 mL ampul (IV) (as sodium salt)
★ Strips: 1 mg and 9 mg (as sodium salt)

17.2 RADIOCONTRAST MEDIA

Ionic

AMIDOTRIZOATE (diatrizoate)
Inj.: (Intravascular and other parenteral routes as appropriate)
150 mg - 650 mg iodine/mL, 20 mL, 25 mL, 30 mL, 50 mL, 100 mL and 200 mL ampul/bottle (as meglumine and/or sodium salt)

IOTHALAMATE
Inj.: 600 mg/mL, 30 mL, 50 mL and 100 mL vial (usually IV) (as meglumine)

★ *iodamide*
Inj.: (Intravascular and other parenteral routes as appropriate)
495 mg/mL equiv. to 300 mg/mL iodine, 30 mL ampul and 50 mL and 100 mL vial/bottle (as meglumine)
627.9 mg/mL equiv. to 380 mg/mL iodine, 50 mL and 100 mL vial/bottle (as meglumine)

ioxithalamic acid
Inj.: (Intravascular)
9.66 g sodium ioxithalamate + 65.09 g meglumine ioxithalamate (equiv. to 35 g iodine), 20 mL, 50 mL and 100 mL vial
19.81 g meglumine ioxithalamate (equiv. to 9 g iodine) per 30 mL bottle
33.015 g meglumine ioxithalamate (equiv. to 15 g iodine) per 50 mL bottle

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
		66.03 g meglumine ioxithalamate (equiv. to 30 g iodine) per 100 mL bottle
Non-Ionic		
IOHEXOL		Inj.: (Intravascular and other parenteral routes as appropriate) 180 mg iodine/mL, 50 mL vial 240 mg iodine/mL, 50 mL vial 300 mg iodine/mL, 50 mL and 100 mL vial 350 mg iodine/mL, 50 mL, 100 mL and 200 mL vial
IOPAMIDOL		Inj.: (Intravascular and other parenteral routes as appropriate) 408 mg/mL equiv. to 200 mg iodine, 10 mL ampul 612 mg/mL equiv. to 300 mg iodine, 10 mL ampul and 30 mL, 50 mL and 100 mL vial 755 mg/mL equiv. to 370 mg iodine, 30 mL ampul and 50 mL and 100 mL vial/bottle
IOPROMIDE		Inj.: 240 mg/mL equiv. to 499 mg iodine, 50 mL vial 300 mg/mL equiv. to 623 mg iodine, 30 mL, 50 mL, 100 mL, 200 mL and 500 mL vial 370 mg/mL equiv. to 769 mg iodine, 50 mL and 100 mL vial
IOVERSOL		Inj.: 636 mg/mL equiv. to 300 mg/mL iodine, 30 mL, 50 mL and 100 mL vial 678 mg/mL equiv. to 320 mg/mL iodine, 50 mL and 100 mL vial 741 mg/mL equiv. to 350 mg/mL iodine, 50 mL and 100 mL vial
	dimeglumine gadopentetate	Inj.: 469 mg/mL aqueous solution, 5 mL, 10 mL, 15 mL and 20 mL vial
	▼ *gadodiamide*	Inj.: 287 mg/mL, aqueous solution, 5 mL, 15 mL, 10 mL and 20 mL vial

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
Other Radiocontrast Media		
BARIUM SULFATE		Oral: powder, USP grade suspended in water 340 g and 454 g, pouch, LDPE bag
★ *GAS FORMING AGENT*		Oral: Components per tablet: Sodium bicarbonate — 470 mg Glutamic acid — 70 mg Tartaric acid — 420 mg Silicon resin — 25 mg

18 DERMATOLOGICAL AND MUCOUS MEMBRANE AGENTS (TOPICAL)

18.1 ANTI-INFECTIVES

18.1.1 Antibacterials

MUPIROCIN
Cream: 2%, 5 g sachet and 15 g tube
Ointment: 2%, 5 g and 15 g tube

SILVER SULFADIAZINE
Cream: 1%, 5 g, 10 g, 15 g, 20 g, 25 g, 30 g and 50 g tube
400 g, 450 g and 500 g jar
(micronized)

fusidate sodium / fusidic acid
Cream: 2%, 5 g tube
Medicated Surgical Dressing: 2% (sterile gauze impregnated with 1.5 g of 2% ointment in single unit foil sachet) (as sodium)
Ointment: 2%, 5 g and 15 g tube

18.1.2 Antifungals

BENZOIC ACID + SALICYLIC ACID
Cream or Ointment:
6% benzoic acid + 3% salicylic acid, 15 g and 30 g tube

IMIDAZOLES, topical (e.g., clotrimazole, econazole, isoconazole, ketoconazole, miconazole, and tioconazole)
Cream: 1%-2%, 3.5 g, 15 g and 450 g tube
Lotion: 10 mL
Shampoo: 6 mL and 10 mL sachet
60 mL and 100 mL bottle
Solution: 10 mg/mL, 15 mL and 25 mL bottle
Vaginal: 100 mg, 300 mg and 500 mg ovule

SODIUM THIOSULFATE
Solution: 2.5% and 5%

●★ *akapulko [Cassia alata Linn. (*Fam. Leguminosae*)]*
Lotion: 50%, 60 mL bottle

nystatin
Oral: 500,000 units tablet
100,000 units/mL suspension, 30 mL bottle
Vaginal: 100,000 units tablet

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
	selenium sulfide	Lotion: 2.5%, 100 mL bottle Shampoo: 1%, 30 mL, 60 mL, 120 mL and 250 mL bottle
	terbinafine	Cream: 1%, 3 g, 5 g, 10 g and 15 g tube (as hydrochloride) Solution: 1%, 30 mL bottle
18.1.3 Scabicides and Pediculicides		
PERMETHRIN		Lotion: 1%, 125 mL bottle 5%, 30 mL and 60 mL bottle Shampoo (Creme Rinse): 1%, 30 mL and 60 mL bottle
	sulfur	Cream or Ointment: 5%, 15 g and 30 g tube
	benzyl benzoate	Lotion: 25%, 60 mL and 120 mL bottle
	crotamiton	Lotion: 10%, 60 mL and 120 mL bottle Cream: 10%, 10 g tube
18.2 ANTI-INFLAMMATORY AND ANTIPRURITICS		
CALAMINE, PLAIN		Lotion: 8%, 60 mL and 120 mL bottle
HYDROCORTISONE (1)		Cream or Ointment: 1%, 5 g and 10 g tube and 500 g jar Lotion: 1% and 2.5%, 25 mL bottle
	betamethasone	Cream or Ointment: 0.05%, 5 g and 10 g tube; (as dipropionate) 0.1%, 5 g tube (as valerate) Lotion: 0.05%, 30 mL bottle (as dipropionate)
	clobetasol	Cream or Ointment: 0.05%, 5 g, 10 g and 15 g tube (as propionate) Shampoo: 0.05%, 25 mL bottle (as propionate)
	fluocinonide	Cream or Ointment: 0.05%, 5 g, 10 g and 15 g tube

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
	fluticasone	Cream: 0.05%, 5 g tube (as propionate) Ointment: 0.005%, 5 g tube (as propionate)
18.3 ANTISEPTICS		
ALCOHOL, ETHYL		Solution: 95%, for dilution to 70% (with BIR seal)
CHLORHEXIDINE		Solution: 0.12% and 4%, 50 mL, 120 mL, 380 mL, 500 mL and 5 L (as gluconate)
POTASSIUM PERMANGANATE		Crystals: for solution to 1:1000 - 1:20,000 for wounds and ulcers; 1:4000 for mouthwash and gargle. Must be freshly prepared.
POVIDONE IODINE		Oral Antiseptic: 1%, 60 mL, 120 mL and 240 mL bottle Ointment: 10%, 5 g, 15 g and 30 g tube Paint: 10%, 10 mL bottle Solution: 10%, 15 mL, 30 mL, 60 mL, 120 mL, 1 L and 1 gallon bottle Surgical Skin Cleanser: 7.5%, 60 mL, 120 mL, 480 mL, 1 L and 1 gallon bottle
	★ *aluminum acetate*	Solution: 13% for the preparation of aluminum acetate lotion (0.65%). Must be freshly prepared.
	hydrogen peroxide	Solution: 3%, 120 mL bottle
	sodium hypochlorite	Solution: 0.5% available chlorine for further dilution for skin and wound
18.4 KERATOLYTICS		
BENZOIC ACID + SALICYLIC ACID		Ointment: 6% benzoic acid + 3% salicylic acid, 15 g and 30 g tube

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths	
BENZOYL PEROXIDE		Cream:	4%, 40 g tube 5%, 20 g tube
		Gel:	2.5%, 10 g and 40 g tube or bottle 5%, 10 g, 15 g, 40 g and 60 g tube or bottle 10%, 10 g, 40 g and 60 g tube or bottle
		Lotion:	5%, 30 mL and 120 mL bottle
		Wash:	5%, 50 g and 100 g tube or bottle
		Soap:	5%, 75 g
COAL TAR		Shampoo:	0.5% and 2.5%, 130 mL bottle 0.1% and 1%, 150 mL bottle
SALICYLIC ACID		Solution:	5%, 30 mL and 60 mL bottle 10%, 15 mL, 30 mL and 120 mL bottle 17%, 13.3 mL bottle
	★ *dithranol*	Ointment:	0.1% - 2%, 50 g tube
	★ *silver nitrate*	Solution: Stick:	0.5% 95%

18.5 ANTI-PSORIASIS

COAL TAR		Shampoo:	5%, 130 mL bottle
		★ Gel:	7.5%, 100 g
SALICYLIC ACID		Solution:	5%, 30 mL and 60 mL bottle
	calcipotriol	Cream:	50 microgram/g, 30 g tube or bottle
		Ointment:	50 microgram/g, 30 g tube or bottle
		Scalp Solution:	50 micrograms/mL, 30 mL bottle
	calcipotriol + betamethasone	Ointment:	50 microgram calcipotriol (as hydrate) + 500 microgram betamethasone (as dipropionate)/g, 30 g tube

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths	
18.6 EMOLLIENT			
	petrolatum / petroleum	Jelly:	USP grade, 25 g, 100 g and 200 g jar

19 OPHTHALMOLOGICAL PREPARATIONS

19.1 ADJUVANT TO SURGERY

intraocular irrigating solution (balanced salt solution)

Solution: 15 mL, 250 mL and 500 mL bottle

Composition:

Sodium chloride	—	0.64%
Potassium chloride	—	0.075%
Calcium chloride	—	0.048%
Magnesium chloride hexahydrate	—	0.03%
Sodium acetate	—	0.39%
Sodium citrate	—	0.17%

Water for injection to make 100%

19.2 ANTI-INFECTIVES

CHLORAMPHENICOL

Eye Ointment:
1%, 2 g, 3.5 g and 4 g tube

Eye Drops Solution:
0.5%, 5 mL, 7.5 mL and 10 mL bottle

ERYTHROMYCIN

Eye Ointment:
0.5%, 3.5 g and 5 g tube

GENTAMICIN

Eye Ointment:
0.3%, 3 g, 3.5 g and 5 g tube (as sulfate)

Eye Drops Solution:
0.3%, 5 mL bottle (as sulfate)
0.5%, 5 mL bottle (as sulfate)

★ *aciclovir*

Eye Ointment:
3%, 4.5 g tube

fusidate sodium/ fusidic acid

Eye Drops Suspension:
1%, 5 g tube (as sulfate)

ganciclovir

Eye Gel: 0.15%, 5 g tube

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
	ofloxacin	Eye Ointment: 0.3%, 3.5 g tube Eye Drops Solution: 0.3%, 5 mL bottle
	★ *povidone-iodine*	Eye Drops Solution: 2% and 5%
	sulfacetamide	Eye Drops Solution: 10%, 5 mL, 10 mL and 15 mL bottle (as sodium salt)
	sulfacetamide + prednisolone	Eye Drops Suspension: 10% sulfacetamide + 0.25% prednisolone (as acetate), 5 mL bottle
	tobramycin	Eye Drops Solution: 0.3%, 5 mL bottle Eye Ointment: 0.3%, 3.5 g tube
	tobramycin + dexamethasone	Eye Drops Suspension: 0.3% tobramycin + 0.1% dexamethasone, 5 mL bottle Eye Ointment: 0.3% tobramycin + 0.1% dexamethasone, 3.5 g tube
19.3 ANTI-INFLAMMATORY		
19.3.1 Steroidal		
PREDNISOLONE		Eye Drops Suspension: 0.5% and 1%, 5 mL bottle (as acetate)
	dexamethasone	Eye Drops Suspension: 0.1%, 5 mL bottle
19.3.2 Non-steroidal		
	▼ *nepafenac*	Eye Suspension: 1 mg/mL, 5 mL bottle

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
19.4 DIAGNOSTICS		
	FLUORESCEIN	Inj.: 10%, 5 mL ampul (IV) (as sodium salt) ★ Strips: 1 mg and 9 mg (as sodium salt)
	★ *rose bengal*	Eye Drops Solution: 1%, 0.5 mL bottle Strips: 1.3 mg
19.5 GLAUCOMA, MEDICINES FOR		
19.5.1 Cholinergic agonists (Miotics)		
	PILOCARPINE	Eye Drops Solution: 1%, 10 mL and 15 mL bottle (as hydrochloride) 2% and 4%, 10 mL and 15 mL bottle (as hydrochloride)
	carbachol	Intraocular Solution: 0.01%, 1.5 mL vial
19.5.2 Beta adrenoceptor blockers		
	TIMOLOL	Eye Drops Solution: 0.25%, 5 mL bottle (as maleate) 0.5%, 5 mL bottle (as maleate)
	betaxolol	Eye Drops Suspension: 0.25%, 5 mL bottle (as hydrochloride) Eye Drops Solution: 0.5%, 5 mL and 10 mL bottle (as hydrochloride)
19.5.3 Adrenergic agonist (alpha 2 selective)		
	brimonidine	Ophthalmic Solution: 0.15%, 5 mL bottle (as tartrate)
19.5.4 Prostaglandin analogues		
	LATANOPROST	Eye Drops Solution: 50 micrograms/mL, 2.5 mL bottle

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
	▼ *travoprost*	Ophthalmic Solution: 0.004%, 2.5 mL bottle
19.5.5 Carbonic anhydrase inhibitors		
Systemic		
ACETAZOLAMIDE **(B)**		Oral: 250 mg tablet
Locally Acting		
	brinzolamide	Ophthalmic Suspension: 1%, 5 mL bottle
	dorzolamide	Eye Drops Solution: 2%, 5 mL vial (as hydrochloride)
19.5.6 Hyperosmotic agents		
GLYCEROL *(glycerin)*		Oral: USP grade
MANNITOL		Inj.: 20%, 250 mL and 500 mL bottle (IV)
19.6 LOCAL ANESTHETICS (see Section 1.1.3)		
LIDOCAINE		Inj.: 1%, 5 mL and 20 mL ampul (as hydrochloride) 2%, 2 mL, 5 mL and 20 mL ampul (as hydrochloride) 2%, 10 mL, 20 mL and 50 mL vial (as hydrochloride)
	bupivacaine	Inj.: 0.5%, 5 mL, 10 mL and 20 mL vial (as hydrochloride)
	proxymetacaine *(proparacaine)*	Eye Drops Solution: 0.5%, 15 mL bottle (as hydrochloride)
19.7 MYDRIATICS		
Anticholinergics (cycloplegics)		
ATROPINE		Eye Drops Solution: 1%, 5 mL and 10 mL bottle (as sulfate)

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
	tropicamide	Eye Drops Solution: 0.5%, 5 mL bottle
Adrenergic Agonist		
PHENYLEPHRINE		Eye Drops Solution: 2.5%, 5 mL bottle (as hydrochloride)
19.8 DYSFUNCTIONAL TEAR SYNDROME (Dry Eyes)		
Immunosuppressive		
	ciclosporin	Ophthalmic Emulsion: 0.05%, 0.4 mL bottle
Lubricants		
	carboxymethylcellulose	Eye Drops Solution: 0.5%, 0.4 mL and 15 mL bottle (as sodium)
	hypromellose	Eye Drops Solution: 5 mg/mL and 10 mg/mL, 10 mL and 15 mL bottle Ophthalmic Solution: 0.3%, 10 mL bottle
	sodium hyaluronate	Ophthalmic Solution: 10 mg/mL, 0.85 mL bottle

20 EAR, NOSE AND THROAT PREPARATIONS

20.1 AGENTS FOR CHEMICAL CAUTERY

★ *SILVER NITRATE*	Crystals:	USP grade (for extemporaneous compounding to 5%, 10% and 30% solution)
	Stick:	95%
★ *TRICHLOROACETIC ACID*	Crystals:	USP grade (for extemporaneous compounding to 10% solution)

20.2 TOPICAL ANESTHETIC

LIDOCAINE	Ointment:	5%, 35 g and 50 g tube (as hydrochloride)
	Spray:	10%, 50 mL (as hydrochloride)
	Jelly:	2%, 30 g (as hydrochloride)

20.3 TOPICAL ANTIBIOTICS

CHLORAMPHENICOL	Ear Drops Solution: 0.5%, 5 mL bottle
OFLOXACIN	Ear Drops Solution: 0.3%, 5 mL bottle

20.4 TOPICAL ANTIMICROBIAL COMBINATIONS

bacitracin + neomycin + polymyxin B	Ointment: 200 units bacitracin + 3 mg neomycin (as sulfate) + 4000 units polymyxin B (as sulfate)/g, 10 g tube 400 units bacitracin + 5 mg neomycin (as sulfate) + 5000 units polymyxin B (as sulfate)/g, 5 g tube and 500 g jar

20.5 TOPICAL ANTIBIOTIC + CORTICOSTEROID

neomycin + polymyxin B + fluocinolone acetonide	Ear Drops Solution: 3.5 mg neomycin (as sulfate) + 10,000 units polymyxin B (as sulfate) + 0.025%

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
		fluocinolone acetonide/mL, 5 mL bottle
20.6 TOPICAL NASAL CORTICOSTEROIDS		
	budesonide	Nasal Aqueous Solution: 100 micrograms/dose x 50 metered doses and 200 metered doses
	fluticasone	Nasal Aqueous Solution: 0.05%/dose x 120 doses (as propionate)
20.7 TOPICAL NASAL DECONGESTANT		
	OXYMETAZOLINE	Nasal Drops Solution: 0.025%, 15 mL bottle (as hydrochloride) Nasal Spray: 0.05%, 10 mL and 15 mL bottle (as hydrochloride)

21 VITAMINS AND MINERALS

21.1 VITAMINS

ASCORBIC ACID *(vitamin C)*	Oral: 100 mg, 250 mg and 500 mg tablet 100 mg/mL drops, 15 mL, 30 mL and 60 mL 100 mg/5 mL syrup, 60 mL, 120 mL and 250 mL
ERGOCALCIFEROL *(calciferol, vitamin D2)*	★ Oral: 1.25 mg (50,000 IU) tablet/capsule 250 micrograms/mL (10,000 IU/mL) solution, 60 mL
FOLIC ACID	Oral: 1 mg and 5 mg tablet/capsule ★ Inj.: 1 mg/mL, 1 mL ampul (IM) (as sodium salt)
★ *HYDROXOCOBALAMIN* *(vitamin B12)*	Oral: 100 microgram and 250 microgram tablet Inj.: 1 mg/mL, 1 mL ampul/vial (IM)
★ *NICOTINAMIDE* *(vitamin B3)*	Oral: 50 mg and 100 mg tablet
PHYTOMENADIONE *(phytonadione, vitamin K1)*	Oral/Inj.: 2 mg/0.2 mL pediatric ampul (IM, IV, PO) (as mixed micelle) Inj.: 10 mg/mL, 1 mL ampul (IM, IV, SC) (as aqueous colloidal solution with benzyl alcohol) 10 mg/mL, 1 mL ampul (IM, IV, SC) (as mixed micelle)
PYRIDOXINE *(vitamin B6)*	Oral: 25 mg and 50 mg tablet (as hydrochloride) Inj.: 100 mg/mL, 10 mL ampul (IM, IV) (as hydrochloride)
RETINOL (2) *(vitamin A)*	Oral: 10,000 IU, 25,000 IU and 50,000 IU soft gel capsule (as palmitate) ★ 10,000 IU/mL, 15 mL and 30 mL bottle (oily solution) (as palmitate) ★ 100,000 IU and 200,000 IU soft gel capsule with nipple (as palmitate) (only for DOH program) **(B)**

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
★ *RIBOFLAVIN* *(vitamin B2)*		Oral: 50 mg tablet
THIAMINE *(vitamin B1)*		Oral: 10 mg, 50 mg, 100 mg and 300 mg tablet (as hydrochloride) ★ Inj.: 100 mg/mL, 1 mL ampul/vial (IV)
	★ *alpha-tocopherol* *(vitamin E)* (for prematures)	Oral: 10 mg/mL suspension, 10 mL (as acetate)
	calcitriol (1, 2)	Oral: 0.25 microgram and ★ 0.5 microgram capsule
	mecobalamin	Oral: 500 microgram tablet Inj.: 500 micrograms/mL, 1 mL ampul (IM, IV)
	multivitamins	Oral:

	for Infants per 1 mL drops	for Children per 5 mL syrup	for Adults per tablet/capsule
vitamin A	325 micrograms RE	350-400 micrograms RE	425-525 microgram RE
vitamin B1	0.3-0.4 mg	0.7-0.9 mg	0.7-1.3 mg
	■ **0.1-0.3 mg**	■ **0.5-1 mg**	■ **1.3-1.7 mg**
vitamin B2	0.3-0.4 mg	0.7-0.9 mg	0.7-1.3 mg
vitamin B6	0.3-0.6 mg	0.9-1.6 mg	1.6-2 mg
vitamin B12	0.5-1.5 micrograms	2-3 micrograms	3-5 microgram
	■ **0.3-0.4 micrograms**	■ **0.9-1.8 micrograms**	■ **2.4 microgram**
vitamin C	30 mg	35-55 mg	65-80 mg
vitamin D	400 IU	400 IU	400 IU
	■ **5 micrograms**	■ **5 micrograms**	■ **5-15 microgram**
vitamin E	3-4 mg	5-7 mg	6-10 mg
	■ **3.4 mg**	■ **5-7 mg**	■ **10-12 mg**
folic acid	20-30 micrograms	40-80 micrograms	100-170 microgram
niacin	5-8 mg	13-17 mg	13-23 mg

▼ Inj.: freeze-dried powder, 10 mL vial
(IV infusion)
(must be diluted before use)
Each 10 mL vial contains:

vitamin B1	—	3.2 mg
vitamin B2	—	3.6 mg
vitamin B6	—	4.0 mg
vitamin B12	—	5.0 micrograms

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
		vitamin C — 100 mg folic acid — 0.4 mg nicotinamide — 40 mg pantothenic acid — 15 mg biotin — 60 micrograms emulsion, 10 mL ampul (IV infusion) (pedia) (must be diluted before use) Each mL contains: vitamin A — 69 micrograms vitamin D2 — 1.0 micrograms vitamin E — 0.64 mg vitamin K1 — 20 micrograms fractionated soybean oil — 100 mg fractionated egg phospholipids — 12 mg emulsion, 10 mL ampul (IV infusion) (adult) (must be diluted before use) Each mL contains: vitamin A — 990 micrograms vitamin D2 — 20 IU vitamin E — 9.1 mg vitamin K1 — 15 micrograms fractionated soybean oil — 100 mg fractionated egg phospholipids — 12 mg
	vitamin B1 B6 B12	Oral: 100 mg B1 + 5 mg B6 + 50 microgram B12 per tablet/capsule 10 mg B1 + 5 mg B6 + 5 micrograms B12 per 0.6 mL drops, 15 mL Inj.: 100 mg B1 + 100 mg B6 + 1 mg B12 per 3 mL ampul (IV) 100 mg B1 + 100 mg B6 + 1 mg B12 per mL, 10 mL vial (IV)

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
21.2 MINERALS		
CALCIUM		Oral: tablet (equiv. to 500 mg elemental calcium) (as lactate) tablet/chewable tablet (equiv. to 500 mg and 600 mg elemental calcium) (as carbonate) ★ 1.437 g calcium glubionate and 295 mg calcium lactobionate (equiv. to 110 mg ionizable calcium), 120 mL Inj.: 10% solution in 10 mL ampul (IV) (as gluconate)
FERROUS SALT		Oral: tablet, (equiv. to 60 mg elemental iron) solution, (equiv. to 15 mg elemental iron/0.6 mL) drops, 15 mL and 30 mL solution, (equiv. to 30 mg elemental iron/5 mL) syrup, 60 mL N.B.: The elemental iron content of a ferrous salt depends on the type of preparation as follows: Ferrous fumarate — 33% Ferrous gluconate — 12% Ferrous lactate — 19% Ferrous sulfate, hydrated — 20% Ferrous sulfate, desiccated — 32%
FLUORIDE (2)		Oral: 250 microgram and 500 microgram tablet (as sodium salt) ★ 250 micrograms/mL and 500 micrograms/15 mL drops (as sodium salt)
IODIZED OIL FLUID		Oral: 500 mg (equiv. to 200 mg elemental iodine) soft gel capsule (only for DOH program)
ZINC		Oral: chewable tablet, (equiv. to 10 mg elemental zinc) (as gluconate) tablet, (equiv. to 30 mg elemental zinc) (as gluconate trihydrate)

CORE LIST	Complementary List	Route of Administration Pharmaceutical Forms and Strengths
		solution, (equiv. to 10 mg elemental zinc/mL) drops, 15 mL, (as sulfate monohydrate) solution, (equiv. to 20 mg elemental zinc/5 mL) syrup, 60 mL (as sulfate monohydrate)
★ *iron dextran*	(1)	Inj.: 50 mg/mL, 2 mL ampul (deep IM, IV)
21.3 VITAMINS AND MINERALS		
FERROUS SALT + FOLIC ACID (nutritional supplement during pregnancy)		Oral: 60 mg elemental iron + 400 microgram folic acid per tablet/ capsule/film coated tablet

22 DISINFECTANTS

ALCOHOL, ETHYL		Solution:	95% (to be diluted to 70%) (with BIR seal)
CHLORHEXIDINE		Solution:	4%, 50 mL and 4 L bottle (as gluconate)
IODINE		Tincture: Solution:	1% and 2% 2% and 5%
POVIDONE - IODINE		Solution:	10%, 15 mL, 30 mL, 60 mL, 120 mL, 240 mL, 1 L and 1 gallon bottle
	glutaraldehyde (glutaral)	Solution:	2% (with alkaline activating solution) 120 mL and 1 L
	hydrogen peroxide	Solution:	3%, 60 mL and 120 mL bottle
	sodium dichloro-isocyanurate (to be used for water purification)	Solution:	3.5 mg tablet (free available chlorine 2 mg) 8.68 mg tablet (free available chlorine 5 mg) 12.5 mg tablet (free available chlorine 8 mg) 17 mg tablet (free available chlorine 10 mg) 67 mg tablet (free available chlorine 40 mg)
	sodium hypochlorite	Solution:	1.25% available chlorine for water purification

APPENDICES

PHILIPPINE NATIONAL DRUG FORMULARY VOL. I, 7TH EDITION

SUMMARY STATISTICS

No. of Sections of Therapeutic Categories	=	22	
No. of Active Ingredients	=	627	
Core List	=	350	
Complementary List	=	315	
No. of pharmaceutical products added	=	45	(*see* Appendix B)
No. of pharmaceutical products deleted	=	36	(*see* Appendix B)
No. of pharmaceutical products not available in the market but considered essential (★)	=	86	(*see* Appendix C)
No. of new drugs under Monitored Release (▼)	=	38	(*see* Appendix D)
No. of Dangerous Drug Preparations **(A1)**	=	19	(*see* Appendix E)
No. of Controlled Chemicals **(A2)**	=	3	(*see* Appendix E)
No. of medicines requiring specific expertise, diagnostic precision, or special equipment for proper use **(1)**	=	153	(*see* Appendix F)
No. of medicines with limited indications or narrow spectrum of activity **(2)**	=	136	(*see* Appendix G)
No. of antibiotics in the PNDF to be used only in hospitals with DOH accredited Antimicrobial Resistance Surveillance Program (ARSP) **(3)**	=	6	(*see* Appendix H)
No. of List B medicines	=	40	(*see* Appendix I)
No. of medicinal plant products registered with BFAD (•)	=	5	(*see* Appendix J)

REVISIONS TO PNDF VOL. I FOR ITS 7TH EDITION

Medicines Deleted = 36

1. Busulfan
2. Calamine, plain
3. Calcitriol
4. Cimetidine
5. Cromolyn sodium
6. Diclofenamide (dichlorphenamide)
7. Enflurane
8. Estramustine
9. Ethinylestradiol + levonorgestrel
10. Fenyramidol (phenyramidol)
11. Formoterol
12. Framycetin
13. Gatifloxacin
14. Gemfibrozil
15. Imipenem + Cilastatin
16. Isopropyl alcohol
17. Levodopa + Benzerazide
18. Mitomycin
19. Mivacurium
20. Nizatidine
21. Oral maintenance salts (triphasic) (OMS)
22. Oral rehydration salts (ORS 90 replacement)
23. Oxytetracycline
24. Phenylpropanolamine (norepinephrine)
25. Polymixin B + acetic acid
26. Pravastatin
27. Prazosin
28. Procaterol
29. Pyrantel pamoate
30. Recombinant tissue plasminogen activated (rTpa)
31. Reserpine
32. Salmeterol
33. Terazosin
34. Tirofiban
35. Trifluridine
36. Vitamin D (alfacalcidol)

Medicines Added = 45

1. Alendronate + cholecalciferol
2. Beractant
3. Brimonidine
4. Brinzolamide

5. Calcipotriol + betamethasone
6. Candesartan
7. Capecitabine
8. Carboxymethylcellulose
9. Cefadroxil
10. Cilosporin
11. Cilostazol
12. Desflurane
13. Eprosartan
14. Escitalopram
15. Ethinyl estradiol + desogestrel
16. Ethinyl estradiol + norgestrel
17. Everolimus
18. Flupentixol
19. Fondaparinux
20. Galantamine
21. Hypromellose
22. Imatinib
23. Ioversol
24. Isoniazid 75 mg + Rifampicin 150 mg + Ethambutol 275 mg
25. Levodopa + carbidopa
26. Medroxyprogesterone (Vitamin D3)
27. Mefloquine
28. Monobasic/dibasic sodium phosphate
29. Mycophenolic acid
30. Nepafenac
31. Oxaliplatin
32. Peginterferon alfa 2A
33. Potassium (as citrate)
34. Quetiapine
35. Rituximab
36. Rivastigmine
37. Rosuvastatin
38. Sodium hyaluronate
39. Telmisartan
40. Telmisartan + hydrochlorothiazide
41. Travoprost
42. Trastuzumab
43. Trimetazidine
44. Valsartan
45. Valsartan + hydrochlorothiazide

PHARMACEUTICAL PRODUCTS IN THE PNDF THAT ARE NOT PRESENTLY AVAILABLE IN THE MARKET BUT ARE CONSIDERED ESSENTIAL (★)

1. Acetated Ringer's Solution

2. Acetylcysteine
   Inj.: 200 mg/mL, 10 mL ampul (IV infusion)

3. Aciclovir
   Eye Ointment: 3%, 4.5 g tube

4. Akapulko [Cassia alata Linn. (Fam. Leguminosae)]
   Lotion: 50%, 60 mL bottle

5. Alcohol, ethyl
   Inj.: absolute, 1 mL ampul (IV)

6. Alpha-tocopherol (vitamin E)
   Oral: 10 mg/mL suspension, 10 mL (as acetate)

7. Aluminum acetate
   Solution: 13% for the preparation of aluminum acetate lotion (0.65%)
   Must be freshly prepared.

8. Antilymphocyte immunoglobulin (ALG) (equine)
   Inj.: 100 mg/5mL vial (IV)

9. Antithymocyte immunoglobulin (ATG) (rabbit)
   Inj.: 25 mg/5 mL vial (IV)

10. Ascorbic acid (Vitamin C)
    Inj.: 250 mg/mL, 2 mL ampul (IV)

11. Azathioprine
    Inj.: freeze-dried powder, 50 mg vial
    (IV, IV infusion) (as sodium salt)

12. Calcium
    Oral: 1.437 g calcium glubionate and 295 mg calcium lactobionate
    (equiv. to 110 mg ionizable calcium), 120 mL

13. Chloral hydrate
    Oral: 500 mg/5 mL syrup

14. Ciclosporin
    Inj.: 50 mg/mL, 5 mL ampul (concentrate)
    (IV infusion) (for organ transplant)

15. Clofazimine
    Oral: 50 mg and 100 mg capsule
    (available under DOH program)

16. Coal tar
    Gel: 7.5%, 100 g

17. Colestyramine
    Oral: powder, 4 g sachet

18. Conjugated estrogens
    Inj.: powder, 25 mg vial + 5 mL diluent (IM, IV)

19. Danazol
    Oral: 100 mg and 200 mg capsule

20. Dantrolene
    Oral: 25 mg and 50 mg capsule (as sodium salt)
    Inj.: 20 mg (with 3 mg mannitol/vial)
    For reconstitution with 60 mL sterile water for injection (IV) (as sodium salt)

21. Daunorubicin
    Inj.: 2 mg/mL, 10 mL and 25 mL vial (IV)

22. Desmopressin
    Inj.: 15 micrograms/mL, 1 mL ampul (IM, SC)
    (as acetate)

23. Diazepam
    Rectal: 5 mg/2.5 mL and 10 mg/2.5 mL in rectal tube

24. Diethylcarbamazine
    Oral: 50 mg + 100 mg tablet

25. Dimercaprol
    Inj.: (in oil) 50 mg/mL, 2 mL ampul (IV)

26. Dimercaptopropane sulphonate (DMPS)
    Inj.: 100 mg/mL, 1 mL ampul, 10 mL vial (IM)

27. Diphtheria antitoxin
    Inj.: 10,000 IU and 20,000 IU, 5 mL and 10 mL (IV)

28. Dithranol
    Ointment 0.1% - 2%, 50 g tube

29. Edrophonium
    Inj.: 10 mg/mL, 1 mL ampul (IM, IV) (as chloride)

30. Ergocalciferol
    Oral: 1.25 mg (50,000 IU) tablet/capsule
    250 micrograms/mL (10,000 IU/mL) solution, 60 mL

31. Esmolol
    Inj.: 10 mg/mL, 10 mL vial (IV) (as hydrochloride)

32. Factor VIII Concentrate
    Inj.: lyophilized powder, 100 IU/g vial + diluent (IV)

33. Factor IX Complex Concentrate (Coagulation Factors; II, VII, IX, X)
    Inj.: 100 IU/mL, 5 mL and 10 mL vial (IV)

34. Flucytosine (5-fluorocystosine)
    Oral: 500 mg tablet

35. Fluorescein
    Strips: 1 mg and 9 mg (as sodium salt)

36. Fluoride
    Oral: 250 micrograms/mL and 500 micrograms/mL drops
    (as sodium salt)

37. Folic Acid
    Inj.: 1 mg/mL, 1 mL ampul (IM) (as sodium salt)

38. Fomepizole
    Inj.: 1 g/mL, 1.5 mL vial (IV)

39. Fosphenytoin
    Inj.: 30 mg/mL, 5 mL (IM, IV)
    75 mg/mL, 10 mL (IM, IV)

40. Gas forming agent
    Oral: Components per tablet:

    Sodium bicarbonate
    Glutamic acid
    Tartaric acid
    Silicon resin

41. Human chorionic gonadotrophin (HCG)
    Inj.: lyophilized powder, 500 IU ampul +1 mL solvent (IM)
    lyophilized powder, 1,000 IU ampul/vial + 1 mL solvent (IM)

42. Human growth hormone (biosynthetic)
    Inj.: lyophilized powder, 5 mg vial + 5 mL diluent (IM, SC)
    lyophilized powder, 4 mg vial + 2 mL diluent (SC)

43. Human menopausal gonadotrophin
    Inj.: lyophilized powder, 500 IU ampul + 1 mL solvent (IM)
    lyophilized powder, 1,000 IU ampul/vial + 1 mL solvent (IM)

44. Hydroxocobalamin (Vitamin B12)
    Oral: 100 microgram and 250 microgram tablet
    Inj.: 1 mg/mL, 1 mL ampul/vial (IM)

45. Indomethacin
    Inj.: 200 micrograms/mL, 5 mL ampul (IV)

46. Iodamide
    Inj.: (Intravascular and other parenteral routes as appropriate)
    495 mg/mL equiv. to 300 mg/mL Iodine, 30 mL ampul; 50 mL and 100 mL vial/bottle (as meglumine)
    627.9 mg/mL equiv. to 380 mg/mL Iodine, 50 mL and 100 mL vial/bottle (as meglumine)

47. Iodine
    Oral: Aqueous iodine solution (Lugol's solution)
    5% iodine, 10 % potassium iodide (total iodine - 130 mg/mL), 30 mL

48. Iron dextran
    Inj.: 50 mg/mL, 2 mL ampul (deep IM, IV)

49. Isoniazid + ethambutol
    Oral: 150 mg + 400 mg tablet

50. Isoniazid + rifampicin
    Oral: 30 mg + 60 mg tablet (pediatric)
    75 mg + 150 mg tablet
    150 mg + 150 mg tablet
    For intermittent use 3x weekly

51. Isoniazid + tiacetazone
    Oral: 300 mg + 150 mg tablet

52. Ivermectin
    Oral: 6 mg tablet
    (available under DOH program)

53. Ketoprofen
    Inj.: 50 mg/mL, 2 mL ampul (IM) lyophilized powder,
    100 mg vial (IV infusion)

54. Lorazepam
    Oral: 1 mg and 2 mg tablet
    Inj.: 4 mg/mL, 1 mL ampul (IM, IV)

55. Methylene blue
    - Oral: 1% solution
      55 mg and 65 mg tablet
    - Inj.: 10 mg/mL, 1 mL and 10 mL ampul/vial

56. Naltrexone
    - Oral: 50 mg tablet (as hydrochloride)

57. Neostigmine
    - Oral: 15 mg tablet (as bromide)

58. Nicotinamide (Vitamin B3)
    - Oral: 50 mg and 100 mg tablet

59. Physostigmine
    - Inj.: 1 mg/mL, 2 mL ampul (IM, IV) (as salicylate)

60. Potassium
    - Oral: 1 mmol/mL syrup, 30 mL and 60 mL (as chloride)

61. Potassium phosphate
    - Inj.: 224 mg monobasic potassium phosphate equiv. to 3 mmol phosphorus
      4.4 mEq K/236 mg dibasic-potassium phosphate anhydrous per mL in 5 mL vial (IV)

62. Povidone-iodine
    Eye Drops Solution 2% and 5%

63. Praziquantel
    - Oral: 600 mg tablet

64. Procarbazine
    - Oral: 50 mg capsule (as hydrochloride)

65. Pyrimethamine
    - Oral: 25 mg tablet

66. Retinol
    - Oral: 10,000 IU/mL, 15 mL and 30 mL bottle (oily solution) (as palmitate)
      100,000 IU and 200,000 IU soft gel capsule with nipple (as palmitate) (only for DOH Program)

67. Riboflavin (Vitamin B2)
    - Oral: 50 mg tablet

68. Rifabutin
    - Oral: 150 mg capsule

69. Ritonavir
    Oral: 100 mg capsule

70. Rose Bengal
    Eye Drops Solution 1%, 0.5 mL bottle
    Strips: 1.3 mg

71. Silver nitrate
    Crystals: USP grade (for extemporaneous compounding to 5%, 10% and 30% solution)
    Solution: 0.5%
    Stick: 95%

72. Sodium calcium edetate
    Inj.: 200 mg/mL, 5 mL ampul (IM)

73. Sodium iodide
    Oral: capsule with radioactivity range of 1.0 to 250 mCi per capsule
    solution with radioactivity range of 3.5 to 150 mCi per vial

74. Sodium nitrite
    Inj.: 30 mg/mL, 10 mL ampul/vial (IV)

75. Sodium nitroprusside
    Inj.: 50 mg powder ampul (IV infusion)

76. Sodium thiosulfate
    Inj.: 250 mg/mL, 50 mL ampul (IV)

77. Spectinomycin
    Inj.: 2 g vial (IM)

78. Succimer
    Oral: 100 mg capsule

79. Terizodone
    Oral: 250 mg capsule

80. Tetracosactide (cosyntropin)
    Inj.: 250 micrograms/mL, 1 mL ampul (IM) (as acetate)
    1 mg/mL, 1 mL ampul (IM) (as hexaacetate)

81. Thiacetazone
    Oral: 150 mg tablet

82. Thiamine
    Inj.: 100 mg/mL, 1 mL ampul/vial (IV)

83. Trichloroacetic acid
    Crystals: USP grade (for extemporaneous compounding to 10% solution)

84. Varicella zoster immunoglobulin (VZIG)
    Inj.: 125 units/1.25 mL vial (IM)

85. Vasopressin
    Inj.: 20 pressor units/mL, 1 mL ampul (IM, IV)

86. Yerba buena
    Oral: 250 mg tablet

NEW DRUGS UNDER MONITORED RELEASE FOR WHICH THE NATIONAL FORMULARY COMMITTEE (NFC) AND THE BUREAU OF FOOD AND DRUGS (BFAD) REQUEST THAT ALL ADVERSE DRUG EVENTS/EXPERIENCES (ADEs) BE REPORTED (▼)

Total No. of Active Ingredients = 38

1. Alendronate + Cholecalciferol (Vitamin D3)
2. Beractant
3. Clopidogrel
4. Didanosine
5. Docetaxel
6. Enoxaparin
7. Epoetin alfa (recombinant human erythropoetin)
   10,000 IU/mL, pre-filled syringe (IV, SC)
   2,000 IU/mL, 1 mL vial (IV, SC)
   4,000 IU/mL, 1 mL vial (IV, SC)
8. Escitalopram
9. Everolimus
10. Famciclovir
11. Fondaparinux
12. Gadodiamide
13. Galantamine
    Oral: 4 mg tablet
    8 mg, 16 mg and 24 mg prolonged release capsule
14. Gemcitabine
15. Goserelin
    Inj.: 3.6 mg depot solution, pre-filled syringe (SC) (as acetate)
16. Human papillomavirus quadrivalent (types 6,11,16,18 recombinant vaccine)
17. Hydroxochloroquine
18. Irinotecan
19. Meropenem
20. Methylphenidate
    Oral: 18 mg and 36 mg ER tablet
21. Multivitamins
    ▼ Inj.: freeze-dried powder 10 mL vial (IV infusion)
    (Must be diluted before use)
22. Mycophenolic acid as mycophenolate sodium
23. Nelfinavir
    Oral: 250 mg tablet (as mesilate), 50 mg/scoop (1 g) powder,
    144 g bottle to be mixed with water, milk or food (as mesilate)
24. Nicardipine
    Inj.: 1 mg/mL, 2 mL and 10 mL ampul (IV) (as hydrochloride)
25. Nimodipine
    Oral: 30 mg tablet
26. Nepafenac
27. Oxycodone

28. Pneumococcal conjugate vaccine
29. Rosuvastatin + Hydrochlorothiazide
30. Sevoflurane
31. Tacrolimus
    Oral: 5 mg capsule
    Inj.: 5 mg /mL, 1 mL ampul (concentrate) (IM, IV infusion)
32. Telmisartan + Hydrochlorothiazide
33. Tinzaparin
34. Tiotropium
35. Travoprost
36. Valaciclovir
37. Valsartan + Hydrochlorothiazide
38. Zolmitriptan

MEDICINES IN PNDF WITH ABUSE POTENTIAL (List A)

A. Dangerous Drug Preparations (A1)
(drugs requiring S-2 License and DDB Prescription Form)
Total = 19

1. Alprazolam
2. Bromazepam
3. Butorphanol (as tartrate)
4. Clonazepam
5. Codeine (as phosphate)
6. Diazepam
7. Fentanyl (as citrate)
8. Flurazepam
9. Ketamine
10. Lorazepam
11. Methylphenidate
12. Midazolam
13. Morphine (as sulfate)
14. Nalbuphine
15. Oxycodone
16. Phenobarbital
17. Pethidine (meperidine)
18. Thiopental sodium
19. Zolpidem

B. Controlled Chemicals (A2)
(drugs requiring S-2 License using Ordinary Prescription Form)
Total = 3

1. Ephedrine (as sulfate)
2. Ergotamine (as tartrate)
3. Methylergometrine (methylergonovine)

MEDICINES IN THE PNDF REQUIRING SPECIFIC EXPERTISE, DIAGNOSTIC PRECISION OR SPECIAL EQUIPMENT FOR PROPER USE (1)

Total = 153

1. Acetylcysteine Inj.
2. Adenosine
3. Albumin, Human
4. Alcohol, ethyl
5. Aminophylline (Theophylline Ethylenediamine)
6. Amphotericin B
7. Antilymphocyte Immunoglobulin (ALG) (equine)
8. Antithymocyte Immunoglobulin (ATG) (rabbit)
9. Ascorbic acid (vitamin C) Inj.
10. Asparaginase
11. Aspirin
12. Atropine (as sulfate)
13. Azathioprine
14. Basiliximab
15. Bleomycin
16. Bromocriptine
17. Bupivacaine
18. Calcitriol
19. Calcium folinate Inj.
20. Calcium gluconate Inj.
21. Capecitabine
22. Carboplatin
23. Carmustine
24. Chlorambucil
25. Ciclosporin
26. Cisplatin
27. Clomifene
28. Clozapine
29. Cobra Antivenin
30. Cyclophosphamide
31. Cyproterone
32. Cytarabine
33. Dacarbazine
34. Dactinomycin (actinomycin D)
35. Dalteparin
36. Dantrolene
37. Danazol
38. Daunorubicin
39. Deferiprone
40. Deferoxamine
41. Desflurane
42. Diazepam
43. Dimercaprol
44. Dimercaptopropane sulphonate (DMPSI)
45. Dobutamine
46. Docetaxel
47. Dopamine
48. Doxorubicin
49. Enoxaparin
50. Epinephrine (adrenaline)
51. Epirubicin
52. Epoetin alfa (recombinant human erythropoietin)
53. Epoetin beta (recombinant erythropoietin)
54. Ergotamine (tartrate)
55. Esmolol
56. Etoposide
57. Factor VIII Concentrate
58. Factor IX Complex Concentrate (coagulation factors II, VII, IX, X)
59. Fenofibrate
60. Filgrastim (G-CS7)
61. Flucytosine (5-fluorocystosine)
62. Flumazenil
63. Fluorouracil
64. Fluoxetine
65. Flupentixol
66. Fluphenazine
67. Flutamide
68. Fomepizole
69. Ganciclovir
70. Gemcitabine
71. Glucagon
72. Glyceryl trinitrate (nitroglycerin)
73. Haloperidol
74. Halothane
75. Human Chorionic Gonadotrophin (HCG)
76. Human Growth Hormone (biosynthetic)

77. Human Menopausal Gonadotrophin (HMG, menotropin)
78. Hydroxyurea
79. Idarubicin
80. Ifosfamide
81. Imatinib
82. Immunoglobulin normal, human (IGIV)
83. Indometacin
84. Interferon Alfa 2A (human)
85. Interferon Alfa 2B (human)
86. Irinotecan
87. Isoflurane
88. Ketamine
89. Leuproreline
90. Lidocaine
91. Lithium carbonate
92. Lomustine
93. Lorazepam
94. Magnesium sulfate
95. Megestrol
96. Melphalan
97. Mercaptopurine
98. Mesalazine
99. Mesna (Sodium-2-mercaptoethane sulphonate)
100. Methotrexate
101. Methylene Blue
102. Methylphenidate
103. Mitoxantrone
104. Molgramostin (Gm-CS7)
105. Montelukast
106. Mycophenolate mofetil
107. Mycophenolic acid (as Mycophenolate sodium)
108. N-Acetyl Penicillamine
109. Nadroparin
110. Naloxone
111. Nitrous oxide
112. Norepinephrine
113. Octreotide
114. Olanzapine
115. Ondansentron
116. Oxaliplatin
117. Paclitaxel
118. Pancuronium
119. Peginterferon Alfa 2A
120. Physostigmine
121. Pralidoxime chloride
122. Procarbazine
123. Propofol
124. Protamine sulfate
125. Pyridostigmine
126. Ramosetron
127. Rituximab
128. Rocuronium
129. Sevoflurane
130. Simvastatin
131. Sirolimus
132. Sodium calcium edetate
133. Sodium Iodide I3II
134. Sodium nitrite
135. Sodium nitroprusside
136. Sodium thiosulfate
137. Somatostatin
138. Streptokinase
139. Succimer
140. Suxamethonium (succinylcholine)
141. Tacrolimus
142. Tamoxifen
143. Tegafur + Uracil
144. Testosterone
145. Thiopental sodium
146. Tinzaparin
147. Tramadol
148. Trastuzumab
149. Unfractionated Heparin
150. Vecuronium
151. Vinblastine
152. Vincristine
153. Warfarin

MEDICINES WITH LIMITED INDICATIONS OR NARROW SPECTRUM OF ACTIVITY (2)

Total = 136

1. Acetylcysteine Inj.
2. Adenosine
3. Albumin, Human
4. Alcohol, ethyl
5. Amiodarone
6. Antilymphocyte immunoglobulin (ALG) (equine)
7. Antithymphocyte immunoglobulin (ATG) (rabbit)
8. Ascorbic acid (vitamin C) inj.
9. Asparaginase
10. Atropine inj.
11. Azathioprine
12. Basiliximab
13. Bleomycin
14. Bromocriptine
15. Butamirate
16. Calcitriol
17. Calcium folinate inj.
18. Calcium gluconate inj.
19. Capecitabine
20. Carboplatin
21. Carmustine
22. Chlorambucil
23. Ciclosporin
24. Cisplatin
25. Clomifene
26. Clozapine
27. Cobra Antivenin
28. Cyclophosphamide
29. Cyproterone
30. Cytarabine
31. Dacarbazine
32. Dactinomycin
33. Dalteparin
34. Daunorubicin
35. Deferiprone
36. Deferoxamine
37. Dextromethorphan
38. Digoxin
39. Dimercaprol
40. Dimercaptopropane-sulphonate (DMPS)
41. Dipyridamole
42. Dobutamine
43. Docetaxel
44. Dopamine
45. Doxorubicin
46. Edrophonium
47. Enoxaparin
48. Epinephrine
49. Epirubicin
50. Epoetin alfa (recombinant human erythropoietin)
51. Epoetin beta (recombinant erythropoietin)
52. Ergotamine tartrate
53. Esmolol
54. Etoposide
55. Everolimus
56. Factor IX Complex Concentrate (coagulation factors II, VII, IX, X)
57. Filgrastim (G-CSF)
58. Flumazenil
59. Fluoride
60. Fluorouracil
61. Flutamide
62. Fomepizole
63. Ganciclovir
64. Gemcitabine
65. Glucagon
66. Griseofulvin
67. Human chorionic gonadotrophin (HCG)
68. Human growth hormone (biosynthetic)
69. Human menopausal gonadotrophin (HMG, menotropin)
70. Hydroxocobalamin
71 Hydroxyurea
72. Idarubicin
73. Ifosfamide
74. Imatinib
75. Interferon Alfa 2A (human)
76. Interferon Alfa 2B
77. Irinotecan
78. Leuproreline

79. Lidocaine
80. Lomustine
81. Lorazepam
82. Magnesium sulfate
83. Medroxyprogesterone
84. Megestrol
85. Melphalan
86. Mercaptopurine
87. Mesna (Sodium-2-mercaptoethane sulphonate)
88. Methylene blue
89. Methylphenidate
90. Mitoxantrone
91. Molgramostim (Gm-CSF)
92. Mycophenolate mofetil
93. Mycophenolic acid
94. N-acetyl penicillamine
95. Nadroparin
96. Naloxone
97. Norepinephrine
98. Norethisterone
99. Octreotide
100. Olanzapine
101. Ondansetron
102. Oxaliplatin
103. Oxytocin (synthetic)
104. Paclitaxel
105. Peginterferon Alfa 2A
106. Penicillin G Crystalline
107. Physostigmine
108. Pralidoxime chloride
109. Procarbazine
110. Protamine sulfate
111. Pyridostigmine
112. Pyridoxine (Vitamin B6)
113. Ramosetron
114. Retinol (Vitamin A)
115. Rituximab
116. Sirolimus
117. Sodium calcium edetate
118. Sodium Iodide I3II
119. Sodium nitrite
120. Sodium nitroprusside
121. Sodium thiosulfate
122. Somastostin
123. Spectinomycin
124. Spironolactone
125. Streptokinase
126. Succimer
127. Tacrolimus
128. Tamoxifen
129. Tegafur + Uracil
130. Tinzaparin
131. Trastuzumab
132. Unfractionated Heparin
133. Vasopressin
134. Vinblastine
135. Vincristine
136. Warfarin

MEDICINES IN THE PNDF WHICH ARE TO BE USED ONLY IN HOSPITALS WITH DOH ACCREDITED ANTIMICROBIAL RESISTANCE SURVEILLANCE PROGRAM (3)

Total = 6

1. Cefepime
2. Ertapenem
3. Levofloxacin
4. Meropenem
5. Piperacillin + Tazobactam
6. Vancomycin

LIST B MEDICINES

List B medicines include immediate release, solid oral dosage forms of multisource (generic) pharmaceutical products that require *in-vivo* bioequivalence studies as proposed by the World Health Organization (WHO):

Active pharmaceutical ingredients (APIs) are classified according to the Biopharmaceutics Classification System (BCS) as follows:

BCS Class I: "high" solubility - "high" permeability
BCS Class II: "low" solubility - "high" permeability
BCS Class III: "high" solubility - "low" permeability
BCS Class IV: "low" solubility - "low" permeability

Depending on the classification, the oral bioavailability of the API may be expected to range from being heavily dependent on the formulation and manufacturing method (e.g. Class II APIs: poorly soluble yet highly permeable), to being mostly dependent on the APIs permeability properties (e.g. Class III APIs: highly soluble yet poorly permeable).

Pharmaceutical formulations that can be eligible for a biowaiver procedure not requiring *in-vivo* bioequivalent studies show the following characteristics:

1. should contain a Class I API
2. should be rapidly dissolving (should release at least 85% of its content in 30 minutes in media with pH 1.2, pH 4.5 and pH 6.8 at 37° Celsius)
3. should not contain excipients which could influence the absorption of the API.
4. should not contain API with narrow therapeutic index.
5. should not be designed to be absorbed from the oral cavity.

High permeability ensures complete uptake of 85% or more of the API during its passage in the small intestines.

The decision to allow a biowaiver based on the BCS should take into consideration the solubility and permeability characteristics as well as the therapeutic use and therapeutic index of the API, its pharmaco-kinetic properties, the similarity of the dissolution profiles of the multisource and comparator products in standard buffers with a pH of 1.2, pH 4.5 and pH 6.8 at 37° Celsius. Data related to the excipients composition in the multisource product are also required.

The WHO noted that in some countries, products may be available at doses exceeding the highest dose on the WHO Essential Medicines List (EML). In such cases, the WHO tables on biowaivers may no longer be appropriate and the dose solubility ratio and permeability will have to be reassessed at the product dose.

List B Medicines in the PNDF vol. 1, 7th edition include the following:

1. Acetazolamide 250 mg
2. Albendazole 400 mg
3. Artemether 20 mg + lumefantrine 120 mg

4. Artesunate 50 mg
5. Azathioprine sodium 50 mg
6. Azithromycin 500 mg
7. Carbamazepine 200 mg
8. Cefixime 400 mg
9. Ciclosporin 25 mg
10. Clofazimine 100 mg
11. Dapsone 100 mg
12. Diloxanide furoate 500 mg
13. Efavirenz 200 mg
14. Erythromycin stearate and ethylsuccinate 250 mg
15. Etoposide 100 mg
16. Furosemide 40 mg
17. Glibenclamide 5 mg
18. Griseofulvin 250 mg
19. Haloperidol 2 mg
20. Indinavir sulfate 400 mg
21. Ivermectin 6 mg
22. Lopinavir 133.3 mg + ritonavir 33.3 mg
23. Mefloquine hydrochloride 250 mg
24. Mercaptopurine 50 mg
25. Nelfinavir mesilate 250 mg
26. Nevirapine 200 mg
27. Nifedipine 10 mg
28. Nitrofurantoin 100 mg
29. Phenytoin sodium
30. Praziquantel 600 mg
31. Pyrimethamine 25 mg
32. Retinol palmitate 110 mg (200,000 IU)
33. Rifampicin 300 mg and rifampicin FDC with other anti-TB medicine
34. Ritonavir 100 mg
35. Saquinavir 200 mg
36. Spironolactone 25 mg
37. Sulfadoxine 500 mg + pyrimethamine 25 mg
38. Sulfamethoxazole + trimethoprim
    400 mg + 80 mg
    800 mg + 160 mg
39. Theophylline anhydrous
40. Verapamil hydrochloride 80 mg

MEDICINAL PLANT PRODUCTS REGISTERED WITH BFAD (•)

Total = 5

1. Akapulko [Cassia alata Linn. (Fam. Leguminosae)]
2. Lagundi [Vitex negundo L. (Fam. Verbenaceae)]
3. Sambong [Blumea balsamifera (L) DC (Fam. Compositae)]
4. Tsaang Gubat [Carmona retusa (Vahl) Masam (Fam. Boraginaceae]
5. Yerba Buena [Mentha cordifolia Opiz (Fam. Labiatae)]

PHILIPPINE DRUG ENFORCEMENT AGENCY

LIST OF DANGEROUS DRUG PREPARATIONS

(1961 and 1971 UN Convention on Narcotic Drugs and Pyschotropic Substances,
DDB Regulation No. 3 s. 2003 & *Other DDB Issuances)

AND

LIST OF DRUG PREPARATIONS CONTAINING ERGOMETRINE / ERGOTAMINE

(1988 UN Convention Against Illicit Traffic of Narcotic Drugs and Psychotropic Substances)

1. DANGEROUS DRUG PREPARATIONS (DDP) — (A1)

1.1 Per DDB Regulation No. 3 s. 2003 - to be prescribed thru DOH Official Rx Form, 1 DDP per Rx, Partial Filling allowed, No Refill.

BUPRENORPHINE — *(Norspan Patch)*
CODEINE as poly styrene divinyl benzene sulfonate — *(Codipront N Capsule ; Codipront N Syrup)*
* DIAZEPAM — *(Ampul : Anxiol, Diazepam, Lorcam, Trankil, Valium, Zopamid)*
* EPHEDRINE SULFATE — *(Ephedrine Sulfate Ampul)*
FENTANYL — *(Patch : Durogesic, Durogesic D-Transdermal)*
FENTANYL CITRATE — *(Ampul : Fentanyl Citrate, Sublimax, Sublimaze, Trofentyl)*
HYDROMORPHONE HYDROCHLORIDE — *(Jurnista Tablet)*
METHYLPHENIDATE — *(Tablet : Concerta, Ritalin)*
* MIDAZOLAM — *(Ampul : Dormicum, Dormizol, Midazolam Hydrochloride, Zedoz)*
MORPHINE SULFATE — *(Ampul : Morin, Morphine Sulfate ; Tablet : Morphine Sulfate, MST Continus MR, MXL Prolonged Release, Relimal CR)*
OXYCODONE HYDROCHLORIDE — *(Oxynorm Capsule ; Oxycontin Prolonged Release Tablet)*
PETHIDINE HYDROCHLORIDE — *(Ampul : Deme, Demerol, Pethidine Hydrochloride ; Vial : Demerol)*
PENTOBARBITAL SODIUM — *(Euthal Vial)*
* PHENOBARBITAL SODIUM — *(Luminal Ampul)*

1.2 * Per DDB Regulation No. 3 s. 2005 — to be prescribed thru Ordinary Rx (Personalized Rx) with S2, 1 DDP per Rx, Partial Filling allowed, No Refill.

KETAMINE — *(Vial : Ketamax. Ketazol, Ketram, Uniket)*

1.3 * Per DDB Regulation No. 4 s. 2005 — preparations not in injectable form i.e. capsule, tablet or syrup, to be prescribed thru Ordinary Rx (Personalized Rx) with S2, 1 DDP per Rx, Partial Filling allowed, No Refill.

PSEUDOEPHEDRINE HYDROCHLORIDE — *(Rhinos SR Tablet)*
PSEUDOEPHEDRINE SULFATE — *(Clarinase Tablet ; Clarinase Syrup)*

1.4 ***** Per DDB Resolution No. 8 s. 2004 — preparations not in injectable form i.e. capsule, tablet or syrup, to be prescribed thru Ordinary Rx (Personalized RX) with S2, 1 DDP per Rx, Partial Filling allowed, No Refill.

ALPRAZOLAM — *(Tablet : Alprazolam, Altrox, Atrest, Praz, Xanor, Xanor XR)*
BROMAZEPAM — *(Lexotan Tablet)*
CLONAZEPAM — *(Tablet : Clonotil, Rivotril)*
CHLORAZEPATE DIPOTASSIUM — *(Tranxene Capsule)*
DIAZEPAM — *(Tablet : Diazepam, Nixtensyn, Solina, Valium)*
ESTAZOLAM — *(Esilgan Tablet)*
FLURAZEPAM — *(Dalmane Capsulet)*
MAZINDOL — *(Mazzol Tablet)*
MIDAZOLAM — *(Dormicum Tablet)*
NITRAZEPAM — *(Mozepam Tablet)*
PHENOBARBITAL SODIUM — *(Phenobarbital Tablet)*
PHENTERMINE RESIN — *(Duromine Capsule)*
ZOLPIDEM — *(Tablet : Niben, Pidezol, Stilnox, Stilnox MR, Ziohex, Zoldem, Zulnap)*

2. PREPARATIONS CONTAINING ERGOMETRINE/ERGOTAMINE (Controlled Chemicals) — (A2)

2.1 Per DDB Regulation No. 3 s. 2003 — to be prescribed thru Ordinary Rx (Personalized Rx) with S2, Partial Filling allowed, No Refill.

ERGOTAMINE TARTRATE — *(Avamigran Tablet)*
METHYLERGOMETRINE MALEATE — *(Ampul : Cethergo, Lerin, Methylergometrine Maleate, Medisyl, Mertgotrex, Methergin, Myometril, Uterine, Utermet; Usamena Tablet)*

PRESCRIPTION LIMITS

Section 32 (6), DDB Regulation No. 3 s. 2003 — The quantities that may be prescribed in a single applicable prescription by a licensed practitioner should not exceed the specified quantities as follows:

a. For Cancer Patients:

i. Morphine Sulfate	(tablets [oral])	=	3,000 mg
	(ampules / vials)	=	448 mg
ii. Fentanyl patch	25 ug/hr	=	30 patches
	50 ug/hr	=	30 patches
Fentanyl ampul	50 ug/mL	=	10 ampuls (1 mL)
		=	03 ampuls (2 mL)
For use in Patient Controlled Analgesic (PCA Machine)		=	50 ampuls (2 mL)
		=	50 ampuls (10 mL)
iii. Oxycodone Hydrochloride		=	1,200 mg
	10 mg		120 tablets
	20 mg		60 tablets
	40 mg		30 tablets
	80 mg		15 tablets
iv. Pethidine Hydrochloride		=	14 vials
v. Other Dangerous Drugs	(ampuls)	=	20 pieces
	(tablets)	=	40 pieces
	(capsules)	=	40 pieces

b. Ordinary circumstances:

i. Benzodiazepines		=	30 tablets or capsules
(as anxiolytic or hypnotic or both)		=	10 ampuls x 1 mL
		=	03 ampuls x 2 mL
		=	02 ampuls x 3 mL
		=	02 ampuls x 5 mL
		=	01 ampul x 10 mL
(for muscle spasm/dystonia/tetanus)		=	90 tablets (5 mg)
ii. Phenobarbital preparations		=	2 weeks supply
(for epilepsy patients)		=	2 bottles x 100 tablets
iii. Pethidine Hydrochloride		=	03 ampuls
iv. Other Dangerous Drugs (hospital use)		=	01 vial

- A prescription may not be issued in order for an individual practitioner to obtain controlled substances for the purpose of general dispensing to patients.
- A prescription may not be issued to a drug dependent person for the purpose of continuing his dependence upon such drugs.

MEDICAL DEVICES / SUPPLIES

Total = 30

1. Infusion administration set with air vent, without needle, adult
2. Infusion administration set with air vent, without needle, pedia
3. Infusion administration set with air vent, with needle, adult*
4. Infusion administration set with air vent, with needle, pedia*
5. Blood transfusion set
6. Precision drip chamber/calibrated burette, 100 mL, 60 drops/mL
7. I.V. infusion pump set
8. Winged needle infusion sets with needle*
9. Scalp vein infusion sets
10. I.V. catheter/cannula with needle*
11. Peritoneal dialysis administration set
12. Nebulizer + aerosol mask/mouthpiece
13. Oxygen catheter/cannula
14. Thoracic catheters**
15. Foley catheters**
16. Urethral catheters**
17. Ureteral catheters**
18. Epidural catheters**
19. Nasogastric tubes**
20. Endotracheal tubes**
21. Disposable needles*
22. Disposable syringes
23. Disposable syringes + needle*
24. Spinal needles
25. Insulin syringe without needle
26. Insulin syringe with needle*
27. Tuberculin syringe without needle
28. Tuberculin syringe with needle*
29. Thermometer (oral, anal)
30. Sterile surgical gloves

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* Specify needle size
** Specify size

PROCESS FOR DRAFTING THE PHILIPPINE NATIONAL DRUG FORMULARY

1. Set the Guidelines for Establishing the Philippine National Drug Formulary (PNDF) based on the WHO Technical Report Series on the "Use of Essential Drugs".
2. Agree on the definition of the Core List and the Complementary List.
3. Devise the algorithm on Drug Selection for the PNDF which is the contracted version of the guidelines (*See* Appendix I).
4. Considering the guidelines, utilize the following inputs to select which drugs will be included in the Core List and Complementary List.
   - 4.1 Latest Philippine Health Statistics
   - 4.2 WHO Essential Drug List
   - 4.3 DOH Formulary for Primary, Secondary and Tertiary Health Care Levels - These were arrived at through a series of weekly deliberations for a total period of six (6) months by members of the DOH Therapeutics Committees for RDU and the DOH Therapeutics Committee of Secondary and Tertiary Hospitals coming from different DOH regional health units.
   - 4.4 PMA - PSECP Formulary - A compilation of proposed drugs from various specialty societies. The initial workshop on "Designing a Formulary for Medical Practice in the Philippines" held on October 4-5, 1986 at the PMA Building was participated in by representatives from all the different specialty societies affiliated with PMA. Each specialty society was asked to list down ten (10) leading diseases encountered in their practice together with the drugs each society recommends for use indicating which ones should fall under the "Main or Core List" and "Complementary List". All the submissions of the various specialty societies were collated by a task force from PMA and PSECP and deliberated on by the various representatives in a series of monthly meetings held at the PMA Bldg. for 1 1/2 years until its submission for approval to the Board of Governors.
   - 4.5 British National Formulary and Charing Cross Formulary
   - 4.6 Others:
     - 4.6.1 BFAD registered pharmaceutical preparations
     - 4.6.2 ADR reports and other recent drug information
     - 4.6.3 Philippine Index of Medical Specialties (PIMS)
     - 4.6.4 Martindale: The Extra Pharmacopoeia
     - 4.6.5 USP Drug Information for the Health Care Professional
     - 4.6.6 List of Psychotropic Substances under International Control
     - 4.6.7 List of Narcotic Drugs under International Control
5. Consult resource persons/experts for specific therapeutic category to deliberate on the draft PNDF.
6. Evaluate the recommendations made by the resource persons/experts.

7. Evaluate the additional inputs from the pharmaceutical industry.
8. Finalize the PNDF for submission to the Undersecretary of Health for External Affairs and subsequently to the Secretary of Health.
9. Review quarterly and update annually the PNDF, as mandated by R.A. 6675 otherwise known as the Generics Act of 1988.

GENERAL GUIDELINES FOR ESTABLISHING THE PHILIPPINE NATIONAL DRUG FORMULARY

Drug selection must be based on the following:

1. **Relevance to disease** - Indicated in the treatment of prevalent diseases.
2. **Efficacy and safety** - based on objective results based on adequate pharmacologic studies including at least expanded Phase II clinical trials and/or additional Phase III studies among Filipinos.
3. **Quality -** The selected pharmaceutical products have to meet adequate quality control standards, including stability, and, when necessary, bioavailability. Where national standards are not for this type of control, the suppliers must provide documentation of the product's compliance with the requested specifications. The WHO "Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce," established in 1975, gives the assurance that the product is manufactured under suitable conditions, i.e., in accordance with good manufacturing practices (GMP) and that manufacturing premises are subject to inspection at suitable intervals. The WHO Certification Scheme also records whether or not the product has been approved for marketing in its country of origin.
4. **Cost** - of treatment regimen (not just the unit cost).
5. **Appropriateness to the capability of health workers at different levels of health care -** The level of expertise required to prescribe, administer and monitor the safety and adverse effects of single drugs or group of drugs in a therapeutic category must be considered. Consideration should be given to the competence of local personnel in making a correct diagnosis.
6. **Local health problems -** The influence of concomittant, locally prevalent diseases or conditions on pharmacokinetic and pharmacodynamic parameters modifying therapeutic response have to be considered in making a selection, e.g. malnutrition, liver disease.
7. **Benefit/Risk ratio** - When several comparable drugs are available for the same therapeutic indication, it is necessary to select the one which provides the most favorable benefit/risk ratio.
8. **Preferential factors for evaluating therapeutically equivalent drugs -** When two or more drugs are therapeutically equivalent, preference should be given to:
    - 8.1 the drug most thoroughly investigated and therefore the best understood with respect to its beneficial properties and limitations.
    - 8.2 the drug possessing clinical utility for the treatment of more than one condition or disease.
    - 8.3 the drug with most favorable pharmacokinetic properties - e.g., to improve compliance, to minimize risk in various pathophysiological states.
    - 8.4 the drugs that are in a dosage form that is easy for the health staff to dispense or easily or safely administered to the patient.

8.5 the drugs that are easy for the patient to take or with greater acceptability to most patients.
8.6 the drugs, pharmaceutical products and dosage forms with favorable stability under anticipated local conditions for which storage facilities exist.
8.7 the drugs for which the local reliable manufacturing facilities exist for its production.

9. **In the great majority of cases, the drugs should be formulated as single compounds -** Fixed-ratio combinations are only acceptable when:

9.1 the value of concomitant use of more than one drug is clinically documented.
9.2 the therapeutic benefit of the combination is greater than the sum of each of the individual components.
9.3 the combination is safer than the use of an individual drug.
9.4 the cost of the combination product is less than or should not exceed the cost of the sum of the individual products.
9.5 compliance is improved.
9.6 the combination must be such that the appropriate drug ratio satisfactory for the majority of the population is maintained.

10. **Period review of drug list** - yearly or whenever necessary to incorporate significant new therapeutic advances and information.

10.1 Generally, new drugs should be introduced only if they offer distinct advantages over drugs previously selected.
10.2 If, on the bases of new information, drugs already on the list are found to no longer possess a favorable benefit/risk ratio, they should be replaced by drugs with higher benefit/risk ratio.

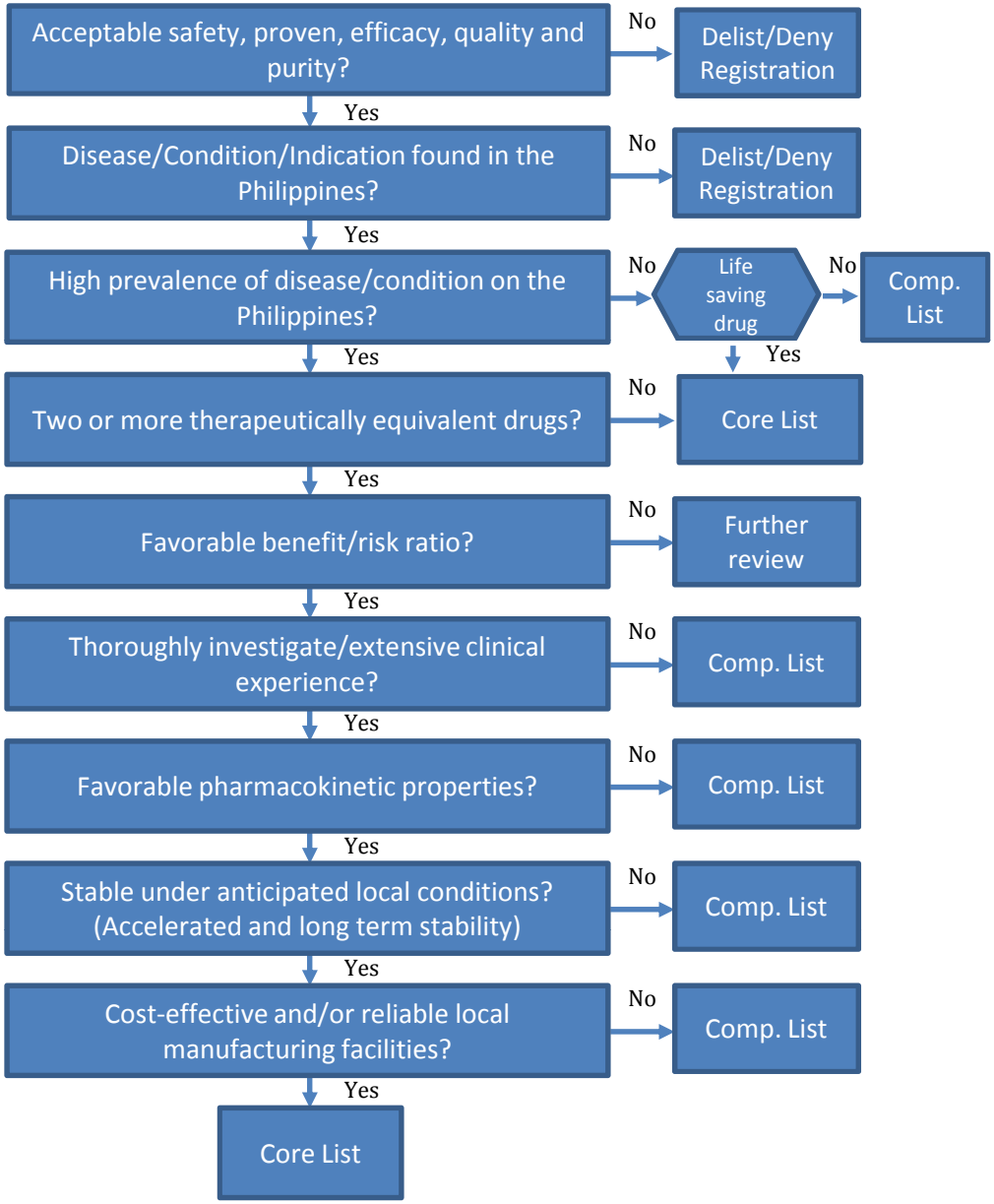
11. International Non-proprietary Names (INN; generic) for drugs should be used.

DEFINITION OF TERMS:

CORE or MAIN LIST - A list of drugs for the health care needs of the majority of the population; the listed drugs should therefore be made available at all times in adequate amounts and in appropriate dosage forms at the lowest possible cost. They are of utmost importance and are basic, indispensable and necessary for the health needs of the population.

COMPLEMENTARY LIST - A list of drugs for treating rare disorders or in exceptional circumstances; alternative drugs when drugs in the main list are known to be ineffective or inappropriate for a given individual; alternative drugs when drugs in the main list cannot be made available; drugs with special pharmacologic properties.

DRUG SELECTION FOR THE PHILIPPINE NATIONAL DRUG FORMULARY



CRITERIA FOR INCLUSION AND DELETION OF DRUGS FROM THE PHILIPPINE NATIONAL DRUG FORMULARY

In addition to the guidelines as stated in Appendix N (*see* page 144 - 145) the National Formulary Committee considered the following criteria for including additional drugs:

1. The drug is needed for the prevention and treatment of conditions not already covered in the existing list;
2. The drug is more effective and/or less toxic than a drug listed for the same indication;
3. The drug is at least as effective and safe and of lower cost than the drug listed for the same indication; and
4. The drug is deemed essential for a specific DOH health program/project.

On the other hand, the following criteria were applied for deleting a drug from the list:

1. A more effective or equally effective but less toxic drug becomes available;
2. In the light of further knowledge, the therapeutic efficacy of the drug is found to be unsatisfactory or questionable;
3. Toxicity/Suspected toxicity or potential for abuse or dangerous interactions prove to outweigh its therapeutic value;
4. The drug has fallen into disuse and is no longer available;
5. The drug is no longer deemed cost-effective to other therapies; and
6. The drug is a fixed dose combination which does not satisfy the requirements of A.O. 96 s. 1990.

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Republic of the Philippines
CONGRESS OF THE PHILIPPINES
Metro Manila

Second Regular Session

Begun and held in Metro Manila, on Monday, the twenty-fifth day of July, nineteen hundred and eighty-eight

[Republic Act No. 6675]

AN ACT TO PROMOTE, REQUIRE AND ENSURE THE PRODUCTION OF AN ADEQUATE SUPPLY, DISTRIBUTION, USE AND ACCEPTANCE OF DRUGS AND MEDICINES IDENTIFIED BY THEIR GENERIC NAMES

Be it enacted by the Senate and House of Representative of the Philippines in Congress assembled:

Sec. 1 Title. - This Act shall be known as the Generics Act of 1988.

Sec. 2 Statement of Policy. - It is hereby declared the policy of the State:

To promote, encourage and require the use of generic terminology in the importation, manufacture, distribution, marketing, advertising and promotion, prescription and dispensing of drugs;

To ensure the adequate supply of drugs with generic names at the lowest possible cost and endeavor to make them available for free to indigent patients;

To encourage the extensive use of drugs with generic names through a rational system or procurement and distribution;

To emphasize the scientific basis for the use of drugs, in order that health professionals may become more aware and cognizant of their therapeutic effectiveness, and

To promote drug safety by minimizing duplication medications and/or use of drugs with potentially adverse drug interactions.

Sec. 3 Definition of Terms. - The following terms are herein defined for purposes of this Act.

1) "Generic Name or Generic Terminology" is the identification of drugs and medicines by their scientifically and internationally recognized active ingredients or by their official generic name as determined by the Bureau of Food and Drugs of the Department of Health.

2) "Active Ingredient" is the chemical component responsible for the claimed therapeutic effect of the pharmaceutical product.

3) "Chemical Name" is the description of the chemical structure of the drug or medicine and serve as the complete identification of a compound.

4) "Drug Product" is the finished product form that contains the active ingredients, generally but not necessarily in association with inactive ingredients.

5) "Drug Establishment" is any organization or company involved in the manufacture, importation, repacking and/or distribution of drugs or medicines.

6) "Drug Outlets" means drugstores, pharmacies, and any other business establishments which sell drugs or medicines.

7) "Essential Drugs List" or "National Drug Formulary" is a list of drugs prepared and periodically updated by the Department of Health on a basis of health conditions obtaining in the Philippines as well as on internationally accepted criteria. It shall consist of a core list and a complementary list.

8) "Core List" is a list of drugs that meets the health care needs of the majority of the population.

9) "Complementary List" is a list of alternative drugs used when there is no response to the core essential drug or when there is a hypersensitivity reaction to the core essential drug or when, for one reason or another, the core essential drug cannot be given.

10) "Brand Name" is the proprietary name given by the manufacturer to distinguish its product from those of competitors.

11) "Generic Drugs" are drugs not covered by patent protection and which are labeled solely by their international non-proprietary or generic name.

Sec. 4 The Use of Generic Terminology for Essential Drugs and Promotional Incentives.

(a) In the promotion of the generic names for pharmaceutical products, special consideration shall be given to drugs and medicines which are included in the Essential Drugs List to be prepared within one hundred eighty (180) days from approval of this Act and updated quarterly by the Department of Health on the basis of health conditions obtaining in the Philippines as well as on internationally accepted criteria.

(b) The exclusive use of generic terminology for in the manufacture, marketing and sales of drugs and medicines, particularly those in the Essential Drugs List, shall be promoted through such a system of incentives as the Board of Investments jointly with the Department of Health and other government agencies as may be authorized by law, shall promulgate in accordance with existing laws, within one hundred eighty (180) days after approval of this Act.

Sec. 5 Posting and Publication. - The Department of Health shall publish annually in at least two (2) newspapers of general circulation in the Philippines the generic names and the corresponding brand names under which they are marketed, of all drugs and medicines available in the Philippines.

Sec. 6 Who Shall Use Generic Terminology. -

(a) All government health agencies and their personnel as well as other government agencies shall use generic terminology or generic names in all transactions related to purchasing, prescribing, dispensing, and administering of drugs and medicines.

(b) All medical, dental and veterinary practitioners, including private practitioners shall write prescriptions using the generic name. The brand name may be included, if so desired.

(c) Any organization or company involved in the manufacture, importation, repacking, marketing and/or distribution of drugs and medicines shall indicate prominently the generic name of the product. In any case of brand name products, the generic name shall appear prominently and immediately above the brand name in all product labels as well as in advertising and other promotional materials.

(d) Drug outlets, including drugstore, hospital and non-hospital pharmacies and non-traditional outlets such as supermarkets and store, shall inform any buyer about any and all other drug products having the same generic name, together with their corresponding prices so that the buyer may adequately exercise his option.

Within one (1) year after approval of this Act, the drug outlets referred to herein, shall post in conspicuous places in their establishments, a list of drug products with the same generic name and their corresponding prices.

Sec. 7 Provision on Quality, Manufacturer's Identity and Responsibility. - In order to assure responsibility for drug quality in all instances, the label of all drugs and medicines shall have the following: name and country of manufacture, dates of manufacture and expiration. The quality of such generically labeled drugs and medicines shall be duly certified by the Department of Health.

Sec. 8 Required Production. - Subject to rules and regulations promulgated by the Secretary of Health, every drug manufacturing company operating in the Philippines shall be required to produce, distribute and make available to the general public the medicines it produces, in the form of generic drugs.

Sec. 9 Rules and Regulations. - The implementation of the provisions of this Act shall be in accordance with the rules and regulations to be promulgated by the Department of Health. Rules and regulations with penal sanctions shall be promulgated within one hundred eighty (180) days after approval of this Act and shall take effect fifteen (15) days after publication in the Official Gazette or in two (2) newspapers of general circulation.

Sec. 10 Authority to Import. - Within three (3) years from the effectivity of this Act, extendible by the President for another two (2) years and during periods of critical shortage and absolute necessity, the Department of Health is hereby authorized to import raw materials of which there is a shortage for the use of Filipino-owned or controlled drug establishments to be marketed and sold exclusively under generic nomenclature. The

President may authorize the importation of raw materials tax and duty-free. The Secretary of Health shall ensure that the imported raw materials are allocated fairly and efficiently among Filipino-owned or controlled drug establishments. He shall submit to the Office of the President and to Congress a quarterly report on the quantity, kind and value of the raw materials imported.

Sec. 11 Education Drive. - The Department of Health jointly with the Department of Education, Culture and Sports, Philippine Information Agency and the Department of Local Government shall conduct a continuous information campaign for the public and a continuing education and training for the medical and allied medical professions on drugs with generic names as an alternative of equal efficacy to the more expensive brand name drugs. Such educational campaign shall include information on the illnesses or symptoms which each generically named drug is supposed to cure or alleviate, as well as its contraindications. The Department of Health with the assistance of the Department of Local Government and the Philippine Information Agency shall monitor the progress of the education drive, and shall submit regular reports to Congress.

Sec. 12 Penalty. -

(A) Any person who shall violate Section 6(a) or 6(b) of this Act shall suffer the penalty graduated hereunder, viz.:

(a) For the first conviction, he shall suffer the penalty of reprimand which shall be officially recorded in the appropriate books of the Professional Regulation Commission.

(b) For the second conviction, the penalty of fine in the amount of not less than two thousand pesos (P 2,000.00) but not exceeding five thousand pesos (P 5,000.00) at the discretion of the court.

(c) For the third conviction, the penalty of fine in the amount of not less than five thousand pesos (P 5,000.00) but not exceeding ten thousand pesos (P 10,000.00) and suspension of his license to practice his profession for thirty (30) days at the discretion of the court.

(d) For the fourth and subsequent convictions, the penalty of fine of not less than ten thousand pesos (P 10,000.00) and suspension of his license to practice his processions for one year or no longer at the discretion of the court.

(B) Any juridical person who violates Section 6(c), 6(d), 7 and 8 shall suffer the penalty of a fine of not less than five thousand pesos (P 5,000.00) nor more than ten thousand pesos (P10,000.00) and suspension or revocation of license to operate such drug establishment or drug outlet at the discretion of the Court: Provided, that its officers directly responsible for the violation shall suffer the penalty of fine and suspension or revocation of license to practice profession, if applicable, and by imprisonment of not less than six (6) months nor more than one (1) year or both fine and imprisonment at

the discretion of the Court: and Provided, further, that if the guilty party is an alien, he shall be ipso facto deported after service of sentence without need of further proceedings.

(C) The Secretary of Health shall have the authority to impose administrative sanctions such as suspension or cancellation of license to operate or recommend suspension of license to practice profession to the Professional Regulation Commission as the case may be for the violation of this Act.

Sec. 13 Separability Clause. - If any provision of this Act is declared invalid, the remainder or any provision hereof not affected thereby shall remain in force and effect.

Sec. 14 Repealing Clause. - The provision of any law, executive order, presidential decree or other issuance's inconsistent with this Act are hereby repealed or modified accordingly.

Sec. 15 Effectivity. - This shall take effect fifteen (15) days after its complete publication in the official Gazette or two (2) newspapers of general circulation.

Approved.,

Signed
RAMON V. MITRA
Speaker of the House of Representatives

Signed
JOVITO R. SALONGA
President of the Senate

This Act which is a consolidation of Senate Bill No. 453 and House Bill No. 10900 was finally passed by the Senate and the House of Representatives on August 25, 1988 and August 31, 1988, respectively.

Signed
QUIRINO D. ABAD SANTOS, JR.
Speaker of the House of Representatives

Signed
EDWIN P. ACOBA
Secretary of the Senate

Approved: September 13, 1988

Signed
CORAZON C. AQUINO
President of the Philippines

MALACAÑANG
Manila

BY THE PRESIDENT OF THE PHILIPPINES

EXECUTIVE ORDER NO. 49

DIRECTING THE MANDATORY USE OF THE PHILIPPINE NATIONAL DRUG FORMULARY (PNDF) VOLUME I AS THE BASIS FOR PROCUREMENT OF DRUG PRODUCTS BY THE GOVERNMENT.

WHEREAS, the 1987 Constitution of the Philippines provides as State Policies that:

a. "The State shall protect and promote the right to health of the people and instill health consciousness among them" (Section 15, Article II, 1987 Constitution)

b. "The State shall adopt an integrated and comprehensive approach to health development which shall endeavor to make essential goods, health and other social services available to all the people at affordable cost" (Section 11, Article XIII, 1987 Constitution)

c. "The State shall establish and maintain an effective food and drug regulatory system and undertake appropriate health manpower development and research responsive to the country's health needs and problems" (Section 12, Article XIII of the 1987 Constitution)

WHEREAS, paragraphs 3 and 4, Section 2, of the Generics Act of 1988 declare as the policy of the State, among others, that:

aa. "To encourage the extensive use of drugs with generic names through a rational system of procurement and distribution".

bb. "To emphasize the scientific basis for the use of drugs, in order that health professionals may become more aware and cognizant of their therapeutic effectiveness".

WHEREAS, Section 4 of the Generics Act of 1988 provides that:

aaa. "In the promotion of the generic names, for pharmaceutical products, special consideration shall be given to drugs and medicines which are included in the essential drugs list to be prepared within one hundred eighty (180) days from approval of this Act and updated quarterly by the Department of Health on the basis of health conditions obtaining in the Philippines as well as on internationally-accepted criteria.

bbb. "The exclusive use of generic terminology in the manufacture, marketing and sales of drugs and medicines, particularly those in the essential drugs list, shall be promoted through such system of incentives as the Board of Investments jointly with the Department of Health and other government agencies as may be authorized by law, shall promulgate in accordance with existing laws, within 180 days after approval of this Act".

WHEREAS, in order to promote rational use of drugs and medicines in government and as a logical extension of the successful implementation of DOH - D.O. 104 s. 1991, which makes mandatory the use of the Philippine National Drug Formulary (PNDF) (Volume I) or Essential Drugs List as the basis for the procurement of drug products by the Department of Health, ALL GOVERNMENT ENTITIES CONCERNED ARE MANDATED TO USE THE CURRENT PNDF (VOLUME I) AS THE BASIS FOR PROCUREMENT OF DRUG PRODUCTS;

WHEREAS, the PNDF (Volume I) is the Essential Drugs List for the Philippines prepared by the National Drug Committee (NDC) in consultation with experts and specialists from organized professional medical societies, medical academe, and pharmaceutical industry, and which is updated every year, consisting of two parts, namely: the Core List and the Complementary List where in the Core List drugs are the essential drugs which are needed by the majority of the population and should therefore be available at all times in appropriate dosage forms and in sufficient quantities, while the Complementary List drugs are those drugs needed for treating rare disorders, drugs with special pharmaceutical properties and alternative drugs to be used when there is no response to the Core List drugs or when the Core List drugs cannot be administered for one reason or another;

NOW, THEREFORE, I, FIDEL V. RAMOS, President of the Philippines, by virtue of the powers vested in me by law, do hereby order:

The following procedures shall be followed to implement this Order:

1. The Therapeutics Committee/Physician-in -charge of the Clinic or Infirmary / Procurement Officer, whichever is applicable, shall be responsible for determining which products and the corresponding quantity to be procured by the respective government entities.
2. Every requisition and issue voucher (RIV) or any request to purchase drug, including those falling under Emergency Purchase authorized under the General Appropriation Act shall be accompanied by a certification signed by the requisitioning officer that the drug products being requisitioned or procured fall within and conform with PNDF Volume I, current edition.
3. The Commission on Audit shall instruct all unit auditors/heads of auditing unit to monitor compliance with this order and to disallow in audit, claims/disbursements, either from regular budget, local and/or trust funds, covering the procurement by any mode, of drugs and medicines which are not within the PNDF Volume I, current edition.
4. For drugs not listed in the PNDF Volume I, a written request with corresponding justification addressed to the Head of the National Drug Policy Office who may approve or disapprove the request. In determining whether the drug(s) requi-

sitioned is justified or not, the said Head may refer such request to the National Drug Committee (NDC), as needed.

Any violation of this Order shall be construed as a conduct grossly prejudicial to the best interest of the service or grave misconduct, as the case may be, per P.D. 807 and CSC - M No. 30 s. 1989.

This Order shall take effect immediately.

Done in the City of Manila, this 21st day of January in the year of our Lord, nineteen hundred and ninety three.

Signed
FIDEL V. RAMOS

By the President:

Signed
ANTONIO T. CARPIO
Chief, Presidential Legal Counsel

ADMINISTRATIVE ORDER NO. 51
Series of 1988

SUBJECT: **IMPLEMENTING GUIDELINES FOR DEPARTMENT OF HEALTH COMPLIANCE WITH REPUBLIC ACT 6675 (GENERICS ACT OF 1988)**

1. **Title:** This Order shall be known as "Implementing Guidelines for the Department of Health Compliance with Republic Act 6675 (Generics Act of 1988)"

2. **Authority:** This Order is issued to implement R.A. 6675 guided by pertinent provisions of R.A. 3720 and related laws as well as E.O. 119 (Reorganization Act of the Ministry of Health).

3. **Purpose:** This Order provides guidelines and instructions for the Department of Health to comply with R.A. 6675 and implement its provisions.

4. **Scope:** This Order applies to all agencies and entities within the supervision of the Secretary of Health that perform the functions of procuring, prescribing, dispensing and administering drugs and medicines as well as promoting, regulating and practicing the use of generic names of drugs. While R.A. 6675 covers agencies and entities other than the Department of Health, this order does not apply to such agencies and entities. Separate issuance shall expressly provide for guidelines applicable to non-DOH agencies and entities.

5. **Specific Roles of the DOH in Implementing R.A. 6675**

This order provides guidelines and instructions for the proper, orderly and efficient performance of the DOH of its various roles under R.A. 6675.

5.1 DOH is the agency tasked with the promulgation of rules and regulations to implement R.A. 6675 [Sec. 9 and 12 C].

5.2 DOH is also one of the key government agencies that shall have to comply with the use of generic terminology or generic names in all transactions related to purchasing, prescribing, dispensing and administering of drugs and medicines [Sec. 6 (a)].

5.3 DOH is also one of the key government agencies mandated to promote use of generic terminology through public information and continuing education of health professionals (Sec. 11).

5.4 DOH is also one of the key government agencies mandate to insure that drugs are generically labeled (Sec. 7) and that generic drugs production are encouraged and promoted (Sec. 8 and 10).

This Order specifically addresses how DOH shall perform the role defined in 5.2 above, but shall also outline how the performance of the other roles shall be guided.

6. **Guidelines of Implementation**

The task of guiding the implementation of R.A. 6675 shall be undertaken principally by the Secretary of Health with the staff assistance of the National Drug Policy Implementation Team created in A.O. No. 46, series of 1988, which is headed by the Assistant Secretary for

Standards and Regulations. The various units in this staff shall formulate draft recommendations for policy guidelines and operational instructions on all matters regarding the implementation of R.A. 6675. These drafts shall be reviewed by the Executive Committee for National Field Operations. All issuance's shall be approved by the Secretary and disseminated prior to effectivity.

6.1 Recommendations should be clear, reasonably implementable, consistent with legal provisions and facilitates the achievement of policy goals.

6.2 Suggestions, comments and similar inputs from affected as well as interested parties should be solicited and considered.

6.3 Discussions in various committees, conferences and meetings should be maximized.

6.4 Formulation of guidelines should proceed promptly, observed stated deadlines and schedules and decisively disposed.

7. **Implementation by Field Units of DOH**

To carry out the rules and regulations in implementing R.A. 6675, the following officials are responsible:

7.1 The Regional Health Directors for all agencies under their supervision in the regions.

7.2 The Provincial Health Officers for all agencies under their supervision in the provinces.

7.3 The Chiefs of District Hospitals in their respective hospitals and catchment areas.

7.4 The City Health Officers for units under their supervision in the cities.

7.5 The chief of national medical centers, special research centers and hospitals, regional medical centers and regional hospitals and sanitaria in their respective institutions.

8. **Duties and Functions of Responsible Officials**

The above mentioned officials responsible for the implementation of R.A. 6675 in their respective areas of jurisdiction shall perform the following duties and functions:

8.1 Issue the necessary office orders and instructions to carry out R.A. 6675 based on implementation guidelines.

8.2 Organize and mobilize their offices and institutions to assure compliance by DOH personnel.

8.3 Establish and activate mechanisms for promoting compliance, eliminating barriers of difficulties to such compliance and initiating supportive activities.

8.4 Manage their organizations towards active and effective observance of laws, rules and regulations.

8.5 Recommend proposals, modifications to existing instructions and otherwise give feedback on the implementation.

8.6 Assume other functions and responsibilities that may be required in related issuances.

9. **Therapeutics Committees**

At all DOH field agencies, a therapeutics committee shall be organized to assist the head of agency in performing his tasks under this Order.

9.1 Requirement: Therapeutics Committees shall be organized at the Regional Health Offices, Provincial Health Offices, District Health Offices, City Health Offices, special hospitals, national medical centers, regional medical centers, regional hospitals and

sanitaria. At the Regional Health Office, the Technical Committee for Drugs and Medicine created under A.O. No. 28, series 1987 shall be dissolved and its functions absorbed by the Regional Therapeutic Committee.

9.2 *Functions:* In support of the agency head, Therapeutic Committee shall have the following functions:

9.2.1 Based on the DOH Drug Formulary (For Hospitals and RHUs), regularly maintain a list, specified in generic terminology, of the drugs that the agency will keep on stock, use buy or prescribe. The list shall be limited to those items in the DOH formulary. Any new item outside the formulary should be recommended to the National Drug Committee for inclusion in the DOH formulary before the agency can include such item in its own list. The list shall be regularly updated and circulated to procurement and supply units, pharmacies and medical staff of the agency. The Therapeutics Committee shall be responsible for clarifying any technical issue regarding use of generic terminology.

9.2.2 Based on the DOH formulary, recommend drug selection, utilization, procurement and stocking policies. Such policies may include establishing allocation criteria in use of resources for different generic items of drugs; resolving problems regarding drug availability and quality; disseminating reliable drug information; proposing measures to facilitate generic prescribing and dispensing; insuring proper and equitable distribution of drug supplies within the agency; identifying other similar initiatives.

9.2.3 Evaluate and recommend appropriate action on:

a) requests for inclusion or exclusion of any drug product in the DOH formulary as well as in the agency drug list.

b) reports of adverse drug reactions and other incidents related to safety, efficacy or quality of drugs.

c) use of agency resources for drug products.

On the last matter, the Therapeutics Committees shall be empowered to require budget and finance units to provide data showing how much of the agency resources are allocated to drugs and medicines and other information on prices, products and suppliers.

9.2.4 Identify and define information, education or training needs of the agency related to the implementation or R.A. 6675, the National Drug Policy, pharmacological science, and rational drug use. In this regard, the Therapeutics Committee is instructed to specify their agency needs for technical information and make proposals for raising the level of knowledge, attitudes and skills needed for effective implementation of R.A. 6675.

9.2.5 Plan an orderly, systematic and thorough process of institutionalizing rational drug use. Such plans should have immediate, medium and long term dimensions. The plans should target 100% adoption of generic terminology in procurement, prescribing and dispensing within DOH agencies within the shortest possible time. Subsequently, the plans should identify specific prob-

lems, obstacles and difficulties to widespread use of generic terminology in the community and propose appropriate solutions. Finally, the plans should seek to promote rational use of drugs.

9.3 *Composition*

9.3.1 Therapeutics Committies shall have at least 5 members except at District Hospitals which may have at least 3 members.

9.3.2 The members shall be designated by the head of the agency and shall have a mix of the following professionals: physician, pharmacist and nurse. A dentist may be included as non-voting member to be consulted on drugs and medicine affecting dental services.

9.3.3 The head of agency shall not be a member.

9.3.4 The members shall elect their chairman.

9.3.5 The NDP compliance officer mentioned below shall be a non-voting member who can attend committee deliberations.

9.3.6 Regional Directors are instructed to contract pharmacologists coming from medical schools to serve as consultants to the Regional Therapeutics Committee or the Therapeutics Committee of the Regional Medical Centers.

9.4 *Organization and Reporting:* Heads of agencies shall designate and organize their respective therapeutic committees not later than December 30, 1988. All heads of agencies shall report the composition of their committees on the first staff meeting in 1989.

10. **NDP Compliance Officer**

At all regional offices and all special hospitals, the head of agency shall designate an NDP Compliance Officer.

10.1 *Functions:* The NDP Compliance Officer is tasked with gathering, analyzing and reporting the data on that agency's compliance with all issued instructions such as:

a) organization and activation of therapeutics committees.
b) issuance's of related internal orders and instructions.
c) reports of specific failures and successes.
d) report of overall progress or setbacks.

10.2 *Qualifications:* The NDP Compliance Officer shall be a DOH employee in position to understand the technical and administrative aspects for compliance with R.A. 6675.

10.3 *Reporting:* Regional Directors and Chiefs of Special Hospitals shall report their designated NDP Compliance Officer no less than December 30, 1988.

11. **Procurement of Drugs and Medicine**

11.1 In addition to existing regulations on procurement, drugs and medicines shall be procured on the basis of their generic name. For this purpose, all heads of agencies that procure drugs and medicines from regular budget, local aid or trust funds shall specify all drug and medicine items in their generic names. All documents relating to procurement and disbursement, such as RIV's bid documents, purchase order, vouchers and others, shall specify drug product items in their generic names. This shall cover both regular as well as emergency procurement, bidding as well as canvass.

11.2 Any issue regarding generic terminology shall be resolved by the Therapeutics Committee. Any issue that it cannot decide shall be referred to the National Drug Committee (NDC). Upon referral, the Therapeutics Committee can adopt a temporary decision until action by the NDC.

11.3 All DOH agencies shall adopt generic specifications in all procurement of drugs and medicines effective March 1, 1989.

11.4 Procurement made on the basis of generic specification may lead to purchase of drug products that are also identified by brand names provided price and availability considerations make it unavoidable. In such cases, products that are also identified by brand names may be kept on stock provided that its identification and use remain exclusively on the basis of generic specification.

12. **Prescribing and Ordering**

12.1 All prescriptions and orders for drugs and medicines in DOH facilities shall be specified in generic terminology. In all written orders, the generic name of the drug's active ingredient shall be stated. While initially brand names may also be added, eventually all orders shall use generic names exclusively.

12.2 Each DOH agency shall set a date no later than March 1, 1989 for the effectivity of mandatory generic prescribing in that agency. Prior to such date, generic prescribing shall be introduced, promoted and encouraged. Information shall be provided to all concerned so that generic prescribing can be facilitated. On the date for starting mandatory generic prescribing, there should be launching activities to bring the decision ot the attention of professionals and the public.

12.3 All DOH agencies shall report not later than December 30, 1988 the date mandatory generic prescribing will start in the agency.

13. **Dispensing and Administering**

13.1 All persons and units that dispense drugs and medicines in DOH agencies (pharmacies, clinics, other service outlets) shall adopt and practice generic dispensing i.e. filling doctor's prescriptions and orders on the basis of the specified generic name of the active ingredient, dose level, dosage form and delivery mode. If no drug preparation is available to comply with what was prescribed, the prescribing physician shall be duly informed so that the prescription can be changed to one that can be filled.

13.2 Allied medical and nursing staff in hospitals, health centers and health stations shall use generic terminology in patient charts and all drugs and medical records.

13.3 Upon effectivity of mandatory generic prescribing, mandatory generic dispensing shall also take effect.

13.4 All agencies shall duly inform all patients when generically dispensing to avoid misunderstanding.

13.5 Branded products may be dispensed and used provided such is based on providing the same generic active ingredient as well as same dose, form and delivery mode specified in the prescription.

14. **Public Information**

14.1 All heads of agencies shall take the necessary and sufficient steps to inform the public about measures to implement R.A. 6675 and the rationale for these measures.

14.2 Whenever public complaint arise, the heads of agencies shall take action to resolve such complaints within the means available while observing rules and regulations.

14.3 The Public Information and Health Education Service (PIHES) at the Central Office shall produce and disseminate informational materials necessary to inform the public on these matters. All agencies are encouraged to translate, summarize, excerpt or adapt materials from PIHES aside from developing their own materials. Copies of all informational materials developed by field agencies on their own shall be sent to PIHES for information.

15. **Professional Promotion**

15.1 Heads of agencies, assisted by their respective Therapeutics Committees, shall plan and undertake promotional activities among DOH personnel, particularly physicians and nurses. These activities should (a) clarify the provisions of the law and the implementing regulations; (b) explain the reasons for generic names in drug use; (c) answer the most common misinformation, apprehensions and complaints.

15.2 The central staff for NDP implementation shall organize and deploy well qualified resource persons for lectures and seminars on NDP implementation. Agencies may access these for their promotional activities through the Office of the Assistant Secretary for Standards and Regulations.

15.3 PIHES shall procure and produce the necessary technical references for the use of Therapeutic Committees. These shall be distributed to all committees in due course.

16. **Central Office Support and Monitoring**

16.1 All communications regarding the implementation of this Order shall be coursed to the Office of the Assistant Secretary for Standards and Regulations. On the basis of the progressor problems, adequate guidance, support or assistance shall be extended. The principal responsibility, however, remains with the heads of agency and their superiors in the chain of command of DOH.

16.2 NDP Compliance Officers shall identify areas, both geographic and functional, where technical weaknesses are noted. In these cases, recommendations regarding what support is needed are expected. A mechanism for sharing technical resources in pharmacy and pharmacology shall be established by the Assistant Secretary for Standards and Regulations.

17. **Violations**

Repeated or substantial violations of this Order shall be regarded as violations of administrative discipline under Presidential Decree 807. Subject personnel shall be liable to administrative action in addition to penalties provided for by R.A. 6675.

18. **Effectivity**

These rules and regulations shall take effect 15 days after its publication in the official gazette, or in two newspapers of general circulation and shall supersede all issuance's inconsistent thereof.

Signed
ALFREDO R.A. BENGZON, M.D.
Secretary of Health

ADMINISTRATIVE ORDER NO. 62
Series of 1989

SUBJECT: RULES AND REGULATIONS TO IMPLEMENT PRESCRIBING REQUIREMENTS UNDER THE GENERICS ACT OF 1988 (R.A. 6675)

Pursuant to Section 9 in relation to Section 6(a), and 6(b) or R.A. 6675 known as the Generics Act of 1988, and the pertinent provision of R.A. 3720 known as the Food, Drugs and Devices and Cosmetics Act, as amended by Executive Order No. 175 s.1987, R.A. 5921 known as the Pharmacy Act and R.A. 4224 and R.A. 5946; R.A. 4419 known as the Dental Act, R.A. 382 known as the Veterinary Act, and R.A. 6425 known as the Dangerous Drugs Act of 1972 as amended, the following rules and regulations are hereby promulgated:

Section 1 **DEFINITION OF TERMS:**

1.1 Prescription is the written order and instruction of a validly-registered physician, dentist or veterinarian for the use of a specific drug product for a specific patient. For the purpose of these Rules and Regulation, the doctor's order on the patient's chart for the use of specific drug(s) shall be considered a prescription.

1.2 Generic Prescribing is prescribing of drugs and medicines using their generic name(s) or generic terminology.

1.3 Dispensing is the act by a validly-registered pharmacist of filling a prescription or doctor's order on the patient's chart.

1.4 Generic Dispensing means dispensing the patient's/buyer's choice from among the generic equivalent i.e., finished pharmaceutical products having the same active ingredient(s), same dosage form and same strength as the prescribed drug.

1.5 Generic name or generic terminology is the identification of drugs and medicines by their scientifically and internationally recognized active ingredients or by their official name as determined by the Bureau of Food and Drugs of the Department of Health.

1.6 Drug means (1) "articles recognized in the current official United States Pharmacopoeia-National Formulary (USP-NF), official Homeopathic Pharmacopoeia of the United States, official Philippine National Drug Formulary, or any supplement to any of them; and (2) articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or animals; and (3) articles (other than foods) intended to affect the structure or function of the body of man or animals; and (4) articles intended for use as a component of any articles specified in clauses (1), (2) or (3) but do not include devices or their components.

1.7 Drug product or medicine is the finished form that contains the active ingredient(s), generally but not necessarily in association with inactive ingredients.

1.7.1 Prescription or ethical drugs are pharmaceutical products or drug preparation that are to be dispensed only upon written order or validly-

registered licensed physician, dentist or veterinarian for the management or treatment of a condition or disease.

1.7.2 Non-prescription or over-the-counter drugs are pharmaceutical products or drug preparations that can be dispensed even without the written order of validly-registered licensed physician, dentist or veterinarian, for the use of consumers for the prevention or symptomatic relief of minor or self-limiting ailments.

1.8 Dangerous drugs refer to either prohibited drugs or regulated drugs which require a special prescription form, the use of which is monitored by the Dangerous Drug Board.

1.8.1 Prohibited drugs include "opium and its active components and derivatives such as heroin and morphine; coca leaf and its derivatives, principally cocaine, alpha and beta Eucaine, hallucinogenic drugs, such as mescaline lysergic acid diethylamide (LSD) and other substances producing similar effects; Indian hemp and its derivatives; all preparations made from any of the foregoing; and other drugs, whether natural or synthetic, with the physiological effects or a narcotic drug".

1.8.2 Regulated drugs includes sleep-inducing sedatives, such as secobarbital, phenobarbital, barbital, amobarbital and other drugs which contain a salt derivative of a salt of an isomer of amphetamine, such as benzedrine or dexedrine, or any drug which produces a pharmacologic action similar to amphetamine; and hypnotic drugs such as methaqualone, or any other compound producing similar pharmacologic effects.

1.9 Drug outlets means drugstores, pharmacies and other business establishments, which dispense or sell drugs or medicines.

Section 2 **GUIDELINES ON PRESCRIBING BASED ON PRIOR LAWS**

Prior to the Generics Act of 1988, the following general guidelines on prescribing have been operative. In order to have an integrated implementation of all relevant guidelines on prescribing, these guidelines based on prior laws are restated here under:

2.1 Only validly-registered medical, dental and veterinary practitioners, whether in private practice or employed in a private institution/corporation or in the government, are authorized to prescribe drugs. Prescribing by unauthorized persons constitutes illegal practice of medicine, dentistry or veterinary medicine punishable under R.A. 2382 or the Medical Act of 1959, R.A. 4419 or the Dental Act, R.A. 382 or the Veterinary Act.

2.2 In accordance with R.A. 5921, or the Pharmacy Act as amended, all prescriptions must contain the following information: name of prescriber, office address, professional registration number, professional tax receipt number, patient's/ client's name, age and sex, and date of prescription.

2.3 For drugs in List A (Annex I) containing the list of Prohibited Drugs and Regulated Drugs as approved by the Dangerous Drugs Board (DDB), the following are required:

2.3.1 The prescriber must have an S-2 license.

2.3.2 The special DDB prescription form must be used.

2.3.3 A recording system following pertinent DDB regulations must be observed.

Section 3 ADDITIONAL GUIDELINES ON PRESCRIBING TO IMPLEMENT THE GENERICS ACT OF 1988

In addition to the guidelines contained in section 2, the following shall specifically guide prescribing under the Generics Act of 1988.

3.1 Generic names shall be used in all prescriptions.

3.1.1 For drugs with a single active ingredient, the generic name of that active ingredient shall be used be used in prescribing.

3.1.2 For drugs with two or more active ingredients, the generic name as determined by BFAD shall be used in prescribing.

3.2 The generic name must be written in full but the salt or chemical form may be abbreviated.

3.3 The generic name of the drug must be clearly written on the prescription immediately after the Rx symbol, or on the order chart.

3.3.1 In addition to the generic name, a brand name may also be indicated. In such cases, the following shall be observed:

3.3.1.1 If written on a prescription pad, the brand name enclosed in parenthesis shall be written below the generic name.

3.3.1.2 If written on a patient's chart, the brand name enclosed in parenthesis shall be written after the generic name.

3.4 In prescribing drugs enumerated in List B (Annex B) which needs strict precaution in their use, the prescriber must comply with the following:

3.4.1 After the Rx symbol but before the generic name, he must write clearly "(List B)".

3.4.2 He must ensure that the following information are accurately written on the prescription:

3.4.2.1 The generic name of the active ingredient(s) and the specific salt or chemical form.

3.4.2.2 The manufacturer

3.4.2.3 The brand name, if so desired

3.4.2.4 The strength or dose level using units of the metric system (see Annex C).

3.4.2.5 The delivery mode or delivery system: quick-dissolve, sustained release, etc. and the corresponding appropriate dose frequency or dose interval.

Section 4 VIOLATIVE, ERRONEOUS AND IMPOSSIBLE PRESCRIPTIONS

4.1 Violative Prescriptions

4.1.1 Where generic name is not written.

4.1.2 Where the generic name is not legible and a brand name which is legible is written.

4.1.3 Where the brand name is indicated and instructions added (such as the phrase "no substitution") which tend to obstruct, hinder or prevent proper generic dispensing.

4.2 What to do with violative prescriptions

Violative prescriptions shall not be filled. They shall be kept and reported by the pharmacist of the drug outlet or any other interested party to the nearest DOH Office for appropriate action. The pharmacist shall advise the prescriber of the problem and/or instruct the customer to get the proper prescription.

4.3 Erroneous Prescriptions

4.3.1 Where the brand name preceeds the generic name

4.3.2 Where the generic name is the one in parenthesis

4.3.3 Where the brand name is not in parenthesis

4.3.4 Where more than one drug product is prescribed on one prescription form.

4.4 What to do with erroneous prescriptions

Erroneous prescriptions shall be filled. Such prescription shall also be kept and reported by the pharmacist of the drug outlet or any other interested party to the nearest DOH Office for appropriate action.

4.5 Impossible Prescriptions

4.5.1 When only the generic name is written but it is not legible

4.5.2 When the generic name does not correspond to the brand name

4.5.3 When both the generic name and the brand name are no legible

4.5.4 When the drug product prescribed is not registered with the BFAD

4.6 What to do with impossible prescriptions

Prescriptions mentioned in 4.5 shall not be filled. They shall be kept and reported by the pharmacist of the drug outlet or any other interested party to the nearest DOH Office for appropriate action. The pharmacist shall advise the prescriber of the problem and/or instruct the customer to get the proper prescription.

4.7 In all cases enumerated in 4.1, 4.3, and 4.5, the local DOH Office shalll be responsible for giving written notice to the erring doctor concerned and for transmitting through channels the report of violation/error to the Professional Regulation Commission (PRC) or to the fiscal's office for appropriate action.

Section 5 **ADMINISTRATIVE SANCTIONS**

For violations of Section 4 of these Rules and Regulations, the Secretary of Health shall recommend the imposition of appropriate administrative sanctions by the PRC.

Section 6 **CRIMINAL LIABILITY**

The imposition of the above sanctions does not preclude the institution of appropriate criminal proceedings pursuant to Section 12 R.A. 6675 known as the "Generics Act of 1988", R.A.

3720 known as the "Food, Drugs and Devices and Cosmetics Act" as amended and R.A. 5921 known as "Pharmacy Law" as amended and R.A. 2383 known as the "Medical Act of 1959", R.A. 4419 or the Dental Act of 1972 as amended, and other relevant laws, by the Regional Health Office concerned, upon receipt of complaints or reports of violations.

Section 7 **TIMETABLE OF IMPLEMENTATION**

In order to give all affected parties adequate time for learning and adjustment, the implementation of these Rules and Regulations shall be in three phases, as follows:

Phase I Education Drive and Information Dissemination

This phase shall be from the date of the effectivity of these Rules and Regulations to May 31, 1989. During this period, the DOH, in cooperation with the Department of Education, Culture and Sports, the Department of Local Government and Philippine Information Agency, shall undertake information dissemination and education drive concerning the provisions of these Rules and Regulations as well as the Generics Act of 1988.

Phase II Monitoring of Compliance Without Sanctions or Penalties

From June 1, 1989 to August 31, 1989, the DOH shall monitor voluntary compliance with the provisions of the Rules and Regulations on Prescribing and Dispensing. During this period, the associations of affected professionals are enjoined to promote compliance in order to achieve a smooth transition to the next phase of full implementation.

Phase III Full Implementation

Beginning September 1, 1989 the DOH and the other relevant agencies of government shall monitor compliance with these Rules and Regulations and all violations shall be subject to the appropriate sanctions and penalties provided for under these Rules and Regulations and the Generics Act of 1988.

Section 8 **SEPARABILITY CLAUSE**

In case any provision of this Administrative Order is declared contrary to law or unconstitutional, other provisions which are not affected thereby shall continue to be in force and effect.

Section 9 **REPEALING CLAUSE**

All Administrative Orders, Rules and Regulations and other Administrative issuances or parts thereof, inconsistent with the provisions of the Administrative Order are hereby repealed and modified accordingly.

Section 10 **EFFECTIVITY**

This Order shall take effect fifteen (15) days after its publication in two newspapers of general circulation.

Signed
ALFREDO R.A. BENGZON, M.D.
Secretary of Health

ADMINISTRATIVE ORDER NO. 63
Series of 1989

SUBJECT: RULES AND REGULATIONS TO IMPLEMENT DISPENSING REQUIREMENTS UNDER THE GENERICS ACT OF 1988 (R.A. 6675)

Pursuant to Section 9 in relation to Section 6(a) and 6(d) or R.A. 6675 known as the Generics Act of 1988, and the pertinent provisions of R.A. No. 3720 known as the Foods, Drugs and Devices and Cosmetics Act as amended by Executive Order No. 175 s. 1989, R.A. 5921 known as the Pharmacy Act, R.A. 6425 known as the Dangerous Drugs Act of 1972, as amended, the following rules and regulations are hereby promulgated.

Section 1 **DEFINITION OF TERMS:**

1.1 Dispensing is the act by validly-registered pharmacist of filling a prescription or doctor's order on the patient's chart.

1.2 Generic Dispensing means dispensing the patient's/buyer's choice from among generic equivalents, i.e. finished pharmaceutical products having the same active ingredient(s), same dosage form and same strength as the prescribed drug.

1.3 Partial filling of prescription means dispensing less than the total number of units prescribed.

1.4 Drug Outlet means drugstores, pharmacy and other business establishment which sells drugs or medicines.

Section 2 **GUIDELINES ON DISPENSING BASED ON PRIOR LAWS**

Prior to the Generics Act of 1988, the following general guidelines on dispensing have been operative. In order to have an integrated implementation of all relevant guidelines on dispensing, these guidelines based on prior laws are restated hereunder:

2.1 Prescription or Ethical Drugs

These drugs can only be dispensed upon a written order of a validly-registered physician, dentist or veterinarian.

2.2 Non-Prescription or Over-the-Counter (OTC) Drugs

These drugs may be dispensed even without a written order of a validly-registered physician, dentist or veterinarian in duly licensed drug outlets. When dispensing OTC drugs without a doctor's prescription, the pharmacist shall give the necessary information and direction for use of the drug.

2.3 All prescriptions dispensed in the drugstores, botica or hospital pharmacy shall be kept in file for two years and recorded in a prescription book duly-registered by BFAD which shall be open for inspection by Food and Drug Inspectors at any time during business hours of the outlet. The prescription book shall be kept for two years after the last entry.

Section 3 ADDITIONAL GUIDELINES ON DISPENSING TO IMPLEMENT THE GENERICS ACT OF 1988

In addition to the guidelines contained in Section 2, the following shall specifically guide dispensing under the Generics Act of 1988.

3.1 All drug outlets are required to practice generic dispensing as defined in Section 1.2 of these Rules and Regulations, with some exceptions, modifications or qualifications in certain cases or circumstances, as described in Section 3.2 & 3.4.

3.1.1 Drug Stores, Boticas, and Other Drug Outlets

3.1.1.1 Inform the patient/buyer of all available drug products generically equivalent to the one prescribed with their corresponding prices. In so doing, the drug outlet shall not favor or suggest any particular product so that the patient/buyer may fully and adequately exercise his option to choose.

3.1.1.2 For this purpose, all drug outlets shall post in a conspicuous place in their establishment a list of drug products using generic names with their brand names, if any, and their corresponding current prices. A handbook or directory containing the above required information, readily accessible to the patient/buyer shall be considered substantial compliance.

3.1.2 Hospital Pharmacies

Recognizing the special needs and circumstances of hospitals, the following modified rules and regulations shall govern generic dispensing in hospital pharmacies, in the case of in-patients only:

3.1.2.1 Upon admission, the patient or his/her responsible relative

3.1.2.2 Hospital pharmacies operating on the acceptable formulary system and pricing policy as determined by the Department of Health (DOH), and using generic terminology in procurement, prescribing, dispensing, and recording of drugs, shall be exempted from the following:

3.1.2.2.1 Recording of prescriptions filled in the prescription book, provided such prescriptions shall be kept in file for two years.

3.1.2.2.2 Individually informing the patient/buyer on the available generic equivalents and their corresponding prices. However, a handbook or directory containing the required drug information must be made available in the wards for patients, responsible relatives of patients, and professional staff.

3.2 In dispensing to the buyer, drug products in unit dose or products which are not in their original containers but transferred to small bottles, tin cans, boxes, plastic and/or paper envelopes and the like, the pharmacist shall place legibly on the required drug outlet's label the following information:

1. Name of the patient
2. Generic name of the drug
3. Brand name, if any
4. Manufacturer
5. Dosage strength
6. Expiry date
7. Directions for use; and
8. Name of pharmacist

3.3 In partial filling of the prescription, the following shall be written on the face of the prescription:

1. The date of partial filling
2. The quantity served and balance of the prescription unserved; and
3. Name and address of the drugstore

The partially-filled prescription shall be returned to the buyer after recording the partial filling in the prescription book. The drugstore which completes the filling of the prescription shall keep the prescription in file.

3.4 Dispensing Drugs in List A and List B

In dispensing drugs included in List A (Prohibited and Regulated Drugs) and List B (Drugs Requiring Strict Precautions in their use), attached as Annex 1 and 2 respectively, the following shall be observed:

3.4.1 Dispensing must be done by the pharmacist who shall affix his/her signature on the prescription filled.

3.4.2 The order and instruction of the doctor as written on the prescription, must be precisely followed.

3.4.3 Partial filling of prescription for drugs belonging to List A shall not be allowed.

Section 4 GUIDELINES ON WHAT TO DO WITH VIOLATIVE, ERRONEOUS AND IMPOSSIBLE PRESCRIPTIONS

4.1 Violative and impossible prescriptions as defined in A.O. 62 (Generic Prescribing) shall not be filled. The pharmacist shall advise the prescriber of the problem and/or instruct the customer to get the proper prescription. These violative and wrong prescriptions shall be kept and reported by the pharmacist or other interested parties to the nearest DOH office for appropriate action.

4.2 Erroneous prescriptions shall be filled, but they shall also be kept and reported to the nearest DOH office for appropriate action.

Section 5 VIOLATIONS ON THE PART OF DISPENSERS AND OUTLETS

The following acts or omissions are considered violations of these rules and regulations:

5.1 Imposing a particular brand or product on the buyer.

5.2 Inaccurate dispensing i.e. dispensing a drug product which does not meet the prescription as to any or all of the following: active ingredient, dosage form and strength.

5.3 Failure to post or make accessible the required up-to-date information on drug products.

5.4 Failure to adequately inform the buyer on available products that meet the prescription.

5.5 Failure to indicate the generic name/official name designated by BFAD and other required information on the drug outlet's label of the dispensed drug.

5.6 Failure to record and keep prescriptions filled.

5.7 Failure to report to the nearest DOH office cases of violative, erroneous, and/or impossible prescriptions within three months after receipt of such prescriptions.

Section 6 **REPORTING AND MONITORING OF NON-COMPLIANCE**

Any interested party may report any verifiable violation of these Rules and Regulations to the nearest DOH office. The local DOH office is responsible for giving notice to erring pharmacist/outlets and for transmitting the report on violations to the Secretary of Health or the fiscal's office for appropriate action.

Section 7 **ADMINISTRATIVE SANCTIONS**

For violation of these Rules and Regulations, the following sanctions, after due notice and summary hearing may be imposed:

7.1 Suspension, or revocation of the license to operate the drug outlet by the Secretary of Health.

7.2 Professionals directly involved in the violations shall be recommended by the Secretary of Health for appropriate administrative sanctions by the PRC.

Section 8 **CRIMINAL LIABILITY**

The imposition of the above sanctions does not preclude the institution of appropriate criminal proceedings pursuant to Section 12 of R.A. 6675 known as the "Generics Act of 1988", R.A. 3720 known as the "Foods, Drugs, Devices and Cosmetics Act" as amended and R.A. 5921 known as "Pharmacy Law" as amended, R.A. 6425 known as the "Dangerous Drugs Act of 1972" as amended and other relevant laws, by the regional health office concerned, upon receipt of complaints or reports of violations.

Section 9 **TIMETABLE OF IMPLEMENTATION**

In order to give all affected parties adequate time for learning and adjustment, the implementation of these Rules and Regulations shall be in three phases, as follows:

Phase 1 Education Drive and Information Dissemination

This phase shall be from date of the effectivity of these Rules and Regulations to May 31, 1989. During this period, the DOH, in cooperation with the Department of Education,

Culture and Sports, the Department of Local Government, and Philippine Information Agency, shall undertake an education drive and information dissemination concerning the provisions of these Rules and Regulations as well as the Generics Act of 1988.

Phase 2 Monitoring of Compliance Without Sanctions or Penalties

From June 1, 1989 to August 31, 1989, the DOH shall monitor voluntary compliance with the provisions of the Rules and Regulations on Prescribing and Dispensing. During this period, the associations of affected professionals are enjoined to promote compliance in order to achieve a smooth transition to the next phase of full implementation.

Phase 3 Full Implementation

Beginning September 1, 1989, the DOH and the other relevant agencies of government shall monitor compliance with these Rules and Regulations and all violations shall be subject to the appropriate sanctions and penalties provided for under these Rules and Regulations and the Generics Act of 1988.

Section 10 **SEPARABILITY CLAUSE**

In case any provision of this Administrative Order is declared contrary to law or unconstitutional, other provisions which are not affected thereby shall continue to be in force and in effect.

Section 11 **REPEALING CLAUSE**

All administrative orders, rules and regulations and other administrative issuances or parts thereof, in consistent with the provisions of this administrative order ar hereby repealed and modified accordingly.

Section 12 **EFFECTIVITY**

This Order shall take effect fifteen (15) days after its publication in two newspapers of general circulation.

Signed
ALFREDO R.A. BENGZON, M.D.
Secretary of Health

April 23, 1990

ADMINISTRATIVE ORDER NO. 90
Series of 1990

SUBJECT: AMENDMENT TO A.O. 62 S. 1989 RE: RULES AND REGULATIONS TO IMPLEMENT PRESCRIBING REQUIREMENTS.

Section 1 **AMENDMENT**

In response to the request of prescribing doctors to allow them to write the name of more than one drug product on the same page of a prescription form for a particular patient, Sections 3.0 and 4.0 are hereby amended by deletion of paragraphs 3.4 and 4.3.4, respectively.

As amended, A.O. 62 thereby permits the writing of the generic names of more than one drug product in one prescription form.

It also no longer regards a prescription form with more than one drug product as erroneous.

Section 2 **EFFECTIVITY**

This Order shall take effect fifteen (15) days after its publication in two newspapers of general circulation.

Signed
ALFREDO R.A. BENGZON, M.D.
Secretary of Health

October 16, 2002

ADMINISTRATIVE ORDER NO. 163
Series of 2002

SUBJECT: **IMPLEMENTING GUIDELINES AND PROCEDURES IN THE PROCUREMENT AND REQUISITION OF DRUGS AND MEDICINES BY THE DEPARTMENT OF HEALTH PURSUANT TO EXECUTIVE ORDER NO. 49 DATED JANUARY 21, 1993.**

Section 1 **RATIONALE**

In compliance with the R.A. No. 6675, otherwise known as the Generics Act of 1988, entitled "An Act to Promote, Require and Ensure the Production of an Adequate Supply, Distribution, Use and Acceptance of Drugs and Medicines Identified by their Generic Names" Section 4(a), the Department of Health (DOH) organized the National Drug Committee (NDC), tasked to formulate the Essential Drugs List known as the Philippine National Drug Formulary (PNDF) Volume I. In the year 2001, the NDC was renamed as the National Formulary Committee (NFC).

The PNDF is a basic component of the National Drug Policy which seeks to bring about the availability of safe, efficacious, and quality drugs at affordable cost. The PNDF is an important step to rationalize drug production, distribution, procurement and consumption through the Essential Drugs concept.

In 1993, Executive Order No. 49 was issued entitled "Directing the Mandatory Use of the Philippine National Drug Formulary (PNDF) Volume I as the Basis for Procurement of Drug Products by the Government."

Implementation was immediately enforced with the use of the PNDF Volume I current edition as the basis for procurement of drug products by the government. The PNDF became the basis for claim reimbursements for drugs and medicines through a Philippine Health Insurance Corporation (PHIC) Board Resolution # 265 s.1999 dated July 15, 1999.

Section 2 **IN IMPLEMENTING THESE GUIDELINES THE FOLLOWING POLICIES AND PROCEDURES SHALL BE ADOPTED:**

1. Only drug products that fall within and conform with the Essential Drugs List, the Philippine National Drug Formulary (PNDF) Volume I, current edition, shall be allowed to be requisitioned and procured by all Government Agencies including government-owned and controlled corporations.

2. Every Requisition and Issue Voucher (RIV) or any request for procurement including Emergency Purchase of drugs and medicines authorized under the General Appropriation Act, shall be accompanied by a certification signed by the requisitioning officer that the drug products being requisitioned or procured fall within and conform with PNDF Vol. I, current edition.

3. Auditors/heads of auditing units shall monitor compliance thereto and shall disallow claims/reimbursements either from regular budget, local/trust funds, covering the procurement of drugs and medicines which are not within the PNDF Volume I, current edition.

4. Drugs and medicines not listed in the PNDF Volume I, current edition may be procured by Government agencies through a written request with corresponding justification addressed to the Head of the National Drug Policy Staff who may approve or disapprove the request. However, in determining whether the drug(s) requested is/are justified or not, the said Head shall refer the request to the National Formulary Committee (NFC).

   4.1 A letter shall be submitted justifying that:
      4.1.1 The drug is needed for the prevention and treatment of conditions not already covered in the existing list.
      4.1.2 The drug is more effective and/or less toxic than a drug listed for the same indication.
      4.1.3 The drug is at least as effective and safe and of lower cost than the drug listed for the same indication.
      4.1.4 The drug is deemed essential for a specific DOH-Health program/project.

   4.2 The said justification letter shall have the following as attached documents:
      4.2.1 Scientific evidence (in table format) supported with literature review for the specific drug (Annex A, B, C and D).
      4.2.2 Report on the disease burden and its ranking relative to the common diseases seen in the hospital.
      4.2.3 Comparison of costs for the total regimen of the drug or its full course of therapy with other comparable drugs listed in the current edition of the PNDF Vol. I.
      4.2.4 Copy of Certificate of Product Registration.

5. The National Formulary Committee is hereby authorized to issue such other guidelines as may be necessary to implement this Administrative Order.

Section 3 **REPEALING CLAUSE**

All previous Orders inconsistent in part or in whole to this Administrative Order are hereby rescinded or amended accordingly.

Section 4 **EFFECTIVITY**

This Order takes effect immediately.

Signed
MANUEL M. DAYRIT, M.D., MSc.
Secretary of Health

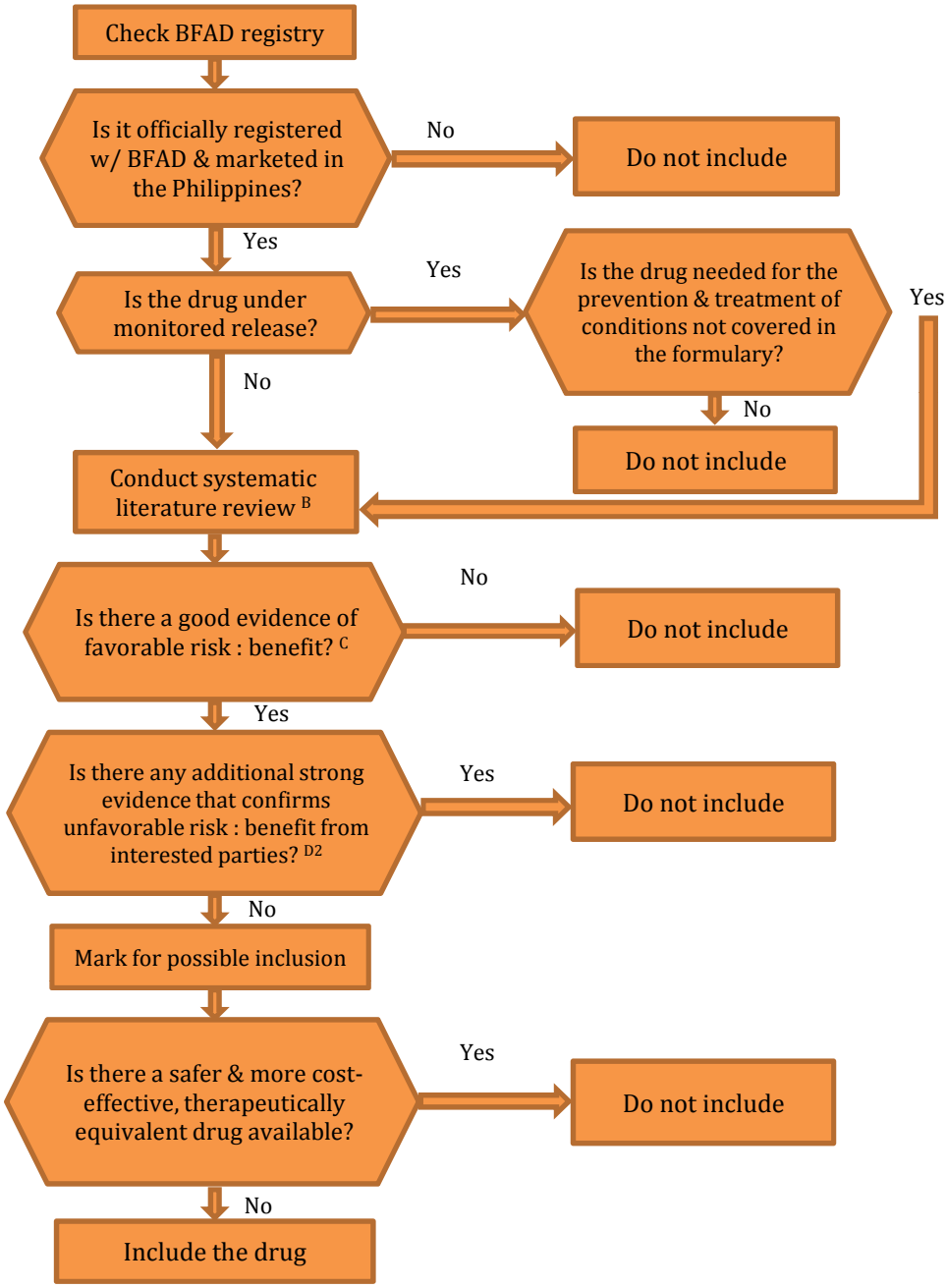
ANNEX A

PROCESS ALGORITHM FOR INCLUSION / DELETION OF PNDF DRUGS

PART I: REVIEW OF CURRENT PNDF DRUGS

ANNEX B

PART II: REVIEW OF NEW DRUGS FOR POTENTIAL INCLUSION



ANNEX C

EVIDENCE TABLE

DRUG:

NO	TITLE / AUTHOR YEAR / JOURNAL	STUDY DESIGN	PARTICIPANT DESCRIPTION	INTERVENTION	RESULTS/ OUTCOMES					GRADE OF EVIDENCE	REMARKS
					EVENTS	TREATMENT DRUG GROUP		CONTROL DRUG GROUP			
					(including adverse events)	no. of events*	total # of patients	no. of events	total # of patients		

** group means with standard deviations may be reported if the data are continuous*

ANNEX D

ANNOTATIONS

A Some drugs of proven efficacy and safety are not available in the market for lack of profitability or perceived demand but are considered essential, hence included in the PNDF marketed with asterisk.

B Systematic literature reviews in which studies are systematically searched, assembled, appraised and summarized using explicit and reproducible approaches that minimizes biases and random errors (after Sacks, Chalmers, Smith. Randomized versus historical controls for clinical trials. Am J Med 1982; 72:233-40.). The steps that the National Formulary Committee take in conducting systematic literature reviews on specific drugs are the following:

1. We pose the question: Is drug X a safe and efficacious drug for condition Y?
2. We conduct a comprehensive search for randomized controlled trials in HERDIN, MEDLINE, EMBASE, the Cochrane Controlled Trials Register in the Cochrane Library. We combine the generic name of the drug and the MESH terms of the indications for its use with the optimum set of keywords and commands for locating RCTs as given in the Cochrane Handbook for Preparing Systematic Reviews. We search for sytematic reviews in the Cochrane Database of Systematic Reviews using the generic name of the drug as keyword.
3. We evaluate the abstracts of the studies to verify whether they are really RCTs or not and their relevance to our question.
4. We extract data on safety and efficacy from the study abstracts or, if needed, from the full texts.
5. We summarize the results of each study in an evidence table and examine similarities and differences of finding across studies. If appropriate, meta-analyses are performed to quantitatively combine the results of several studies.

C Benefits are expressed in risk differences and/or numbers needed to treat (NNT). We define risk as the proportion of people who develop a bad event among all of those who are at risk for developing it. The efficacy of drug X is reflected by the size of the difference in the risk of developing a bad event with and without drug X (the absolute risk difference or ARR). Alternatively, the number of people who need to be treated with drug X to prevent one bad event (the NNT) may be obtained by the formula NNT = 1/ARR such that the smaller the NNT the more efficacious the drug. Safety is inversely proportional to the risk for adverse effects and is similarly expressed in risk differences and/or numbers needed to harm (NNH). Thus, as the risk difference rises or the NNH decreases the drug is deemed less and less safe.

D1 Recently completed RCTs or systematic reviews that show new drugs to be more efficacious or safe (see C for definitions of efficacy and safety) than other drugs in the same class may be grounds for their inclusion in lieu of or as a complement to formulary drugs. However, the NFC may choose to perform a cost-effectiveness analysis when newer, more efficacious drugs are more expensive than formulary drugs.

D2 The bases for deletion include the following: (1) recently completed RCTs or systematic reviews that show formulary drugs to be less efficacious or safe (see C for definitions of efficacy and safety) than other drugs in the same class; (2) cost-effectiveness analysis favors newer drugs of the same therapeutic class as the formulary drugs.

Republic of the Philippines
CONGRESS OF THE PHILIPPINES
Metro Manila

Fourteenth Congress
First Regular Session

Begun and held in Metro Manila, on Monday, the twenty-third day of July, two thousand seven.

[Republic Act No. 9502]

AN ACT PROVIDING FOR CHEAPER AND QUALITY MEDICINES, AMENDING FOR THE PURPOSE REPUBLIC ACT NO. 8293 OR THE INTELLECTUAL PROPERTY CODE, REPUBLIC ACT NO. 6675 OR THE GENERICS ACT OF 1988, AND REPUBLIC ACT NO. 5921 OR THE PHARMACY LAW, AND FOR OTHER PURPOSES

Be it enacted by the Senate and House of Representatives of the Philippines in Congress assembled:

CHAPTER 1
GENERAL PROVISIONS

SECTION 1. *Short Title*. — This Act shall be known as the "Universally Accessible Cheaper and Quality Medicines Act of 2008".

SECTION 2. *Declaration of Policy*. — It is the policy of the State to protect public health and, when the public interest or circumstances of extreme urgency so require, it shall adopt appropriate measures to promote and ensure access to affordable quality drugs and medicines for all. Pursuant to the attainment of this general policy, an effective competition policy in the supply and demand of quality affordable drugs and medicines is recognized by the State as a primary instrument. In the event that full competition is not effective, the State recognizes as a reserve instrument the regulation of prices of drugs and medicines, with clear accountability by the implementing authority as mandated in this Act, as one of the means to also promote and ensure access to quality affordable medicines.

SECTION 3. *Construction in Favor of Protection of Public Health*. — All doubts in the implementation and interpretation of the provisions of this Act, including its implementing rules and regulations, shall be resolved in favor of protecting public health.

SECTION 4. *Definition of Terms*. — For purposes of this Act, the following terms are to mean as follows:

(a) "Compulsory License" is a license issued by the Director General of the Intellectual Property Office to exploit a patented invention without the permission of the patent holder, either by manufacture or through parallel importation;

(b) "Drug outlet" refers to drugstores, pharmacies, and any other business establishments which sell drugs and medicines;

(c) "Drugs and medicines" refers to any chemical compound or biological substance, other than food, intended for use in the treatment, prevention or diagnosis of disease in humans or animals, including but not limited to:

(1) any article recognized in the official United States Pharmacopoeia-National Formulary (USP-NF), official Homeopathic Pharmacopoeia of the United States, Philippine Pharmacopoeia, Philippine National Drug Formulary, British Pharmacopoeia, European Pharmacopoeia, Japanese Pharmacopoeia, Indian Pharmacopoeia, any national compendium or any supplement to any of them;

(2) any article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals;

(3) any article other than food intended to affect the structure or any function of the human body or animals;

(4) any article intended for use as a component of any articles specified in clauses (1), (2), and (3) not including devices or their components, parts, or accessories;

(5) herbal and/or traditional drugs which are articles of plant or animal origin used in folk medicine which are:

(i) recognized in the Philippine National Drug Formulary;
(ii) intended for use in the treatment or cure or mitigation of disease symptoms, injury or body defects in humans;
(iii) other than food, intended to affect the structure or any function of the human body;
(iv) in finished or ready-to-use dosage form; and
(v) intended for use as a component of any of the articles specified in clauses (i), (ii), (iii), and (iv);

(d) "Essential drugs list or national drug formulary" refers to a list of drugs prepared and periodically updated by the Department of Health on the basis of health conditions obtaining in the Philippines as well as on internationally accepted criteria;

(e) "Importer" refers to any establishment that imports raw materials, active ingredients and finished products for its own use or for distribution to other drug establishments or outlets;

(f) "Manufacture" includes any process or part of a process for making, altering, finishing, packing, labeling, breaking or otherwise treating or adapting any drug with a view to its sale and distribution, but does not include the compounding or dispensing of any drug in the ordinary course of retail business;

(g) "Manufacturer" refers to any establishment engaged in the operations involved in the production of a drug with the end view of storage, distribution, or sale of the product;

(h) "Multisource pharmaceutical products" refers to pharmaceutically equivalent or pharmaceutically alternative products that may or may not be therapeutically equiva-

lent. Multisource pharmaceutical products that are therapeutically equivalent are interchangeable;

(i) "Retailer" refers to a licensed establishment carrying on the retail business of sale of drugs and medicines to customers;

(j) "Trader" refers to any licensed establishment which is a registered owner of a drug product that procures the materials and packaging components, and provides the production monographs, quality control standards and procedures, but subcontracts the manufacture of such products to a licensed manufacturer;

(k) "TRIPS Agreement" or Agreement on Trade-Related Aspects of Intellectual Property Rights refers to the international agreement administered by the WTO that sets down minimum standards for many forms of intellectual property regulation; and

(l) "Wholesaler" refers to a licensed establishment or drug outlet who acts as merchant, broker or agent, who sells or distributes for resale or wholesale drugs and medicines.

CHAPTER 2
AMENDMENTS TO REPUBLIC ACT NO. 8293, OTHERWISE KNOWN AS THE INTELLECTUAL PROPERTY CODE OF THE PHILIPPINES

SECTION 5. Section 22 of Republic Act No. 8293, otherwise known as the Intellectual Property Code of the Philippines, is hereby amended to read as follows:

"SEC. 22. *Non-Patentable Inventions*. – The following shall be excluded from patent protection:

"22.1. Discoveries, scientific theories and mathematical methods, and in the case of drugs and medicines, the mere discovery of a new form or new property of a known substance which does not result in the enhancement of the known efficacy of that substance, or the mere discovery of any new property or new use for a known substance, or the mere use of a known process unless such known process results in a new product that employs at least one new reactant. "For the purpose of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations, and other derivatives of a known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy;

"22.2. x x x;

"22.3. x x x;

"22.4. x x x;

"22.5. x x x; and

"22.6. x x x."

SECTION 6. Section 26 of Republic Act No. 8293, otherwise known as the Intellectual Property Code of the Philippines, is hereby amended to read as follows:

"SEC. 26. *Inventive Step*. – 26.1. An invention involves an inventive step if, having regard to

prior art, it is not obvious to a person skilled in the art at the time of the filing date or priority date of the application claiming the invention. *(n)*

"26.2. In the case of drugs and medicines, there is no inventive step if the invention results from the mere discovery of a new form or new property of a known substance which does not result in the enhancement of the known efficacy of that substance, or the mere discovery of any new property or new use for a known substance, or the mere use of a known process unless such known process results in a new product that employs at least one new reactant."

SECTION 7. Section 72 of Republic Act No. 8293, otherwise known as the Intellectual Property Code of the Philippines, is hereby amended to read as follows:

"SEC. 72. *Limitations of Patent Rights* . – The owner of a patent has no right to prevent third parties from performing, without his authorization, the acts referred to in Section 71 hereof in the following circumstances:

"72.1. Using a patented product which has been put on the market in the Philippines by the owner of the product, or with his express consent, insofar as such use is performed after that product has been so put on the said market: *Provided* , That, with regard to drugs and medicines, the limitation on patent rights shall apply after a drug or medicine has been introduced in the Philippines or anywhere else in the world by the patent owner, or by any party authorized to use the invention: *Provided, further* , That the right to import the drugs and medicines contemplated in this section shall be available to any government agency or any private third party;

"72.2. Where the act is done privately and on a non-commercial scale or for a non-commercial purpose: *Provided* , That it does not significantly prejudice the economic interests of the owner of the patent;

"72.3. Where the act consists of making or using exclusively for experimental use of the invention for scientific purposes or educational purposes and such other activities directly related to such scientific or educational experimental use;

"72.4. In the case of drugs and medicines, where the act includes testing, using, making or selling the invention including any data related thereto, solely for purposes reasonably related to the development and submission of information and issuance of approvals by government regulatory agencies required under any law of the Philippines or of another country that regulates the manufacture, construction, use or sale of any product: *Provided* , That, in order to protect the data submitted by the original patent holder from unfair commercial use provided in Article 39.3 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), the Intellectual Property Office, in consultation with the appropriate government agencies, shall issue the appropriate rules and regulations necessary therein not later than one hundred twenty (120) days after the enactment of this law;

"72.5. Where the act consists of the preparation for individual cases, in a pharmacy or by a medical professional, of a medicine in accordance with a medical prescription or acts concerning the medicine so prepared; and

"72.6. Where the invention is used in any ship, vessel, aircraft, or land vehicle of any other country entering the territory of the Philippines temporarily or accidentally: *Provided*, That such invention is used exclusively for the needs of the ship, vessel, aircraft, or land vehicle and not used for the manufacturing of anything to be sold within the Philippines. (Secs. 38 and 39, R.A. No. 165a)"

SECTION 8. Section 74 of Republic Act No. 8293, otherwise known as the Intellectual Property Code of the Philippines, is hereby amended to read as follows:

"SEC. 74. *Use of Invention by Government*. – 74.1. A Government agency or third person authorized by the Government may exploit the invention even without agreement of the patent owner where:

"(a) The public interest, in particular, national security, nutrition, health or the development of other sectors, as determined by the appropriate agency of the government, so requires; or

"(b) A judicial or administrative body has determined that the manner of exploitation, by the owner of the patent or his licensee, is anti-competitive; or

"(c) In the case of drugs and medicines, there is a national emergency or other circumstance of extreme urgency requiring the use of the invention; or

"(d) In the case of drugs and medicines, there is public non-commercial use of the patent by the patentee, without satisfactory reason; or

"(e) In the case of drugs and medicines, the demand for the patented article in the Philippines is not being met to an adequate extent and on reasonable terms, as determined by the Secretary of the Department of Health."

"74.2. Unless otherwise provided herein, the use by the Government, or third person authorized by the Government shall be subject, where applicable, to the following provisions:

"(a) In situations of national emergency or other circumstances of extreme urgency as provided under Section 74.1 (c), the right holder shall be notified as soon as reasonably practicable;

"(b) In the case of public non-commercial use of the patent by the patentee, without satisfactory reason, as provided under Section 74.1 (d), the right holder shall be informed promptly: *Provided*, That, the Government or third person authorized by the Government, without making a patent search, knows or has demonstrable ground to know that a valid patent is or will be used by or for the Government;

"(c) If the demand for the patented article in the Philippines is not being met to an adequate extent and on reasonable terms as provided under Section 74.1 (e), the right holder shall be informed promptly;

"(d) The scope and duration of such use shall be limited to the purpose for which it was authorized;

"(e) Such use shall be non-exclusive;

"(f) The right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization; and

"(g) The existence of a national emergency or other circumstances of extreme urgency, referred to under Section 74.1 (c), shall be subject to the determination of the President of the Philippines for the purpose of determining the need for such use or other exploitation, which shall be immediately executory.

"74.3. All cases arising from the implementation of this provision shall be cognizable by courts with appropriate jurisdiction provided by law. "No court, except the Supreme Court of the Philippines, shall issue any temporary restraining order or preliminary injunction or such other provisional remedies that will prevent its immediate execution.

"74.4. The Intellectual Property Office (IPO), in consultation with the appropriate government agencies, shall issue the appropriate implementing rules and regulations for the use or exploitation of patented inventions as contemplated in this section within one hundred twenty (120) days after the effectivity of this law."

SECTION 9. Section 76.1 of Republic Act No. 8293, otherwise known as the Intellectual Property Code of the Philippines, is hereby amended to read as follows:

"SEC. 76. *Civil Action for Infringement* . – 76.1. The making, using, offering for sale, selling, or importing a patented product or a product obtained directly or indirectly from a patented process, or the use of a patented process without the authorization of the patentee constitutes patent infringement: *Provided* , That, this shall not apply to instances covered by Sections 72.1 and 72.4 (Limitations of Patent Rights); Section 74 (Use of Invention by Government); Section 93.6 (Compulsory Licensing); and Section 93-A (Procedures on Issuance of a Special Compulsory License under the TRIPS Agreement) of this Code.

"76.2. x x x;
"76.3. x x x;
"76.4. x x x;
"76.5. x x x; and
"76.6. x x x."

SECTION 10. Section 93 of Republic Act No. 8293, otherwise known as the Intellectual Property Code of the Philippines, is hereby amended to read as follows:

"SEC. 93. *Grounds for Compulsory Licensing.* – The Director General of the Intellectual Property Office may grant a license to exploit a patented invention, even without the agreement of the patent owner, in favor of any person who has shown his capability to exploit the invention, under any of the following circumstances:

"93.1. National emergency or other circumstances of extreme urgency;

"93.2. Where the public interest, in particular, national security, nutrition, health or the development of other vital sectors of the national economy as determined by the appropriate agency of the Government, so requires; or

"93.3. Where a judicial or administrative body has determined that the manner of exploitation by the owner of the patent or his licensee is anti-competitive; or

"93.4. In case of public non-commercial use of the patent by the patentee, without satisfactory reason;

"93.5. If the patented invention is not being worked in the Philippines on a commercial scale, although capable of being worked, without satisfactory reason: *Provided* , That the importation of the patented article shall constitute working or using the patent; (Secs. 34, 34-A, 34-B, R.A. No. 165a) and

"93.6. Where the demand for patented drugs and medicines is not being met to an adequate extent and on reasonable terms, as determined by the Secretary of the Department of Health."

SECTION 11. A new Section 93-A is hereby inserted after Section 93 of Republic Act No. 8293, otherwise known as the Intellectual Property Code of the Philippines, to read as follows:

"SEC. 93-A. *Procedures on Issuance of a Special Compulsory License under the TRIPS Agreement.* – 93-A.1. The Director General of the Intellectual Property Office, upon the written recommendation of the Secretary of the Department of Health, shall, upon filing of a petition, grant a special compulsory license for the importation of patented drugs and medicines.

The special compulsory license for the importation contemplated under this provision shall be an additional special alternative procedure to ensure access to quality affordable medicines and shall be primarily for domestic consumption: *Provided* , That adequate remuneration shall be paid to the patent owner either by the exporting or importing country. The compulsory license shall also contain a provision directing the grantee the license to exercise reasonable measures to prevent the re-exportation of the products imported under this provision.

"The grant of a special compulsory license under this provision shall be an exception to Sections 100.4 and 100.6 of Republic Act No. 8293 and shall be immediately executory. "No court, except the Supreme Court of the Philippines, shall issue any temporary restraining order or preliminary injunction or such other provisional remedies that will prevent the grant of the special compulsory license.

"93-A.2. A compulsory license shall also be available for the manufacture and export of drugs and medicines to any country having insufficient or no manufacturing capacity in the pharmaceutical sector to address public health problems: *Provided* , That, a compulsory license has been granted by such country or such country has, by notification or otherwise, allowed importation into its jurisdiction of the patented drugs and medicines from the Philippines in compliance with the TRIPS Agreement.

"93-A.3. The right to grant a special compulsory license under this section shall not limit or prejudice the rights, obligations and flexibilities provided under the TRIPS Agreement and under Philippine laws, particularly Section 72.1 and Section 74 of the Intellectual Property Code, as amended under this Act. It is also without prejudice to the extent to which drugs and medicines produced under a compulsory license can be exported as allowed in the TRIPS Agreement and applicable laws."

SECTION 12. Section 94 of Republic Act No. 8293, otherwise known as the Intellectual Property Code of the Philippines, is hereby amended to read as follows:

"SEC. 94. *Period for Filing a Petition for a Compulsory License.* – 94.1. A compulsory license may not be applied for on the ground stated in Subsection 93.5 before the expiration of a period of four (4) years from the date of filing of the application or three (3) years from the date of the patent whichever period expires last.

"94.2. A compulsory license which is applied for on any of the grounds stated in Subsections 93.2, 93.3, 93.4, and 93.6 and Section 97 may be applied for at any time after the grant of the patent. (Sec. 34(1), R. A. No. 165)"

SECTION 13. Section 95 of Republic Act No. 8293, otherwise known as the Intellectual Property Code of the Philippines, is hereby amended to read as follows:

"SEC. 95. *Requirement to Obtain a License on Reasonable Commercial Terms.* – 95.1. The license will only be granted after the petitioner has made efforts to obtain authorization from the patent owner on reasonable commercial terms and conditions but such efforts have not been successful within a reasonable period of time.

"95.2. The requirement under Subsection 95.1 shall not apply in any of the following cases:

"(a) Where the petition for compulsory license seeks to remedy a practice determined after judicial or administrative process to be anti-competitive;

"(b) In situations of national emergency or other circumstances of extreme urgency;

"(c) In cases of public non-commercial use; and

"(d) In cases where the demand for the patented drugs and medicines in the Philippines is not being met to an adequate extent and on reasonable terms, as determined by the Secretary of the Department of Health.

"95.3. In situations of national emergency or other circumstances of extreme urgency, the right holder shall be notified as soon as reasonably practicable.

"95.4. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly. (n)

"95.5. Where the demand for the patented drugs and medicines in the Philippines is not being met to an adequate extent and on reasonable terms, as determined by the Secretary of the Department of Health, the right holder shall be informed promptly."

SECTION 14. Section 147 of Republic Act No. 8293, otherwise known as the Intellectual Property Code of the Philippines, is hereby amended to read as follows:

"SEC. 147. Rights Conferred. – 147.1. Except in cases of importation of drugs and medicines allowed under Section 72.1 of this Act and of off-patent drugs and medicines, the owner of a registered mark shall have the exclusive right to prevent all third parties not having the owner's consent from using in the course of trade identical or similar signs or containers for

goods or services which are identical or similar to those in respect of which the trademark is registered where such use would result in a likelihood of confusion. In case of the use of an identical sign for identical goods or services, a likelihood of confusion shall be presumed.

"There shall be no infringement of trademarks or trade names of imported or sold patented drugs and medicines allowed under Section 72.1 of this Act, as well as imported or sold off patent drugs and medicines: *Provided*, That, said drugs and medicines bear the registered marks that have not been tampered, unlawfully modified, or infringed upon, under Section 155 of this Code.

"147.2. x x x."

SECTION 15. Section 159 of Republic Act No. 8293, otherwise known as the Intellectual Property Code of the Philippines, is hereby amended to read as follows:

"SEC. 159. *Limitations to Actions for Infringement*. – Notwithstanding any other provision of this Act, the remedies given to the owner of a right infringed under this Act shall be limited as follows:

"159.1. x x x;

"159.2. x x x;

"159.3. x x x and

"159.4 There shall be no infringement of trademarks or tradenames of imported or sold drugs and medicines allowed under Section 72.1 of this Act, as well as imported or sold off-patent drugs and medicines: *Provided*, That said drugs and medicines bear the registered marks that have not been tampered, unlawfully modified, or infringed upon as defined under Section 155 of this Code."

SECTION 16. *Implementing Rules and Regulations on Amendments to Republic Act No. 8293, otherwise known as the Intellectual Property Code of the Philippines*. – Unless otherwise provided herein, the Intellectual Property Office, in coordination with the Department of Health and the Bureau of Food and Drugs, shall issue and promulgate, within one hundred twenty (120) days after the enactment of this Act, the implementing rules and regulations to effectively implement the provisions of this Act that relate to Republic Act No. 8293, otherwise known as the Intellectual Property Code of the Philippines.

CHAPTER 3
DRUGS AND MEDICINES PRICE REGULATION

SECTION 17. *Drugs and Medicines Price Regulation Authority of the President of the Philippines*. – The President of the Philippines, upon recommendation of the Secretary of the Department of Health, shall have the power to impose maximum retail prices over any or all drugs and medicines as enumerated in Section 23. The power to impose maximum retail prices over drugs and medicines shall be exercised within such period of time as the situation may warrant as determined by the President of the Philippines. No court, except the Supreme Court of the Philippines, shall issue any temporary restraining order or preliminary injunction or preliminary mandatory injunction that will prevent the immediate execution of the exercise of this power of the President of the Philippines.

SECTION 18. *Drugs and Medicines Price Monitoring and Regulation Authority of the Secretary of the Department of Health* . – To implement the policies of this Act under this Chapter, the Secretary of the Department of Health is hereby authorized to establish and initiate a price monitoring and regulation system for drugs and medicines within one hundred twenty (120) days after the enactment of this Act. The Secretary of the Department of Health may also create such bodies, consultative councils, from which advice may be sought in the implementation of a drug or medicine price monitoring and regulation policy. Such bodies or consultative councils created by the Secretary of the Department of Health shall coordinate its efforts together with other government agencies.

SECTION 19. *Functions and Responsibilities of the Secretary of the Department of Health* . – Pursuant to Section 18 of this Act, the Secretary of the Department of Health shall have the following powers:

(A) Power to Recommend the Maximum Retail Price of Drugs and Medicines Subject to Price Regulation – (1) Upon application or *motu proprio* when the public interest so requires, the Secretary of the Department of Health shall have the power to determine the maximum retail prices of drugs and medicines which shall be recommended to the President of the Philippines for approval. In order that affordable prices of drugs and medicines from the different manufacturers, importers, traders, distributors, wholesalers, or retailers shall be made available to the public, the Secretary of the Department of Health, as he/she may deem fit and after a proper determination, shall have such approved maximum retail prices of drugs and medicines published; (2) In recommending the maximum retail price, the Secretary of the Department of Health shall consider the following factors:

(a) Retail prices of drugs and medicines that are subject to regulation in the Philippines and in other countries;
(b) The supply available in the market;
(c) The cost to the manufacturer, importer, trader, distributor, wholesaler or retailer of the following, but not limited to:

(i) The exchange rate of the peso to the foreign currency with which the drug or any of its component, ingredient or raw material was paid for;
(ii) Any change in the amortization cost of machinery brought about by any change in the exchange rate of the peso to the foreign currency with which the machinery was bought through credit facilities;
(iii) Any change in the cost of labor brought about by a change in minimum wage; or
(iv) Any change in the cost of transporting or distributing the medicines to the area of destination;

(d) Such other factors or conditions which will aid in arriving at a just and reasonable maximum price; and

(3) No retailer shall sell drugs and medicines at a retail price exceeding the maximum retail price approved by the President of the Philippines as provided in Section 17 of

Act: *Provided*, That, the Secretary of the Department of Health shall immediately undertake a study on the prevailing prices of drugs and medicines subject to price regulation and provide an initial list of drugs and medicines, which maximum retail prices he/she shall recommend to the President of the Philippines.

(B) Power to Include Other Drugs and Medicines in the List Subject to Price Regulation – Upon application or *motu proprio* when the public interest so requires and after proper determination, the Secretary of the Department of Health may order the inclusion of drugs and medicines to the list subject of price regulation under Section 23 hereof.

(C) Power to Implement Cost-Containment and Other Measures – (1) The Secretary of the Department of Health shall have the power to implement the fair price of drugs and medicines for purposes of public health insurance and government procurement based on the order of the President of the Philippines imposing maximum retail prices; and (2) The Secretary of the Department of Health shall have the power to implement any other measures that the government may avail of to effectively reduce the cost of drugs and medicines that shall include, but not limited to, competitive bidding, price volume negotiations, and other appropriate mechanisms that influence supply, demand and expenditures on drugs and medicines.

(D) Power to Impose Administrative Fines and Penalties – After due notice and hearing, the Secretary of the Department of Health shall have the power to impose administrative fines against any person, manufacturer, importer, trader, distributor, wholesaler, retailer, or any other entity, in such amount as it may deem reasonable, which in no case shall be less than Fifty thousand pesos (Php50,000.00) nor more than Five million pesos (Php5,000,000.00) for violations of the maximum retail price approved by the President of the Philippines pursuant to the provisions of this Chapter.

(E) Power to Deputize Government Entities – The Secretary of the Department of Health shall have the power to call upon and deputize any official, agent, employee, agency, or instrumentality of the national and local government for any assistance that it may deem necessary to carry out the purposes of this Chapter.

(F) Other Powers Necessary to Implement Provisions of this Chapter – The Secretary of the Department of Health shall exercise such powers and functions as may be necessary to implement and enforce the provisions of this Chapter of this Act, including the power to require the production and submission of records, documents, books of account, bills of lading, input documents, records of purchase and sale, financial statements, and such other documents, information and papers as may be necessary to enable the Secretary of the Department of Health to carry out its functions, duties, and responsibilities. Accordingly, within thirty (30) days from the effectivity of this Act and every December 31st of every year thereafter, every manufacturer, importer, trader, distributor, wholesaler, and retailer of a drug and medicine whether included in or excluded from the list of drugs and medicines that are subject to price regulation shall furnish the Secretary of the Department of Health a list, containing on the minimum the corresponding prices and inventory, of all drugs and medicines it manufactures, imports, trades, distributes, wholesales, or retails, data pertaining to the factors enume-

rated under Section 19(A)(2), and any and all necessary information that the Secretary of the Department of Health may require.

SECTION 20. *Procedures for Inquiries, Studies, Hearings, Investigations, and Proceedings*. – All inquiries, studies, hearings, investigations and proceedings conducted by the Secretary of the Department of Health shall be governed by the rules adopted by him/her, and in the conduct thereof shall not be bound by the technical rules of evidence.

SECTION 21. *Effectivity of the Decisions or Orders of the Secretary of the Department of Health* . – All decisions or orders of the Secretary of the Department of Health pursuant to Section 19 Paragraphs (A) Power to Recommend the Maximum Retail Price of Drugs and Medicines Subject to Price Regulation, (B) Power to Include Other Drugs and Medicines in the List Subject to Price Regulation, (C) Power to Implement Cost-Containment and Other Measures, (D) Power to Impose Administrative Fines and Penalties, (E) Power to Deputize Government Entities, or (F) Other Powers Necessary to Implement Provisions of this Chapter, shall be immediately operative.

SECTION 22. *Review of the Decisions or Orders of the Secretary of the Department of Health* . – A party adversely affected by a decision, order or ruling of the Secretary of the Department of Health may, within thirty (30) days from notice of such decision, order or ruling, or in case of a denial of a motion for reconsideration thereof, within fifteen (15) days after notice of such denial, file an appeal with the Court of Appeals, which shall have jurisdiction to review such decision, order or ruling. The filing of a petition for a writ of *certiorari* or other special remedies in the Supreme Court shall in no case supersede or stay any decision, order or ruling of the Secretary of the Department of Health, unless the Supreme Court shall so direct, and the petitioner may be required by the Supreme Court to give bond in such form and of such amount as may be deemed proper.

SECTION 23. *List of Drugs and Medicines that are Subject to Price Regulation* . – The list of drugs and medicines that are subject to price regulation shall include, *inter alia* :

(a) All drugs and medicines indicated for treatment of chronic illnesses and life threatening conditions, such as, but not limited to, endocrine disorders, e.g., diabetes mellitus; gastrointestinal disorders, e.g., peptic ulcer; urologic disorders, e.g., benign prostatic hyperplasia (BPH); cardiovascular diseases, e.g., hypertension; pulmonary diseases, e.g., pulmonary tuberculosis (PTB), asthma; auto-immune diseases, e.g., systemic lupus erythematosus (SLE); skin diseases, e.g., psoriasis; neuro-psychiatric disorders; other infectious diseases, e.g., human immunodeficiency virus-acquired immune deficiency syndrome (HIV-AIDS); and other conditions such as organ transplants and neoplasm;
(b) Drugs and medicines indicated for prevention of diseases, e.g., vaccines, immunoglobulin, anti-sera;
(c) Drugs and medicines indicated for prevention of pregnancy, e.g., oral contraceptives;
(d) Anesthetic agents;
(e) Intravenous fluids;
(f) Drugs and medicines that are included in the Philippine National Drug Formulary (PNDF) Essential Drug List; and

(g) All other drugs and medicines which, from time to time, the Secretary of the Department of Health determines to be in need of price regulation.

SECTION 24. *Illegal Acts of Price Manipulation* . – Without prejudice to the provisions of existing laws on goods not covered by this Act, it shall be unlawful for any manufacturer, importer, trader, distributor, wholesaler, retailer, or any person engaged in any method of disposition of drugs and medicines to engage in acts of price manipulation such as hoarding, profiteering, or illegal combination or forming cartel, as defined under Section 5 of Republic Act No. 7581, otherwise known as the Price Act, and all other acts committed in restraint of trade.

SECTION 25. *Penalty for Illegal Acts of Price Manipulation* . – Any person or entity who commits any act of illegal price manipulation of any drug and medicine subject to price regulation shall suffer the penalty of imprisonment for a period of not less than five (5) years nor more than fifteen (15) years or shall be imposed a fine of not less than One hundred thousand pesos (Php100,000.00) nor more than Ten million pesos (Php10,000,000.00), at the discretion of the court. The court may also order the suspension or revocation of its license to operate (LTO), professional or business license. Whenever any act of illegal price manipulation of any drug and medicine subject to price regulation is committed by a juridical person, its officials or employees, or in case of a foreign corporation or association, its agent or representative in the Philippines who are responsible for the violation, shall be held liable therefore.

SECTION 26. *Display of Maximum Retail Price Fixed and Approved by Order of the President of the Philippines for Drugs and Medicines Subject to Price Regulation* . –

(a) Within a reasonable period as may be determined by the Secretary of the Department of Health, and: *Provided* , That it conforms to existing drug product labeling requirements, every manufacturer, importer, distributor, wholesaler, trader, or retailer of a drug and medicine intended for sale shall display the retail price which shall not exceed the maximum retail price approved by order of the President of the Philippines. The maximum retail price shall be printed on the label of the immediate container of the drug and medicine and the minimum pack thereof offered for retail sale with the words "RETAIL PRICE NOT TO EXCEED" preceding it, and "UNDER DRUG PRICE REGULATION" on a red strip.

(b) Within a period as may be determined by the Secretary of the Department of Health from time to time, every manufacturer, importer, or trader shall issue a price list to wholesalers, distributors, retailers and to the Secretary of the Department of Health, indicating the retail price, the maximum retail price, and such other information as may be required by the Secretary of the Department of Health.

SECTION 27. *Reports from Local Government Units (LGUs) and the Department of Trade and Industry (DTI)* . – All local government units and the Department of Trade and Industry shall help ensure the implementation of pricing policies provided under this Chapter by submitting quarterly price monitoring reports to the Secretary of the Department of Health of drugs and medicines identified by the latter, and any and all necessary information that the Secretary of the Department of Health may require.

SECTION 28. *Role of the Department of Health (DOH) and the Department of Trade and Industry (DTI)*. – The Department of Health and the Department of Trade and Industry shall conduct independent periodic surveys and studies of the selling prices of all drugs and medicines referred to in Section 23 of this Act all over the country as well as their share or effect on the family income of the different economic groups in the country for purposes of serving as data base for government efforts to promote access to more affordable medicines, as well as evaluating the effectivity of the measures undertaken to promote access to more affordable medicines. The DTI shall always officially provide the Secretary of the Department of Health copies of these independent reports.

SECTION 29. *Rules and Regulations*. – The Secretary of the Department of Health, in consultation with the Department of Trade and Industry, the Congressional Oversight Committee and other appropriate government agencies, shall, within one hundred twenty (120) days from the effectivity of this Act, promulgate the rules and regulations necessary to effectively implement the provisions of this Chapter.

SECTION 30. *Reportorial and Public Notice Requirements*. –

(a) The Secretary of the Department of Health shall submit a bi-annual Monitoring Report of its performance on the implementation of this Act to the Office of the President. This report submitted to the Office of the President shall be published in a newspaper of general circulation within thirty (30) days upon submission.

(b) It shall also submit annually a report of its performance on the implementation of this Act to both Houses of Congress, within fifteen (15) days from the opening of the regular session. It shall also regularly report and comply immediately to any order of the Congressional Oversight Committee.

(c) The order of the President of the Philippines imposing maximum retail prices on drugs and medicines, including the conditions implementing it, shall be published within fifteen (15) days from issuance in at least two (2) newspapers of general circulation. All wholesalers, manufacturers, distributors, importers, or traders shall have a copy of the order of the President of the Philippines and provide the same to their clients and customers for every transaction.

(d) All drug outlets are required to post in a conspicuous area within its premises a clear copy of the order of the President of the Philippines which shall be easily accessible to the consuming public and updated regularly as the situation may warrant.

CHAPTER 4
STRENGTHENING OF THE BUREAU OF FOOD AND DRUGS

SECTION 31. *Strengthening of the Bureau of Food and Drugs (BFAD)* . –

(a) For a more effective and expeditious implementation of this Act, the Director or head of the Bureau of Food and Drugs shall be authorized to retain, without need of a separate approval from any government agency, and subject only to existing accounting and auditing rules and regulations, all the fees, fines, royalties and other charges, collected

by the Bureau of Food and Drugs under this Act and other laws that it is mandated to administer based on the immediately prior year of operations, for use in its operations, like upgrading of its facilities, equipment outlay, human resource development and expansion, and the acquisition of the appropriate office space, among others, to improve the delivery of its services to the public. This amount, which shall be in addition to the annual budget of the Bureau of Food and Drugs, shall be deposited and maintained in a separate account or fund, which may be used or disbursed directly by the Director or head.

(b) After five (5) years from the coming into force of this Act, the Director or head of the Bureau of Food and Drugs shall, subject to the approval of the Secretary of the Department of Health, determine if the fees and charges, mentioned in Subsection (a) hereof, are sufficient to meet its budgetary requirements. If so, it shall retain all the fees and charges it shall collect under the same conditions indicated in said Subsection (a) but shall forthwith, cease to receive any funds from the annual budget of the National Government; if not, the provisions of Subsection (a) shall continue to apply until such time when the Director or head of the Bureau of Food and Drugs, subject to the approval of the Secretary of the Department of Health, certifies that the above stated fees and charges the Bureau of Food and Drugs shall collect are enough to fund its operations.

(c) The Bureau of Food and Drugs shall submit a yearly performance report to the Quality Affordable Medicines Oversight Committee, as provided in Section 45 of this Act. The report shall itemize the use of such retained funds in the past year up to the present and the budgeted use of the same in the succeeding periods.

SECTION 32. *Quality Assurance of Drugs* . – The Bureau of Food and Drugs shall take the necessary steps to ensure that all drugs authorized for marketing in the country shall conform to international standards for the content, purity and quality of pharmaceutical products as established in the International Pharmacopoeia: *Provided,* That imported products in finished dosage forms, should be certified under the World Health Organization (WHO) certification scheme on the quality of pharmaceutical products moving in international commerce: *Provided, further,* That the registration for multisource pharmaceutical products should conform to the WHO guidelines on registration requirements to establish interchangeability.

CHAPTER 5
NON-DISCRIMINATORY CLAUSE

SECTION 33. *Non-Discriminatory Clause* . – It shall be unlawful for any retail drug outlet to refuse to carry either by sale or by consignment, or offer for sale drugs and medicines brought into the country, as allowed under Section 7 of this Act which amends Section 72.1 of the Intellectual Property Code of the Philippines or Republic Act No. 8293, by the government or authorized third party which have been previously approved for distribution or sale by the Bureau of Food and Drugs. For this purpose, the said products shall be displayed with equal prominence as all other products sold in the establishment.

SECTION 34. *Refusal to Sell Drugs and Medicines* . – No manufacturer, importer, trader, distributor,

wholesaler shall withhold from sale or refuse to sell to a wholesaler or retailer any drug or medicine without good and sufficient reasons.

SECTION 35. *Penalties.* – Any person or entity who shall refuse to carry or sell drugs and medicines pursuant to the provisions of this Chapter shall be punished with a fine of not less than One hundred thousand pesos (Php100,000.00) but not more than Five hundred thousand pesos (Php500,000.00), at the discretion of the court. For the succeeding offense, the penalties shall not be less than Five hundred thousand pesos (Php500,000.00) but not more than One million pesos (Php1,000,000.00), at the discretion of the court, and suspension or revocation of its license to operate (LTO), business or professional license, as the case may be.

SECTION 36. *Implementing Rules and Regulations on the Non-Discriminatory Clause.* – Within one hundred twenty (120) days from the effectivity of this Act, the Department of Health, in consultation with the Department of Trade and Industry, shall promulgate the rules and regulations necessary to effectively implement the provisions of this Chapter.

CHAPTER 6
AMENDMENTS TO REPUBLIC ACT NO. 6675, OTHERWISE KNOWN AS THE GENERICS ACT OF 1989

SECTION 37. Section 5 of Republic Act No. 6675, otherwise known as the Generics Act of 1988, is hereby amended to read as follows:

> "SEC. 5. *Posting and Publication*. – The Department of Health shall publish annually in acceptable means of public dissemination in at least two (2) newspapers of general circulation in the Philippines the generic names, and the corresponding brand names under which they are marketed, of all drugs and medicines available in the Philippines."

SECTION 38. Section 6 of Republic Act No. 6675, otherwise known as the Generics Act of 1988, is hereby amended to read as follows:

> "SEC. 6. *Who Shall Use Generic Terminology* . –
>
> (a) All government health agencies and their personnel as well as other government agencies shall use generic terminology or generic names in all transactions related to purchasing, prescribing, dispensing and administering of drugs and medicines.
>
> (b) All medical, dental and veterinary practitioners, including private practitioners, shall write prescriptions using the generic name. The brand name may be included if so desired.
>
> (c) Any organization or company involved in the manufacture, importation, repacking, marketing and/or distribution of drugs and medicines shall indicate prominently the generic name of the product. In the case of brand name products, the generic name shall appear prominently and immediately above the brand name in all product labels as well as in advertising and other promotional materials.
>
> (d) Drug outlets, including drugstores, hospital and non-hospital pharmacies and non-

traditional outlets such as supermarkets and stores, shall inform any buyer about any and all other drug products having the same generic name, together with their corresponding prices so that the buyer may adequately exercise his option. Within one (1) year after the approval of this Act, the drug outlets referred to herein shall post in conspicuous places in their establishments a list of drug products with the same generic name and their corresponding prices.

(e) There shall appear prominently on the label of a generic drug the following statement: THIS PRODUCT HAS THE SAME THERAPEUTIC EFFICACY AS ANY OTHER GENERIC PRODUCT OF THE SAME NAME. SIGNED: BFAD."

SECTION 39. Section 8 of Republic Act No. 6675, otherwise known as the Generics Act of 1988, is hereby amended to read as follows:

"SEC. 8. *Required Production*. – Subject to the rules and regulations promulgated by the Secretary of Health, every drug manufacturing company operating in the Philippines shall be required to produce, distribute and make widely available to the general public an unbranded generic counterpart of their branded product."

SECTION 40. Section 11 of Republic Act No. 6675, otherwise known as the Generics Act of 1988, is hereby amended to read as follows:

"SEC. 11. Education Drive. – The Department of Health jointly with the Philippine Information Agency and the Department of the Interior and Local Government shall conduct a continuous information campaign for the public and a continuing education and training for the medical and allied medical professions on drugs with generic names as an alternative of equal efficacy to the more expensive brand name drugs. Such educational campaign shall include information on the illnesses or symptoms which each generically named drug is supposed to cure or alleviate, as well as in contraindications. The Department of Health with the assistance of the Department of the Interior and Local Government and the Philippine Information Agency shall monitor the progress of the education drive, and shall submit regular reports to Congress."

SECTION 41. Section 12 of Republic Act No. 6675, otherwise known as the Generics Act of 1988, is hereby amended to read as follows:

"SEC. 12. *Penalty*. – (A) Any person who shall violate Section 6(a) or 6(b) of this Act shall suffer the penalty graduated hereunder, *viz*:

(a) for the first conviction, he shall suffer the penalty of reprimand which shall be officially recorded in the appropriate books of the Professional Regulation Commission.

(b) for the second conviction, the penalty of fine in the amount of not less than Ten thousand pesos (Php10,000.00) but not exceeding Twenty-five thousand pesos (Php25,000.00), at the discretion of the court.

(c) for the third conviction, the penalty of fine in the amount of not less than Twenty-five thousand pesos (Php25,000.00) but not exceeding Fifty thousand pesos (Php50,000.00)

and suspension of his license to practice his profession for sixty (60) days at the discretion of the court.

(d) for the fourth and subsequent convictions, the penalty of fine of not less than One hundred thousand pesos (Php100,000.00) and suspension of his license to practice his profession for one (1) year or longer at the discretion of the court.

"(B) Any juridical person who violates Sections 6(c), 6(d), 7 or 8 shall suffer the penalty of a fine of not less than One hundred thousand pesos (Php100,000.00) and suspension or revocation of license to operate such drug establishment or drug outlet at the discretion of the court: *Provided*, That its officers directly responsible for the violation shall suffer the penalty of fine of at least Forty thousand pesos (Php40,000.00) and suspension or revocation of license to practice profession, if applicable, and by imprisonment of not less than six (6) months nor more than one (1) year or both fine and imprisonment at the discretion of the court: and, *Provided, further*, That if the guilty party is an alien, he shall be *ipso facto* deported after service of sentence without need of further proceedings.

"(C) The Secretary of Health shall have the authority to impose administrative sanctions such as suspension or cancellation of license to operate or recommend suspension of license to practice profession to the Professional Regulation Commission as the case may be for the violation of this Act.

"The administrative sanctions that shall be imposed by the Secretary of the Department of Health shall be in a graduated manner in accordance with Section 12.A.

"An administrative case may be instituted independently from the criminal case: *Provided* That, the dismissal of the criminal case or the withdrawal of the same shall in no instance be a ground for the dismissal of the administrative case."

SEC. 42. *Implementing Rules and Regulations to the Amendments to the Generics Act of 1988* . – The Department of Health, in consultation with the appropriate government agencies, shall, within one hundred twenty (120) days from the effectivity of this Act, promulgate the rules and regulations necessary to effectively implement the provisions of this Act that relate to Republic Act No. 6675, or the Generics Act of 1988.

CHAPTER 7
AMENDMENTS TO REPUBLIC ACT NO. 5921, AS AMENDED, OTHERWISE KNOWN AS THE PHARMACY LAW

SECTION 43. Section 25 of Republic Act No. 5921, as amended, otherwise known as the Pharmacy Law, is hereby amended to read as follows:

"SEC. 25. Sale of medicine, pharmaceuticals, drugs and devices. – No medicine, pharmaceutical, or drug, except for those which are non-prescription or over-the-counter, of whatever nature and kind or device shall be compounded, dispensed, sold or resold, or otherwise be made available to the consuming public except through a prescription drugstore or hospital pharmacy, duly established in accordance with the provisions of this Act. Non-prescription or over-the-counter drugs may be sold in their original packages,

bottles, containers or in small quantities, not in their original containers to the consuming public through supermarkets, convenience stores and other retail establishments.

"Pharmaceutical, drug or biological manufacturing establishments, importers and wholesalers of drugs, medicines, or biologic products, shall not sell their products for re-sale except only to retail drug outlets, hospital pharmacies or to other drug wholesalers under the supervision of a registered pharmacist, and supermarkets, convenience stores, other retail establishments for over-the-counter drugs, duly licensed by the Bureau of Food and Drugs."

SECTION 44. *Implementing Rules and Regulations to the Amendments to the Pharmacy Law*. – The Department of Health, in consultation with the appropriate government agencies, within one hundred twenty (120) days from the effectivity of this Act, shall promulgate the rules and regulations necessary to effectively implement the provisions of this Chapter.

CHAPTER 8
MISCELLANEOUS PROVISIONS

SECTION 45. Congressional Oversight Committee. – For the effective implementation of this Act, there shall be created a Congressional Oversight Committee, hereinafter referred to as the Quality Affordable Medicines Oversight Committee, to be composed of five (5) members from the Senate, which shall include the Chairpersons of the Senate Committees on Trade and Commerce and Health and Demography, and, five (5) members from the House of Representatives, which shall include the Chairpersons of the House of Representatives Committees on Trade and Industry and Health. The Quality Affordable Medicines Oversight Committee shall be jointly chaired by the Chairpersons of the Senate Committee on Trade and Commerce and the House of Representatives Committee on Trade and Industry. The Vice-Chair of the oversight committee shall be jointly held by the Chairpersons of the Senate Committee on Health and Demography and the House of Representatives Committee on Health.

SECTION 46. Appropriations. – For the initial implementation of this Act, the amount of Twenty-five million pesos (Php25,000,000.00), in addition to the budget of the Department of Health, shall be provided for the operations of the Office of the Secretary of the Department of Health. The Quality Affordable Medicines Oversight Committee shall be provided an initial budget of Five million pesos (Php5,000,000.00) to perform its functions as mandated under this Act. Thereafter, such sum as may be necessary for its continued implementation shall be included in the annual General Appropriations Act.

SECTION 47. *Separability Clause*. – Any portion or provision of this Act that may be declared unconstitutional or invalid shall not have the effect of nullifying other portions and provisions hereof as long as such remaining portion or provision can still subsist and be given effect in their entirety.

SECTION 48. *Repealing Clause*. – All laws, decrees, executive orders, proclamations and administrative regulations or parts thereof inconsistent herewith are hereby repealed or modified accordingly.

SECTION 49. *Effectivity Clause* . – This Act shall take effect fifteen (15) days after its publication in at least two (2) national papers of general circulation.

Approved:

PROSPERO C. NOGRALES
Speaker of the House of Representatives

MANNY VILLAR
President of the Senate

This Act which is a consolidation of Senate Bill No. 1658 and House Bill No. 2844 was finally passed by the Senate and the House of Representatives on April 29, 2008.

MARILYN B. BARUA-YAP
Secretary General
House of Representatives

EMMA LIRIO-REYES
Secretary of the Senate

Approved: June 6, 2008

GLORIA MACAPAGAL-ARROYO
President of the Philippines

JOINT DOH-DTI-IPO-BFAD ADMINISTRATIVE ORDER NO. 2008-01

THE IMPLEMENTING RULES AND REGULATIONS OF REPUBLIC ACT 9502 OTHERWISE KNOWN AS THE "UNIVERSALLY ACCESSIBLE CHEAPER AND QUALITY MEDICINES ACT OF 2008"

WHEREAS, Republic Act No. 9502, otherwise known as the "Universally Accessible Cheaper and Quality Medicines Act of 2008", became effective on July 4, 2008;

WHEREAS, Republic Act No 9502 amends Republic Act No. 8293, or the Intellectual Property Code of the Philippines, Republic Act No. 6675, or the Generics Act of 1998, and Republic Act No. 5921, or the Pharmacy Law;

WHEREAS, the Department of Health, the Department of Trade and Industry, the Intellectual Property Office and the Bureau of Food and Drugs are mandated to issue and promulgate the rules and regulations to implement the provisions of Republic Act 9502;

NOW THEREFORE, the following Joint Administrative Order covering the rules and regulations implementing Republic Act 9502 are hereby adopted and prescribed for the information and guidance of all concerned.

CHAPTER I
GENERAL PROVISIONS

Rule 1. Declaration of Policy. It is the policy of the State to protect public health and, when the public interest or circumstances of extreme urgency so require, it shall adopt appropriate measures to promote and ensure access to affordable quality drugs and medicines for all.

Pursuant to the attainment of this general policy, an effective competition policy in the supply and demand of quality affordable drugs and medicines is recognized by the State as a primary instrument. In the event that full competition is not effective, the State recognizes as a reserve instrument the regulation of prices of drugs and medicines as one of the means to also promote and ensure access to quality affordable medicines. *(2)*

Rule 2. Effective Competition. Effective Competition shall encourage a milieu where there are a significant number of players at each level of the pharmaceutical supply chain that shall ensure availability and affordability of these health products. It exists in an environment where the consumers are well informed and are able to exercise their right to choose from a variety of variable options to access affordable, quality drugs and medicines. *(n)*

Rule 3. Construction in Favor of Protection of Public Health. All doubts in the implementation and interpretation of these implementing rules and regulations shall be resolved in favor of protecting public health.

Rule 4. Coverage. Unless otherwise provided by law, these Implementing Rules and Regulations shall apply to all drugs and medicines, and to all those who manufacture, trade, distribute, import, export, wholesale, retail, offer for sale, transfer, or donate drugs and medicines including medical and allied medical practitioners and to all persons, juridical or natural, involved in the provision of healthcare. *(n)*

Rule 5. Jurisdiction. The Intellectual Property Office (IPO) shall have jurisdiction over all issues concerning the requirements for patentability of drugs and medicines, infringement and/or violations of intellectual property rights, use of invention by government, compulsory licensing and special compulsory licensing. The Bureau of Food and Drugs (BFAD) shall have jurisdiction over all issues concerning the safety, quality and efficacy of drugs and medicines and procedures on parallel importation.

Rule 6. License to Import and Product Registration.

Section 1. Authority to Import. All interested parties, including government agencies must first secure a license to import from BFAD before they can import any drugs and medicines. *(n)*

Section 2. Product Registration. No drugs and medicines shall be manufactured, imported, exported, sold, offered for sale, distributed, or transferred without being registered with BFAD.

Section 3. Philippine National Drug Formulary (PNDF). Only drugs and medicines in the latest edition of the PNDF can be procured by government agencies or reimbursed by PhilHealth. *(n)*

Rule 7. Definition of Terms. The following terms as used in these Implementing Rules and Regulations shall be defined as follows:

(a) ***"Act"*** refers to Republic Act No. 9502 otherwise known as the Universally Accessible Cheaper Quality Medicines Act of 2008.

(b) ***"BFAD"*** refers to the Bureau of Food and Drugs.

(c) ***"BLA"*** refers to the Bureau of Legal Affairs of IPO.

(d) ***"Compulsory License"*** is a license issued by the Director General of the Intellectual Property Office to exploit a patented invention without the permission of the patent holder, either by manufacture or through parallel importation;

(e) ***"Conspicuous places"*** refers to places which must be public, more or less permanently fixed, must be seen always or frequently noticeable. *(n)*

(f) ***"Director General"*** refers to the Director General of the Intellectual Property Office of the Philippines. *(n)*

(g) ***"DOH"*** refers to the Department of Health. *(n)*

(h) ***"Drug outlets"*** refers to drugstores, pharmacies, and any other business establishments duly licensed by the BFAD to sell drugs and medicines. (AO No. 82,2000)

(i) ***"Drugs and medicines"*** refer to any chemical compound or biological substance, other than food, intended for use in the alleviation of symptoms and the treatment, prevention or diagnoses of diseases in humans or animals, including but no limited to: *(4C,n)*

(1) Articles recognized in the current official United States Pharmacopoeia-National Formulary (USP-NF), official Homeopathic Pharmacopoeia of the United States, Philippine Pharmacopoeia, official Philippine National Drug Formulary (PNDF), British Pharmacopoeia, European Pharmacopoeia, Japanese Pharmacopoeia, Indian Pharmacopoeia, any national compendium or any supplement to any of them;

(2) Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals;

(3) Articles other than food intended to affect the structure or any function of the human body or animals;

(4) Articles intended for use as a component of articles specified in clauses (1), (2), or (3) not including devices or their components, parts, or accessories; and

(5) Herbal and/or traditional drugs which are articles of plant or animal origin used in folk medicine that are:

(i) Recognized in the Philippine National Drug Formulary Vol. I (Essential Drugs List);

(ii) Intended for use in the treatment, cure or mitigation of disease symptoms, injury or body defects in humans;

(iii) Other than food, intended to affect the structure or any function of the human body;

(iv) In finished or ready-to-use dosage form; and

(i) Intended for use as a component of any of the articles specified in clauses (i), (ii), (iii), and (iv). *(4c, n)*

(6) In case of conflicts, the BFAD drug classification will prevail. *(n)*

(j) ***"DTI"*** refers to the Department of Trade and Industry.

(k) ***"Essential Drugs List" or "National Drug Formulary"*** refers to a list of drugs prepared and periodically updated by the DOH on the basis of health conditions obtaining in the Philippines as well as on internationally-accepted criteria. It shall consist of a core list and a complementary list. *(4d)*

(l) ***"Fair Price"*** Unless otherwise stated by the Secretary of Health, fair price shall refer to the lowest price of an available quality, non-branded generic drug. *(n)*

(m) ***"Generic Drugs"*** refer to drugs that have the same active pharmaceutical ingredient as the innovator drugs and are not covered by patent protection. These drugs are labeled by their international nonproprietary or generic name and may or may not have brand names. *(n)*

(n) ***"Importer"*** refers to any establishment that imports raw materials, active ingredients and finished products for its own use or for distribution to other drug establishments or outlets. *(4e)*

(o) ***"Immediate container or Primary packaging"*** refers to packaging materials where the approved safe keeping units are placed. It also refers to the first pack containing the individually wrapped products such as, but not limited to, foil strips, blister packs, and sachets. *(n)*

(p) ***"Innovator or Comparator Drug"*** refers to a drug with an active pharmaceutical ingredient or molecule that was first or originally marketed anywhere in the world on the basis of documentation of quality, safety and efficacy by a specific company or an entity which is expressed in its international non-proprietary name and usually carries a brand name. Such may be patented, non-patented or off-patent. *(n)*

(q) ***"Interchangeable pharmaceutical product"*** refers to a drug which is therapeutically equivalent to an innovator drug and can be interchanged with the innovator drug in clinical practice. It does not necessarily refer to Bioavailability/Bioequivalence (BA/BE), which is not applicable to all drug products. *(n)*

(r) ***"IP Code"*** means Republic Act No. 8293 otherwise known as the Intellectual Property Code of the Philippines as amended by Republic Act 9502 or otherwise known as "Universally Accessible Cheaper and Quality Medicines Act of 2008." *(n)*

(s) ***"IPO"*** refers to the Intellectual Property Office of the Philippines. *(n)*

(t) ***"Manufacture"*** includes any process or part of a process for making, altering, finishing, packing, labeling, breaking or otherwise treating or adapting any drug with a view to its sale and distribution, but does not include the compounding or dispensing of any drug in the ordinary course of retail business. *(4f)*

(u) ***"Manufacturer"*** refers to any establishment duly licensed by the BFAD to engage in the operations involved in the production of a drug with the end view of storage, distribution, or sale of the product. *(4g)*

(v) ***"Multisource pharmaceutical products"*** refers to pharmaceutically equivalent or pharmaceutically alternative products that may or may not be therapeutically equivalent. Multisource pharmaceutical products that are therapeutically equivalent are interchangeable. *(4h)*

(w) ***"Non-traditional outlets"*** refers to supermarkets, convenience stores, other retail establishments duly licensed by the BFAD to sell over-the-counter drugs. *(n)*

(x) ***"Pharmaceutical alternative"*** refers to products that contain the same molar amount of the same active pharmaceutical moiety(s) but differ in dosage form (e.g. tablets versus capsules), and/or chemical form (e.g. different salts, different esters). Pharmaceutical alternatives deliver the same active moiety by the same route of administration but are otherwise not pharmaceutically equivalent. They may or may not be bioequivalent or therapeutically equivalent to the comparator product. *(WHO Technical Report Series no. 937, 2006)*

(y) ***"Pharmaceutical equivalence"*** refers to drug products that contain the same molar amount of the same active pharmaceutical ingredient(s) in the same dosage form, if they meet comparable standards, and if they are intended to be administered by the same

Pharmaceutical equivalence does not necessarily imply therapeutic equivalence, as differences in the excipients and/or the manufacturing process and some other variables can lead to differences in product performance. *(WHO Technical Report Series no. 937, 2006)*

(z) ***"Pharmaceutical products"*** refer to drugs and medicines. (*n)*

(aa) ***"PPI"*** refers to Philippine International Trading Corporation Pharma Inc. *(n)*

(bb) ***"Retailer"*** refers to any establishment licensed by the BFAD to carry on the retail business of sale of drugs and medicines to consumers. *(4i)*

(cc) ***"Special Compulsory License" or "Special Compulsory Licensing"*** shall mean the import and/or export of patented drugs and medicines as referred to in Section 93-A of the IP Code. *(n)*

(dd) ***"Therapeutically equivalent"*** refers to two pharmaceutical products that are pharmaceutically equivalent or pharmaceutical alternatives and after administration in the same molar dose, their effects, with respect to both efficacy and safety, are essentially the same when administered to patients by the same route. The appropriate instruments and measures for determining such equivalence shall be those that are recognized by BFAD. *(WHO Technical Report Series no. 937, 2006, n)*

(ee) ***"Therapeutic efficacy"*** is synonymous to therapeutic equivalence with reference to their clinical effects on patients. *(n)*

(ff) ***"Trader"*** refers to any establishment licensed by the BFAD which is a registered owner of a drug product that procures the materials and packaging components, and provides the production monographs, quality control standards and procedures, but subcontracts the manufacture of such products to a licensed manufacturer; *(4j)*

(gg) ***"TRIPS Agreement"*** or Agreement on Trade-Related Aspects of Intellectual Property Rights refers to the international agreement administered by the WTO that sets down minimum standards for many forms of intellectual property regulation; *(4k)*

(hh) ***"Wholesaler"*** refers to any establishment or drug outlet licensed by the BFAD which acts as merchant, broker or agent, who sells or distributes for resale or wholesale drugs and medicines on a wholesale basis. *(4l)* ; and

(ii) ***"WTO"*** shall mean the World Trade Organization. *(n)*

CHAPTER II
INTELLECTUAL PROPERTY

Rule 8. Patents.

Section 1. Non-Patentable Inventions. The following shall be excluded from patent protection:

(a) Discoveries; scientific theories; mathematical methods; and in the case of drugs and medicines: the mere discovery of a new form or new property of a known substance

which does not result in the enhancement of the known efficacy of that substance, or the mere discovery of any new property or new use for a known substance or the mere use of a known process unless such known process results in a new product that employs at least one new reactant;

(b) Schemes, rules and methods of performing mental acts, playing games or doing business, and programs for computers;

(c) Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body. This provision shall not apply to products and compositions for use in any of these methods;

(d) Plant varieties or animal breeds or essentially biological process for the production of plants or animals. This provision shall not apply to microorganisms and non-biological and microbiological processes;

(e) Aesthetic creations; and

(f) Anything which is contrary to public order or morality.

For the purposes of subsection (a) salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations, and other derivatives of a known substance, shall be considered to be the same substance unless they differ significantly in properties with regard to efficacy. *(22)*

Section 2. Inventive Step. In the case of drugs and medicines, there is no inventive step if the invention results from: (a) the mere discovery of a new form or new property of a known substance which does not result in the enhancement of the known efficacy of that substance; or (b) the mere discovery of any property or new use for a known substance; or (c) the mere use of a known process unless such known process results in a new product that employs at least one new reactant. *(26)*

For the purpose of this section, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of a known substance shall be considered the same substance, unless they differ significantly in properties with regard to efficacy.

Section 3. Determination of Enhanced Efficacy. When assessing the extent of enhancement in efficacy, the patent examiner may call on representatives of the BFAD and/or its delegated experts to provide an expert opinion with regard to significant enhancement of therapeutic efficacy.

The criteria for determining inventive step with respect to efficacy shall be embodied in the Manual for Substantive Examination Procedure (MSEP) of the IPO. *(n)*

Rule 9. Limitations on Patent Rights. The owner of a patent has no right to prevent third parties from performing, without his authorization, the acts referred to in Section 71 of the IP Code as enumerated hereunder:

(i) Introduction in the Philippines or Anywhere Else in the World. Using a patented product which has been put on the market in the Philippines by the owner of the product, or with his express consent, insofar as such use is performed after that product has been so put on the said market: *Provided*, That, with regard to drugs and medicines, the limitation on patent rights shall apply after a drug or medicine has been introduced in the Philippines or anywhere else in the world by the patent owner, or by any party authorized to use the invention: *Provided, further*, That the right to import the drugs and medicines contemplated in this section shall be available to any government agency or any private third party. *(72.1)*

The drugs and medicines are deemed introduced when they have been sold or offered for sale anywhere else in the world. *(n)*

The procedures for parallel importation shall be governed by Chapter III of these rules. *(n)*

(ii) Private and Non-Commercial Scale or Purpose. Where the act is done privately and on a non-commercial scale or for a non-commercial purpose: *Provided,* That it does not significantly prejudice the economic interests of the owner of the patent. *(72.2)*

(iii) Experimental Use for Scientific or Educational Purpose. Where the act consists of making or using exclusively for experimental use of the invention for scientific purposes or educational purposes and such other activities directly related to such scientific or educational experimental use. *(72.3)*

(iv) Regulatory Evaluation and Approval. In case of drugs and medicines, where the act includes testing, using, making or selling the invention including any data related thereto, solely for purposes reasonably related to the development and submission of information and issuance of approvals by government regulatory agencies required under any law of the Philippines or of another country that regulates the manufacture, construction, use or sale of any product. *(72.4)*

(iv.a) Use of Data by BFAD. The BFAD shall not be precluded from using all data, including, but not limited to, pre-clinical and clinical trials, of an applicant when evaluating other applications. *(n)*

(iv.b) Data Protection from Unfair Commercial Use. Data submitted by the original patent holder shall be protected against unfair commercial use as provided in Article 39.3 of the TRIPS. *(72.4)*

When required as a condition of approving the marketing of drugs and medicines which utilize new chemical entities, any submitted undisclosed test or other data, the origination of which involves a considerable effort, shall be protected against unfair commercial use. In addition, such data shall be protected against disclosure, except where necessary to protect the public or unless steps are taken to ensure that the data are protected against unfair commercial use. *(39.3)*

(v) Preparation in a Pharmacy or by a Medical Professional. Where the act consists of the preparation for individual cases, in a pharmacy or by a medical professional, of a medical

in accordance with a medical prescription or acts concerning the medicine so prepared. *(72.5)*

(vi) Ship, Vessel, Aircraft or Land Vehicle Use. Where the invention is used in any ship, vessel, aircraft or land vehicle of any other country entering the territory of the Philippines temporarily or accidentally; *Provided,* that such invention is used exclusively for the needs of the ship, vessel, aircraft, or land vehicle and not used for the manufacturing of anything to be sold within the Philippines. *(72.6)*

Rule 10. Use of Invention by Government.

Section 1. Grounds for Use of Invention by Government. Any government agency or third person authorized by the government may exploit the invention even without agreement of the patent owner where:

(a) The public interest, in particular, national security, nutrition, health or the development of other sectors, as determined by the appropriate agency of the government, so requires; or

(b) A judicial or administrative body has determined that the manner of exploitation by the owner of the patent or his licensee, is anticompetitive; or

(c) In the case of drugs and medicines, there is a national emergency or other circumstances of extreme urgency requiring the use of the invention; or

(d) In the case of drugs or medicines, there is public noncommercial use of the patent by the patentee, without satisfactory reason; or

(e) In the case of drugs and medicines, the demand for the patented article in the Philippines is not being met to an adequate extent and on reasonable terms, as determined by the Secretary of the Department of Health. *(74)*

Section 2. Authorization for the Use of Invention by the Government, or Third Person Authorized by the Government. The use of the government agency or third person authorized by the government to exploit the invention shall be covered by a written authorization to be issued by the Director General. *(n)*

Upon written request by the government agency or third person authorized by the government, the Director General shall issue a written authorization. In case of national emergency or other circumstances of extreme urgency under Section 74 of the IP Code, the Director General shall notify the patent owner of the grant of the written authorization as soon as reasonably practicable. In case of public non-commercial use of the patent by the patentee without satisfactory reason, as provided under Section 74.1(d) of the IP Code, the right holder shall be informed promptly that a valid patent will be used by or for the government, or third person authorized by the government of the grant of the written authorization. The written authorization by the Director General shall be exempted from the procedures on compulsory licensing under Rule 12. *(n)*

Section 3. Judicial Review. All cases arising from the implementation of this Rule shall be cognizable by courts with appropriate jurisdiction by law. *(74.3)*

No courts, except the Supreme Court of the Philippines, shall issue any temporary restraining order or preliminary injunction or such other provisional remedies that will prevent its immediate execution. *(74.3)*

Section 4. Conditions for Use by the Government, or Third Person Authorized by the Government. Unless otherwise provided herein, the use by the Government or third person authorized by the Government shall be subject, where applicable, to the following provisions:

(a) In situations of national emergency or other circumstances of extreme urgency as provided under Section 74.1(c) of the IP Code, the right holder shall be notified as soon as reasonably practicable;

(b) In the case of public non-commercial use of the patent by the patentee, without satisfactory reason, as provided under Section 74.1(d) of the IP Code, the right holder shall be informed promptly; *Provided,* That, the Government or third person authorized by the Government without making a patent search, knows or has demonstrable ground to know that a valid patent is or will be used by or for the Government;

(c) If the demand for the patented article in the Philippines is not being met to an adequate extent and on reasonable terms as provided under Section 74.1(e) of the IP Code, the right holder shall be informed promptly;

(d) The scope and duration of such use shall be limited to the purpose for which it was authorized;

(e) Such use shall be non-exclusive;

(f) The right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization; and

(g) The existence of a national emergency or other circumstance of extreme urgency, referred to under Section 74.1(c) of the IP Code, shall be subject to the determination of the President of the Philippines for the purpose of determining the need for such use or other exploitation, which shall be immediately executory. *(74.2)*

Where applicable and to the extent that the same has not been repealed by the IP Code, the other conditions for the issuance of a Compulsory License may also apply to use of Government or third person authorized by the Government. *(n)*

Rule 11. Civil Action for Infringement.

Section 1. Patent Infringement. The making, using, offering for sale, selling, or importing a patented product or a product obtained directly or indirectly from a patented process, or the use of a patented process without the authorization of the patentee constitutes patent infringement: *Provided,* That, this shall not apply to instances covered by Sections 72.1 and 72.4 (Limitations of Patent Rights); Section 74 (Use of Invention by Government); Section 93.6 (Compulsory Licensing); and Section 93-A (Procedures on Issuance of a Special Compulsory License under the TRIPS Agreement) of the IP Code. *(76.1)*

Section 2. Civil Action. Any patentee, or anyone possessing any right, title or interest in and to the patented invention, whose rights have been infringed, may bring a civil action before a court of competent jurisdiction, to recover from the infringer such damages sustained thereby, plus attorney's fees and other expenses of litigation, and to secure an injunction for the protection of his rights. *(76.2)*

Section 3. Damages. If the damages are inadequate or cannot be readily ascertained with reasonable certainty, the court may award by way of damages a sum equivalent to reasonable royalty. *(76.3)*

Section 4. Damages Over and Above Actual Damages. The court may, according to the circumstances of the case, award damages in a sum above the amount found as actual damages sustained: *Provided* that the award does not exceed three (3) times the amount of such actual damages. *(76.4)*

Section 5. Disposition or Destruction of Infringing Goods. The court may, in its discretion, order that the infringing goods, materials and implements predominantly used in the infringement be disposed of outside the channels of commerce or destroyed, without compensation. *(76.5)*

Section 6. Contributory Infringement. Anyone who actively induces the infringement of a patent or provides the infringer with a component of a patented product or of a product produced because of a patented process knowing it to be especially adopted for infringing the patented invention and not suitable for substantial non-infringing use shall be liable as a contributory infringer and shall be jointly and severally liable with the infringer. *(76.6)*

Rule 12. Compulsory Licensing.

Section 1. Applicability of Regulations on Interpartes Proceedings. The Regulations on Interpartes Proceedings, as amended by Office Order No. 79, Series of 2005 issued by the IPO, shall continue to be valid and in force and shall apply *mutatis mutandis* to the provisions of this IRR except where otherwise specifically indicated. In case of conflict, the provisions of this IRR shall prevail over the provisions of the Regulations on Interpartes Proceedings. *(n)*

Section 2. Coverage. Invention patents, industrial design registration and utility model registration are all subject to proceedings for compulsory licensing. *(n)*

Section 3. Authority to Grant a Compulsory License. The authority to grant a compulsory license shall be vested with the Director General. *(93)*

Section 4. Period for Filing a Petition for Compulsory License. A compulsory license may not be applied for on the ground stated in Section 5(e) below before the expiration of a period of four (4) years from the date of filing of the application or three (3) years from the date of the patent whichever period expires last. A compulsory license which is applied for on any of the grounds stated in Sections 5(b), 5(c), 5(d), 5(f) and 6 of this Rule may be applied for at any time after the grant of the patent. *(94.1)*

Section 5. Grounds for Compulsory Licensing. The Director General of the Intellectual Property Office may grant a license to exploit a patented invention, even without the agreement of

the patent owner, in favor of any person who has shown his capability to exploit the invention, under any of the following circumstances:

(a) National emergency or other circumstances of extreme urgency;

(b) Where the public interest, in particular, national security, nutrition, health or the development of other vital sectors of the national economy as determined by the appropriate agency of the Government, so requires; or

(c) Where a judicial or administrative body has determined that the manner of exploitation by the owner of the patent or his licensee is anticompetitive; or

(d) In case of public non-commercial use of the patent by the patentee, without satisfactory reason;

(e) If the patented invention is not being worked in the Philippines on a commercial scale, although capable of being worked, without satisfactory reason: *Provided,* that the importation of the patented article shall constitute working or using the patent; and

(f) Where the demand for patented drugs and medicines is not being met to an adequate extent and on reasonable terms, as determined by the Secretary of the Department of Health. *(93)*

Section 6. Compulsory License Based on Interdependence of Patents. If the invention protected by a patent, hereafter referred to as the "second patent," within the country cannot be worked without infringing another patent, hereafter referred to as the "first patent," granted on a prior application or benefiting from an earlier priority, a compulsory license may be granted to the owner of the second patent to the extent necessary for the working of his invention, subject to the following conditions:

(a) The invention claimed in the second patent involves an important technical advance of considerable economic significance in relation to the first patent;

(b) The owner of the first patent shall be entitled to a cross-license on reasonable terms to use the invention claimed in the second patent;

(c) The use authorized in respect of the first patent shall be nonassignable except with the assignment of the second patent; and

(d) The terms and conditions of Sections 95, 96 and 98 to 100 of the IP Code. *(97)*

Section 7. Terms and Conditions for Compulsory License. The basic terms and conditions, including the rate of royalty of the compulsory license, shall be fixed by the Director of the BLA subject to the following conditions:

(a) The scope and duration of such use shall be limited to the purpose for which it was authorized; *(100.1)*

(b) Such use shall be non-exclusive; *(100.2)*

(c) The right holder shall be paid adequate remuneration in the circumstances of each case,

taking into account the economic value of the grant or authorization, except that in cases where the license was granted to remedy a practice which was determined after judicial or administrative process to be anti-competitive, the need to correct the anti-competitive practice may be taken into account in fixing the amount of remuneration; *(100.6)*

(d) In case of patents involving semi-conductor technology, the license may only be granted in case of public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive; *(96)*

(e) The license shall be non-assignable, except with that part of the enterprise or business with which the invention is being exploited; *(100.3)*

(f) Use of the subject matter of the license shall be devoted predominantly for the supply of the Philippine market: *Provided,* That this limitation shall not apply where the grant of the license is based on the ground that the patentee's manner of exploiting the patent is determined by judicial or administrative process, to be anti-competitive; *(100.4)*

(g) The license may be terminated upon proper showing that the circumstances which led to its grant have ceased to exist and are unlikely to recur: *Provided,* that adequate protection shall be afforded to the legitimate interests of the licensee; *(100.5)*

(h) In case of a compulsory license based on interdependence of patents, the conditions in Section 6 above shall apply. *(97)*

Section 8. Requirement to Obtain License on Reasonable Commercial Terms. The license will only be granted after the petitioner has made efforts to obtain authorization from the patent owner on reasonable commercial terms and conditions but such efforts have not been successful within a reasonable period of time. *(95.1)*

The requirement above shall not apply in any of the following cases:

(a) Where the petition for compulsory license seeks to remedy a practice determined after judicial or administrative process to be anti-competitive;

(b) In situations of national emergency or other circumstances of extreme urgency;

(c) In cases of public non-commercial use; and

(d) In cases where the demand for the patented drugs and medicines in the Philippines is not being met to an adequate extent and on reasonable terms, as determined by the Secretary of the Department of Health. *(95.2)*

Section 9. Notification of Right Holder. In situations of national emergency or other circumstances of extreme urgency, the right holder shall be notified as soon as reasonably practicable. *(95.3)*

Section 10. Public Non-commercial use. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly. *(95.4)*

Section 11. Authority of DOH Secretary. Where the demand for the patented drugs and medicines in the Philippines is not being met to an adequate extent and on reasonable terms, as determined by the Secretary of the Department of Health, the right holder shall be informed promptly. *(95.5)*

Section 12. Anti-competitive Practice. The Director General has the authority to determine if a patentee's manner of exploiting the patent is anti-competitive and there is a need to correct the anti-competitive practice. *(n)*

Section 13. Procedure for Compulsory License. The procedures for Compulsory Licensing are as follows –

(i) Form and Content of Petition. The petition for compulsory licensing must be in writing, verified by the petitioner and accompanied by payment of the required filing fee. It shall contain the name and address of the petitioner as well as those of the respondents, the number and date of issue of the patent in connection with which compulsory license is sought, the name of the patentee, the title of the invention, the statutory grounds upon which compulsory license is sought, the ultimate facts constituting the petitioner's cause of action, and the relief prayed for. The petition shall be accompanied by the affidavits of witnesses and originals of the documents which shall constitute as the evidence of the Petitioner which shall be marked consecutively beginning with Exhibit "A". *(IPP Rules)*

(ii) **Notice to Answer.** Within three (3) working days from receipt of the petition, the BLA shall issue a Notice to Answer for the Respondent to file an Answer together with the Affidavits of the witnesses and originals of documents, and at the same time notify all parties required to be notified in the IP Code and these Rules, provided that in case of public documents, certified true copies may be submitted in lieu thereof. *(IPP Rules)*

(iii) **Filing of Answer.** Within a non-extendible period of thirty (30) days from receipt of the Notice to Answer, the Respondent shall file an Answer together with the Affidavits of its witnesses and other original documents constituting its evidence to be marked consecutively beginning with Exhibit "1". *(IPP Rules)*

(iv) **Filing of Reply and Rejoinder.** The petitioner may file a reply within a non-extendible period of ten (10) days from receipt of the copy of the Answer. On the other hand, the Respondent may file a rejoinder also within a non-extendible period of ten (10) days from receipt of the Reply. *(IPP Rules)*

(v) **Effect of Failure to File an Answer.** In case the Respondent fails to file an Answer or if the Answer is filed out of time, the case shall be decided on the basis of the petition, the affidavits of witnesses and the documentary evidence submitted by the petitioner. *(IPP Rules)*

(vi) **Decision on the Pleadings.** Within fifteen (15) days after the last responsive pleading has been filed, the Director of the BLA may render the decision on the case if the same does not warrant further proceedings. *(IPP Rules)*

(vii) **Preliminary Conference**. A preliminary conference shall be conducted within thirty (30) days from receipt of the last responsive pleading for the following purposes:

(a) Submission of the case for mediation under applicable laws, rules and regulations on mediation;
(b) Possibility of amicable settlement;
(c) Clarification of issues;

The parties themselves are required to appear during the preliminary conference. The presence of a party may be dispensed with if said party is represented by counsel provided with a duly notarized power of attorney and the corporate authorization to make admissions and/or accept and approval compromise proposals.

Immediately after the termination of the preliminary conference, the Director of the BLA shall require the parties to submit their respective position papers and, if so desired, draft decisions within a non-extendible period of ten (10) days from termination thereof. *(IPP Rules)*

(viii) **Submission for Decision.** After the lapse of the reglementary period provided above, the Director of the BLA shall order the case submitted for decision. *(n)*

(ix) Recommendation of the Director of BLA on the Petition for Compulsory Licensing. Within thirty (30) days after the case is submitted for decision, the Director of the BLA shall make the recommendation to the Director General on whether or not to give due course to the petition for compulsory licensing.

The Director General shall review and approve the recommendation of the Director of BLA, and shall have the authority to uphold, in whole or in part, or deny the recommendation on the petition for compulsory license. *(100, n)*

(x) **Publication of Notice to Answer.** In every case, the Director of the BLA shall cause the notice to be published in a newspaper of general circulation once a week for three (3) consecutive weeks and once in the IPO Gazette at the expense of the applicant. *(IPP Rules)*

Section 14. Compulsory License Based on Sections 93.1. and 93.2. of the IP Code. The following procedures shall be observed when the petition for compulsory license is based on any of the following grounds: (a) national emergency or other circumstances of extreme urgency; or (b) where the public interest, in particular, national security, nutrition, health or the development of other vital sectors of the national economy as determined by the appropriate government agency, so requires: *(93.1, 93.2)*

(i) **Form and Contents of Petition.** The petition for compulsory licensing must be in writing, verified by the petitioner and accompanied by payment of the required filing fee. It shall contain the name and address of the petitioner as well as those of the respondents, the number and date of issue of the patent in connection with which compulsory license is sought, the name of the patentee, the title of the invention, the statutory grounds upon which compulsory license is sought, the ultimate facts constituting the petitioner's cause of action, and the relief prayed for. The petition shall be accompanied by the affidavits of witnesses and originals of the documents which shall constitute as the evidence of the Petitioner which shall be marked consecutively beginning with Exhibit "A". *(IPP Rules)*

(ii) **Notice to Answer.** Within three (3) working days from receipt of the petition, the BLA shall issue a Notice to Answer for the Respondent to file an Answer together with the Affidavits of the witnesses and originals of documents, and at the same time notify all parties required to be notified in the IP Code and these Regulations, provided that in case of public documents, certified true copies may be submitted in lieu thereof. *(n)*

(iii) **Filing of Answer.** Within a non-extendible period of ten (10) working days from receipt of the Notice to Answer, the Respondent shall file an Answer together with the Affidavits of its witnesses and other original documents constituting its evidence to be marked consecutively beginning with Exhibit "1". *(n)*

(iv) **Effect of Failure to File an Answer.** If the Respondent fails to file an Answer or if the Answer is filed out of time, the case shall be decided on the basis of the petition, the affidavits of witnesses and the documentary evidence submitted by the petitioner. *(IPP Rules)*

(v) **Prohibited Pleadings and Procedures.** No reply, rejoinder, motion and other pleadings shall be allowed. There shall be no preliminary conference and no requirement of publication of the Notice to Answer. *(n)*

(vi) **Submission for Decision.** The petition is deemed submitted for decision upon the filing of the Answer within the allowed period, or upon the lapse of the period to file the Answer. *(n)*

(vii) **Recommendation and Decision on the Petition.** Within fifteen (15) days after the case is deemed submitted for decision, the Director of the BLA shall make the recommendation to the Director General on whether or not to give due course to the petition for compulsory licensing. The Director General shall review and approve the recommendation of the Director of BLA, and shall have the authority to uphold, in whole or in part, or deny the recommendation on the petition for compulsory license. *(100, n)*

Section 15. Amendment of Compulsory License. Upon the request of the patentee or the licensee, the Director General may amend the decision granting the compulsory license, upon proper showing of new facts or circumstances justifying such amendment. *(101)*

Section 16. Appeal and Review by the Competent Courts. All appeals and review of the decision of the Director General to grant a compulsory license shall be filed in accordance with the procedures under the Rules of Court. *(n)*

Rule 13. Special Compulsory Licensing.

Section 1. Coverage. Special Compulsory Licensing shall only be available for drugs and medicines. *(n)*

Section 2. Procedure. The Director General of the IPO, upon the written recommendation of the Secretary of the Department of Health, shall, upon filing of a petition, grant a special compulsory license for the importation of patented drugs and medicines. The special compulsory license for the importation contemplated under this provision shall be an additional special alternative procedure to ensure access to quality affordable medicines and shall be primarily for domestic consumption:

Provided, that adequate remuneration shall be paid to the patent owner either by the exporting or importing country. The compulsory license shall also contain a provision directing the grantee the license to exercise reasonable measures to prevent the re-exportation of the products imported under this provision.

The grant of a special compulsory license under this provision shall be an exception to Sections 100.4 and 100.6 of the IP Code and shall be immediately executory.

No court, except the Supreme Court of the Philippines, shall issue any temporary restraining order or preliminary injunction or such other provisional remedies that will prevent the grant of the special compulsory license. *(93-A.1)*

Section 3. Special Compulsory License for Manufacture and Export. A compulsory license shall also be available for the manufacture and export of drugs and medicines to any country having insufficient or no manufacturing capacity in the pharmaceutical sector to address public health problems: *Provided,* that, a compulsory license has been granted by such country or such country has, by notification or otherwise, allowed importation into its jurisdiction of the patented drugs and medicines from the Philippines in compliance with the TRIPS Agreement. *(93-A.2)*

Section 4. Flexibilities. The right to grant a special compulsory license under this section shall not limit or prejudice the rights, obligations and flexibilities provided under the TRIPS Agreement and under Philippine laws, particularly Section 72.1 and Section 74 of the IP Code, as amended under this Act. It is also without prejudice to the extent to which drugs and medicines produced under a compulsory license can be exported as allowed in the TRIPS Agreement and applicable laws. *(93-A.3)*

Section 5. Suppletory Application of the Procedures under the TRIPS Protocol. The following procedure outlined under the Annex to the Protocol Amending the TRIPS Agreement (ref: WT/L/641) shall be suppletory to the procedure for the granting of a Special Compulsory License under the IP Code. The Annex is also referred to in this Rule as Article 31bis. The Protocol is hereby attached to these IRR as Annex "A."

Rule 14. Rights Conferred.

Section 1. Exception to the Rights of Registered Trademark Owners. Except in the cases of importation of drugs and medicines allowed under Section 72.1 of the IP Code and of off-patent drugs and medicines, the owner of a registered mark shall have the exclusive right to prevent all third parties not having the owner's consent from using in the course of trade identical or similar signs or containers for goods or services which are identical or similar to those in respect of which the trademark is registered where such use would result in a likelihood of confusion. In case of the use of an identical sign for identical goods or services, a likelihood of confusion shall be presumed. *(147.1)*

There shall be no infringement of trademarks or tradenames of imported or sold patented drugs and medicines allowed under Section 72.1 of the IP Code, as well as imported or sold off-patent drugs and medicines: *Provided,* that, said drugs and medicines bear the registered marks that have not been tampered, unlawfully modified, or infringed upon, under Section 155 of the IP Code. *(147.1)*

Section 2. Well-Known Marks. The exclusive right of the owner of a well-known mark defined in Subsection 123.1(e) of the IP Code which is registered in the Philippines, shall extend to goods and services which are not similar to those in respect of which the mark is registered: *Provided,* that use of that mark in relation to those goods or services would indicate a connection between those goods or services and the owner of the registered mark: *Provided, further,* that the interests of the owner of the registered mark are likely to be damaged by such use. *(147.2)*

Rule 15. Limitations to Actions for Infringement.

Section 1. Limitations. Notwithstanding any other provision of these Rules, the remedies given to the owner of a right infringed under this Rules shall be limited as follows: *(159)*

(i) **Use of a Mark in Good Faith.** Notwithstanding the provisions of Section 155 of the IP Code, a registered mark shall have no effect against any person who, in good faith, before the filing date or the priority date, was using the mark for the purposes of his business or enterprise: *Provided,* that his right may only be transferred or assigned together with his enterprise or business or with that part of his enterprise or business in which the mark is used. *(159.1)*

(ii) **Innocent Infringer.** Where an infringer who is engaged solely in the business of printing the mark or other infringing materials for others is an innocent infringer, the owner of the right infringed shall be entitled as against such infringer only to an injunction against future printing. *(159.2)*

(iii) Advertisement or other similar communication. Where the infringement complained of is contained in or is part of paid advertisement in a newspaper, magazine, or other similar periodical or in an electronic communication, the remedies of the owner of the right infringed as against the publisher or distributor of such newspaper, magazine, or other similar periodical or electronic communication shall be limited to an injunction against the presentation of such advertising matter in future issues of such newspapers, magazines, or other similar periodicals or in future transmissions of such electronic communications. The limitations of this subparagraph shall apply only to innocent infringers: *Provided,* that such injunctive relief shall not be available to the owner of the right infringed with respect to an issue of a newspaper, magazine, or other similar periodical or an electronic communication containing infringing matter where restraining the dissemination of such infringing matter in any particular issue of such periodical or in an electronic communication would delay the delivery of such issue or transmission of such electronic communication is customarily conducted in accordance with the sound business practice, and not due to any method or device adopted to evade this section or to prevent or delay the issuance of an injunction or restraining order with respect to such infringing matter. *(159.3)*

(iv) **Importation of Patented and Off-Patent Drugs and Medicines.** There shall be no infringement of trademarks or tradenames of imported or sold drugs and medicines allowed under Section 72.1 of the IP Code, as well as imported or sold off-patent drugs and medicines: *Provided,* that said drugs and medicines bear the registered marks that have not been tampered, unlawfully modified, or infringed upon as defined under Section 155 of the IP Code. *(159.4)*

CHAPTER III
PARALLEL IMPORTATION

Rule 16. General Provisions.

Section 1. Centralized Importation for Government. Except for specific programs and instances allowed by DOH, for purposes of ascertaining the best and most affordable prices and quality of drugs and medicines to be imported, all government agencies must centrally procure through PPI. *(n)*

Section 2. Sourcing of Medicines from Reputable and Reliable Suppliers. Private parties may course through PPI, to avail of its facility for undertaking procurement, sourcing and marketing of quality essential and low priced medicines through drug importations and sourcing of medicines from reputable and reliable suppliers and ensuring the widest distribution of these medicines nationwide as determined with BFAD. *(n)*

Section 3. Requirements for Every Incoming Shipment of Drugs and Medicines. The BFAD in coordination with the Bureau of Customs, Bureau of Quarantine and other concerned agencies is mandated to undertake and adopt measures relating to sampling and examination in accordance with relevant existing laws and regulations of every incoming shipment of drugs and medicines. *(n)*

Rule 17. Non-Discriminatory Clause.

Section 1. General Rule. It shall be unlawful for any retail drug outlet to refuse to carry either by sale or by consignment, or offer for sale drugs and medicines brought into the country, as allowed under Section 7 of the Act, by the government or authorized third party which has been previously approved for distribution or sale by the BFAD. For this purpose, the said products shall be displayed with equal prominence as all other products sold in the establishment. *(33)*

Section 2. Patented Drugs. This rule shall apply only to importation of patented drugs and medicines made by the government or any authorized third party. *(7)*

Section 3. Permit to Import and Distribute. All interested parties must, in addition to existing requirements, secure a license/permit to import and to distribute such drugs from the BFAD. *(n)*

Section 4. Requirements for Request for Mandatory Carry. Such parties shall submit the following information: a) volume to be procured, b) purchase prices, c) shelf life of products, d) area of distribution, and e) other specific information/conditions, as may be required by the BFAD. *(n)*

Section 5. Mandatory Carry. Imported drugs to be carried by retail outlets shall be based on the reported health needs of a community. A mechanism that will determine the carrying capacity and demands for parallel imports at the level of retailers shall be established so that demands for drugs to be covered will match their carrying capacity. After proper determination by BFAD, the concerned LGUs shall ensure that retail outlets in the area of distribution shall carry said patented drugs. *(n)*

Section 6. Refusal to Sell Drugs and Medicines. No manufacturer, importer, trader, distributor, wholesaler shall withhold from sale or refuse to sell to a wholesaler or retailer any drug or medicine without good and sufficient reasons Good and sufficient reasons may include fortuitous events or force majeure, acts of God and other analogous cases as may be determined by BFAD. *(34, n)*

CHAPTER IV
POWERS OF THE SECRETARY OF HEALTH

Rule 18. Inclusion Drugs and Medicines in the List Subject to Price Regulation. Upon application or motu propio when the public interest so requires and after proper determination, the Secretary of Health may order the inclusion of drugs and medicines to the list subject of price regulation under Section 23 of the Act. *(19B)*

Rule 19. Determination of Maximum Retail Prices of Drugs and Medicines. Upon application or motu propio when the public interest so requires, the Secretary of Health shall have the power to determine the MRP of drugs and medicines which shall be recommended to the President of the Philippines for approval. *(19A1)*

Rule 20. Implementation of Fair Price of Drugs and Medicine. The Secretary of Health shall have the power to implement the fair price of drugs and medicines for purposes of public health insurance and government procurement based on the order of the President of the Philippines imposing MRP. *(19C1)*

Rule 21. Implementation of Cost Containment Measures. The Secretary of Health shall have the power to implement any other measures that the government may avail of to effectively reduce the cost of drugs and medicines, such as, but not limited to, competitive bidding, price volume negotiations, and other appropriate mechanisms that influence supply, demand and expenditures on drugs and medicines. *(19C2)*

Rule 22. Imposition of Administrative Fines and Penalties. After due notice and hearing, the Secretary of Health shall have the power to impose administrative fines against any person, manufacturer, importer, trader, distributor, wholesaler, retailer, or any other entity, in such amount as it may deem reasonable, which in no case shall be less than Fifty thousand pesos (Php 50,000.00) nor more than Five million pesos (Php 5,000,000.00) for violations of the MRP approved by the President of the Philippines. *(19D)*

Rule 23. Deputization of Government Entities. The Secretary of Health shall have the power to call upon and deputize any official, agent, employee, agency, or instrumentality of the national and local government for any assistance that he may deem necessary to carry out the purposes of the rules on drugs and medicines price regulation. *(19E)*

Rule 24. Inquiries, Studies, Hearings, Investigations, and Proceedings. All inquiries, studies, hearings, investigations and proceedings conducted by the Secretary of Health shall be governed by the rules adopted by him, and in the conduct thereof shall not be bound by the technical rules of evidence. *(20)*

Rule 25. Other Powers Necessary to Implement this Act. The Secretary of Health shall exercise such powers and functions as may be necessary to implement and enforce price regulation of drugs and medicines including the power to require the production and submission of records, documents, books of account, bills of lading, input documents, records of purchase and sale, financial statements, and such other documents, information and papers as may be deemed as necessary, to enable him to carry out his functions, duties, and responsibilities. *(19F)*

CHAPTER V
PRICE MONITORING AND REGULATION SYSTEM AND THE CREATION OF ADVISORY BODIES AND CONSULTATIVE COUNCILS

Rule 26. Establishment of Price Monitoring for Drug Regulation Price System. To implement the policies of this Act, the Secretary of Health shall establish and initiate an electronic price monitoring and regulation system for drugs and medicines. *(18, n)*

Rule 27. Creation of Institutional Office to Implement the Price Regulation. In implementing the price monitoring and regulation system, a policy and operational office shall be established directly under the authority of the Secretary of Health. This institutional office shall be adequately provided with the requisite personnel complement, budgetary support, and where necessary, sufficient capital outlay. *(n)*

Section 1. Powers and Functions of the Institutional Office. The institutional office shall have the following powers, among others: *(n)*

(a) Manage and implement the National Drug Policy. *(n)*

(b) Undertake policy studies and make appropriate recommendations to contribute to improved access to drugs and medicines; *(n)*

(c) Engage and coordinate with relevant stakeholders to build coalitions, forge agreements and for other purposes as necessary. *(n)*

(d) Provide Secretariat support to any Council or body created in pursuit of the effective implementation of the Act. *(n)*

(e) Shall be involved in the processing, coordinating, generating and analyzing inter-agency price monitoring reports from the DTI and local government units. *(n)*

(f) Such other functions as maybe incidental to the above or as may be directed by the Secretary of Health. *(n)*

Section 2. Role of Private Sector and NGOs. In pursuit of a comprehensive and effective price monitoring and regulation system, the Secretary of Health shall seek the assistance of representatives from non-governmental organizations, civil societies, and other proponents of the private sector to help monitor, advocate, or report violations of the provisions of these implementing rules. *(n)*

Rule 28. Creation of Advisory Bodies and Consultative Councils. The Secretary of Health may create such bodies and consultative councils, from which advice may be sought in the implemen-

tation of a drug or medicine price monitoring and regulation policy. Such bodies or consultative councils shall coordinate their efforts together with other government agencies including but not limited to DTI, BIR, BFAD, PITC, and PhilHealth. *(18, n)*

Section 1. Composition of Advisory Bodies and Consultative Councils. The composition of such advisory bodies and councils shall include representatives from various stakeholders both from government and private sectors, as may be determined by the Secretary of Health. *(n)*

Rule 29. Conflict of Interest. Any person, institution, and/or organization identified by the Secretary of Health to form part of the advisory council and bodies or any part of the drugs and medicines price monitoring system shall declare any and all conflict of interests through an appropriate instrument as shall be issued by the DOH in accordance with existing laws, rules and regulations. *(n)*

CHAPTER VI
MAXIMUM RETAIL PRICE (MRP)

Rule 30. General Provisions.

Section 1. Power of the President to Impose MRP. The President of the Philippines, upon recommendation of the Secretary of Health, shall have the power to impose MRP over any or all drugs and medicines. *(17)*

Section 2. Duration on Imposing MRP. The power to impose MRP over drugs and medicines shall be exercised within such period of time as the situation may warrant as determined by the President of the Philippines. *(17)*

Section 3. Coverage of MRP. The MRP shall be construed as the imposition of maximum prices at all levels of the supply chains including but not limited to manufacturer's price, trader's price, distributor's price and wholesaler's price, and retailer's price. *(19A, 19F, 26a).*

Section 4. Senior Citizens Discounts and Discounts for People with Disabilities. For drugs and medicines with MRPs, Senior Citizen's discounts and discounts for people with disabilities shall continue to be honored. *(n)*

Section 5. List of Drugs and Medicines that are Subject to Price Regulation. The list of drugs and medicines that are subject to price regulation shall include, inter alia:

(a) Drugs and medicines that are included in the current edition of the Philippine National Drug Formulary (PNDF) Essential Drugs List;

(b) All drugs and medicines indicated for treatment of chronic illnesses and life threatening conditions, such as, but not limited to, endocrine disorders, e.g., diabetes mellitus; gastrointestinal disorders, e.g., peptic ulcer; urologic disorders, e.g., benign prostatic hyperplasia (BPH); cardiovascular diseases, e.g., hypertension; pulmonary diseases, e.g., pulmonary tuberculosis (PTB), asthma; auto-immune diseases, e.g., systemic lupus erythematosus (SLE); skin diseases, e.g., psoriasis; neuro-psychiatric disorders; other infectious diseases, e.g., human immunodeficiency virus-acquired immune deficiency syndrome (HIV-AIDS); and other conditions such as organ transplants and neoplasm;

(c) Drugs and medicines indicated for prevention of diseases, e.g., vaccines, immunoglobulin, anti-sera;

(d) Drugs and medicines indicated for prevention of pregnancy, e.g., oral contraceptives;

(e) Anesthetic agents;

(f) Intravenous fluids; and

(g) All other drugs and medicines which, from time to time, the Secretary of Health, in accordance with the relevant provisions of these Implementing Rules and Regulations, determines to be in need of price regulation. *(23)*

Section 6. Order of Priority. The Secretary of Health shall determine the prioritization of the drugs and medicines subject to MRP. *(n)*

Section 7. Factors to Consider in Recommending the MRP. In recommending the maximum retail price, the Secretary of Health shall consider the following factors:

(a) Retail prices of drugs and medicines that are subject to regulation in the Philippines and in other countries;

(b) Supply available in the market;

(c) Cost to the manufacturer, importer, trader, distributor, wholesaler or retailer such as but not limited to:

  (i) The exchange rate of the peso to the foreign currency with which the drug or any of its component, ingredient or raw material was paid for;
  (ii) Any change in the amortization cost of machinery brought about by any change in the exchange rate of the peso to the foreign currency with which the machinery was bought through credit facilities;
  (iii) Any change in the cost of labor brought about by a change in minimum wage; or
  (iv) Any change in the cost of transporting or distributing the medicines to the area of destination. *(19A2)*

(d) In addition to the immediately preceding section, other such factors or conditions that may aid in arriving at a just and reasonable determination of the MRP shall include:

  (i) Marketing Costs (per drug and total global costs);
  (ii) Research Costs (local and global/ per drug);
  (iii) Promotion Costs;
  (iv) Advertising Costs;
  (v) Incentives and Discounts;
  (vi) Taxes and other fees, impost, duties, and other charges imposed by competent authority; and
  (vii) Other analogous cases *(n)*

Section 8. Publication of MRP. In order that affordable prices of drugs and medicines from the different manufacturers, importers, traders, distributors, wholesalers, or retailers shall be made

available to the public, shall have such approved MRP of drugs and medicines published in papers of general circulation and shall also be posted in the internet. *(19A1, n)*

Section 9. Prohibition Against Exceeding the MRP. Upon effectivity of the MRP, no retailer shall sell drugs and medicines at a retail price exceeding the MRP approved by the President of the Philippines. *(19A3)*

Rule 31. Labeling and Publication.

Section 1. Labeling Requirements of Drugs and Medicines Subject to Price Regulation. Within a reasonable period as may be determined by the Secretary of Health, and provided, that it conforms to existing drug product labeling requirements, every manufacturer, importer, distributor, wholesaler, trader, or retailer of a drug and medicine intended for sale shall display the retail price which shall not exceed the MRP approved by order of the President of the Philippines. The MRP shall be printed on the label of the immediate container of the drug and medicine and the minimum pack thereof offered for retail sale with the words "**RETAIL PRICE NOT TO EXCEED**" preceding it, and "**UNDER DRUG PRICE REGULATION**" on a red strip. *(26)*

Section 2. Issuance of Price List. Within a period as may be determined by the Secretary of Health from time to time, every manufacturer, importer, or trader shall issue a price list to wholesalers, distributors, retailers and to the Secretary of Health, indicating the retail price, the MRP, and such other information as may be required by the Secretary of Health. *(26b)*

In issuing the retail price, the importers, manufacturers, and traders shall notify the wholesalers, distributors, retailers, and the Secretary of Health whenever there are changes in their prices. *(n)*

Section 3. Publication of the Order of the President on MRP. The order of the President of the Philippines imposing MRP on drugs and medicines, including the conditions implementing it, shall be published within fifteen (15) days from issuance in at least two newspapers of general circulation. All wholesalers, manufacturers, distributors, importers, or traders shall have a copy of the order of the President of the Philippines and provide the same to their clients and customers that transact with them. *(30c)*

Section 4. Posting of MRP. All drug outlets are required to post in a conspicuous area within their premises a clear copy of the MRP order. They shall always maintain a copy of the said order to be easily accessible and readable to the consuming public and shall update it regularly as the situation may warrant. *(30d)*

Rule 32. Prohibition against Injunction. No court, except the Supreme Court of the Philippines, shall issue any temporary restraining order or preliminary injunction or preliminary mandatory injunction that will prevent the immediate execution of the exercise of the power of the President of the Philippines to impose MRP. *(17)*

Rule 33. Procedure and Decision Systems on Drugs and Medicine Price Regulation Proceedings.

Section 1. Power to Conduct Inquiries, Studies, Hearings, Investigations, and Proceedings. Pursuant to Section 7 of the Act, of the Powers of the Secretary of Health and

principles of administrative due process, he may conduct inquiries, studies, hearings, investigations and proceedings as he may deem appropriate in implementing the Law. *(20)*

Section 2. Effectivity of the Decisions or Orders of the Secretary of Health. All decisions or orders of the Secretary of Health pursuant to the Powers of the Secretary, particularly: (A) Power to Recommend the Maximum Retail Price of Drugs and Medicines Subject to Price Regulation, (B) Power to Include Other Drugs and Medicines in the List Subject to Price Regulation, (C) Power to Implement Cost-Containment and Other Measures, (D) Power to Impose Administrative Fines and Penalties, (E) Power to Deputize Government Entities, or (F) Other Powers Necessary to Implement Provisions of this Chapter, shall take effect immediately. *(21)*

Section 3. Review of the Decisions or Orders of the Secretary of Health. A party adversely affected by a decision, order or ruling of the Secretary of Health may, within thirty (30) days from notice of such decision, order or ruling, or in case of a denial of a motion for reconsideration thereof, within fifteen (15) days after notice of such denial, file an appeal with the Court of Appeals, which shall have jurisdiction to review such decision, order or ruling.

The filing of a petition for a writ of certiorari or other special remedies in the Supreme Court shall in no case supersede or retain any decision, order or ruling of the Secretary of Health, unless the Supreme Court shall so direct, and the petitioner may be required by the Supreme Court to give bond in such form and of such amount as may be deemed proper. *(22)*

CHAPTER VII
COST CONTAINMENT MEASURES

Rule 34. PhilHealth Actions. It is one of the objectives of the Act to reduce, if not, eliminate out-of-pocket expenses on the part of the patients who should be the primary beneficiaries of social health welfare. Henceforth, notwithstanding provisions to the contrary, the Secretary of Health shall require the Philippine Health Insurance Corporation (PHIC) to implement the following measures in support of the fair prices of drugs and medicines to ensure availability, affordability, and accessibility: *(19C1)*

(a) Intensify and accelerate the Outpatient Drug Benefit Packages,

(b) Accreditation of all health-related units such as hospital pharmacies, commercial pharmacies, and other DOH recognized drug outlets,

(c) Imposition of penalties through a penalty structure for erring accredited professionals that would not prescribe quality, generic medicine within the MRP or PhilHealth List for reimbursements,

(d) Reimbursements must be based on the current edition of the PNDF and limited to drug products covered by prescriptions containing the corresponding generic names of the drug products,

(e) Drug products that may be covered by the reimbursements shall be purchased only from hospital pharmacies. In case of unavailability of drug products in the hospital pharmacies, reimbursements may be made directly to the patients but shall be charged to the reim-

bursements earmarked for the hospital or the medical doctor for the same service provided,

(f) Reimbursement of drug products and services related to rational, quality drug access including, but not limited to, setting fixed reimbursement prices/drug price reference index to selected drugs and medicines,

(g) Rational reimbursement of health facilities and health professional that principally provide health services to the poor, and

(h) Any other measures as may be determined by the Secretary of Health that will benefit patients and rationalize and ensure availability, affordability, and accessibility to quality drugs and medicines. *(n)*

Rule 35. Consignment. Rules governing consignment shall follow appropriate DOH Guidelines as outlined under AO 145 series of 2005. *(n)*

Rule 36. Government Procurement. All government agencies, including local government units, shall procure drugs and medicines within the Philippine National Drug Formulary current edition in accordance with Republic Act No. 9184 and any other pertinent procurement reforms. *(n)*

Rule 37. Philippine National Drug Formulary System. In pursuit of efficiency and cost-affectivity in the procurement and reimbursement of essential medicines, and as a critical cost containment measure, the Secretary of Health shall set-up an improved Philippine National Drug Formulary System and endeavor to have this updated on a regular quarterly basis. Corollary to this, for drugs and medicines perceived to be necessary and essential for specific cases and circumstances but are not listed in the PNDF; a system shall be put in place to allow the facilitated review of specific drugs and medicines for such special cases upon request. The request should mention the reasons why a certain drug should be listed, procured, and reimbursed by PhilHealth. If such request has not been acted upon within forty five (45) calendar days, then the request is deemed approved only for that particular purpose stated and only for that specific transaction. Such approval shall be valid for a year or until decided with finality by the Secretary of Health. *(n)*

Rule 38. Power to Implement other Cost Containment Measures. The Secretary of Health shall have the power to implement any other measures that the government may avail of to effectively reduce the cost of drugs and medicines that shall include, but not limited to, competitive bidding, price volume negotiations, consignment and other appropriate mechanisms that influence supply, demand and expenditures on drugs and medicines. *(19C2, n)*

In particular, the following cost containment measures shall be adopted and followed by the government agencies:

(1) All government agencies, including local government units, shall ensure transparency on the procurement of the drugs and medicines, including the prices and inventory,

(2) All government agencies, including local government units, shall procure their drugs and medicines requirement from suppliers which are registered with the Department of Health,

(3) A common procurement ordering facility shall be established by the DOH to ensure economies of scale, when appropriate,

(4) A common essential drug list requirement of all government agencies, including local government units, based on the PNDF current edition shall be prepared by the DOH for purposes of undertaking competitive pooled procurement and price volume negotiation, and

(5) Consignment procedures shall comply with DOH rules and regulations. *(n)*

Rule 39. Rationalization of Marketing Practice. Subject to existing laws on consumer protection, as a cost containment measure, the Secretary of Health may promulgate policies and directives that would rationalize promotional and marketing practices, such as scientific and product information dissemination and advocacy activities when appropriate. *(n)*

Rule 40. Prohibited Promotions by Medical and Para- or Allied Medical Practitioners. No medical practitioner or health worker shall promote, advertise or endorse any drugs and medicines in quad media, in print or visual display. *(n)*

CHAPTER VIII
ILLEGAL ACTS OF PRICE MANIPULATIONS

Rule 41. Coverage. This Rule only covers the drugs and medicines enumerated under Section 23 of the Act, of whatever brand or generic name, the sale of which to the general public has been previously approved by the BFAD for which a Certificate of Product Registration was previously issued by the BFAD. *(n)*

Rule 42. Illegal Acts of Price Manipulation.

Section 1. Illegal Acts of Price Manipulation. Without prejudice to the provisions of existing laws on goods not covered by the Act, it shall be unlawful for any manufacturer, importer, trader, distributor, wholesaler, retailer, or any person engaged in acts of price manipulation such as hoarding, profiteering, or illegal combination or forming cartel, as defined under Section 5 of Republic Act No. 7581, otherwise known as the Price Act, and all other acts committed in restraint of trade. *(24)*

Section 2. Hoarding.

(i) Definition. The following shall constitute hoarding:

a. The undue accumulation by a person or combination of persons of any drug or medicine beyond his/their normal inventory level; or
b. The unreasonable limitation or refusal to dispose, sell or distribute said drug or medicine; or
c. The unjustifiable taking out of said drug or medicine from the channels of production, trade, commerce and industry. *(n)*

(ii) Prima Facie Evidence of Hoarding. The following shall constitute *prima facie* evidence of hoarding:

a. When a person has stocks of any drug or medicine fifty percent (50%) higher than his usual inventory, and
b. Unreasonably limits, refuses or fails to sell the same to the general public at the time of discovery of the stocks.

A person's usual inventory shall be reckoned from the third month immediately preceding before the discovery of the stocks in case the person has already been engaged in the business for at least three (3) months; otherwise, it shall be reckoned from the time he started his business. *(n)*

Section 3. Profiteering.

(i) Definition. Profiteering is the sale or offering for sale of any drug or medicine at a price grossly in excess of its true worth. *(n)*

(ii) Prima Facie Evidence of Profiteering. There shall be *prima facie* evidence of profiteering whenever a drug or medicine being sold:
a. Has no price tag; or
b. Is misrepresented as to its weight or measurement; or
c. Is adulterated or diluted; or
d. Whenever a person raises the price of said drug or medicine which he sells or offers for sale to the general public by more than ten percent (10%) of its price in the immediately preceding month. *(n)*

Section 4. Cartel.

(i) Definition. Refers to any combination of, or agreement between, two or more persons engaged in the production, manufacturing, processing, storage, supply, distribution, marketing, sale or disposition of any drug or medicine designed to artificially and unreasonably increase or manipulate its price.

(ii) Prima Facie Evidence of Engaging in a Cartel. There shall be *prima facie* evidence of engaging in a cartel whenever two (2) or more persons or business enterprises competing for the same market and dealing in the same drugs or medicines that are pharmaceutical equivalents, commit any of the following:
a. Perform uniform or complementary acts among themselves which tend to bring about artificial and unreasonable increase in the price of any drug or medicine that are pharmaceutical equivalents; or
b. Simultaneously and unreasonably increase prices on their competing products that are pharmaceutical equivalents thereby lessening competition among them. *(n)*

CHAPTER IX
GENERICS LAW

Rule 43. Posting and Publication. The DOH shall publish annually in acceptable means of public dissemination such as posting in its official websites, or in at least two (2) newspapers of general circulation, the generic names and the corresponding brand names under which they are marketed, of all drugs and medicines available in the Philippines. *(37, n)*

Rule 44. Who Shall Use Generic Terminology.

(a) Government – All government health agencies and their personnel as well as other government agencies, including government owned and controlled corporations shall use generic names in all transactions related to purchasing, prescribing, dispensing, reimbursing and administering of drugs and medicines. *(38a, n)*

(b) Private – All private medical, dental and veterinary practitioners shall prescribe using the generic name. The brand name may be included, if so desired. *(38b, n)*

(c) Health workers in government and all employed by the government practicing or working in private institutions shall use generic terminology only all transactions related to purchasing, prescribing, dispensing, reimbursing and administering of drugs and medicines such as but not limited to:

1. All those employed by government, whether full or part time, while in government facilities.
2. Medical and other Consultants, whether for free or otherwise working in government institutions/facilities
3. Medical Doctors having private practice in government facilities,
4. And all other government public health workers. *(n)*

(d) Any organization or company involved in the manufacture, importation, repacking, marketing and/or distribution of drugs and medicines shall indicate prominently the generic name of the product. In the case of branded products, the generic name shall appear prominently and immediately above the brand name in all product labels as well as in advertising and other promotional materials. *(38c)*

(e) Drug outlets, including drugstores, hospital and non-hospital pharmacies and non-traditional outlets such as supermarkets, convenience stores and other retail establishments, shall inform any buyer about any and all other drug products having the same generic name, together with their corresponding prices so that the buyer may adequately be informed to exercise his option. *(38d, n)*

(f) Consumer empowerment – Consumers shall have the right to demand for information on all generic equivalents available. All drug outlets are obligated to provide their clients all generic equivalents offered for sale in their establishment. *(n)*

(g) The drug outlets referred to herein shall post in conspicuous places as determined by the BFAD in their establishments a list of drug products with the same generic names and their corresponding prices and shall form part of the licensing requirements for such outlets. (38d, n) Posting of information shall be through, but not limited to, the following: hard copies, printed materials, or through programmed computers accessible to the public. *(n)*

(h) All government auditors shall disallow in audit claims/disbursements, either from regular budget, and/or trust funds, covering the procurement by any mode, of drugs and medicines which are not within the PNDF current edition or in generic names only. *(EO49)*

Rule 45. Additional Statement on the Generic Label. There shall appear prominently on the label of a generic drug the following statement: "THIS PRODUCT HAS THE SAME THERAPEUTIC EFFICACY AS ANY OTHER GENERIC PRODUCT OF THE SAME NAME. SIGNED: BFAD" or, in the alternative "THIS PRODUCT HAS THE SAME THERAPEUTIC EFFICACY AS THE INNOVATOR PRODUCT OF THE SAME GENERIC NAME." at the option of BFAD.

Rule 46. Required Production. Subject to the rules and regulations promulgated by the Secretary of Health, every drug manufacturing company operating in the Philippines shall be required to produce, distribute and make widely available to the general public an unbranded generic counterpart of their branded product. *(39)*

In the event that an essential drug becomes off-patent in the Philippines and there are no generic versions applied for or registered with the BFAD, or sold commercially in the Philippines, the Secretary of Health shall require such manufacturing companies to manufacture or cause to manufacture generic counterparts. *(n)*

Priority shall be given to essential drugs listed in the PNDF where the unmet needs for these products have not been served. Such shall include, but shall not be limited to, drugs for priority government programs, endemic conditions and other drugs and medicines as may be determined by the DOH. Regulatory and other incentives may be given for compliant manufacturers. *(n)*

Rule 47. Education Drive. The DOH jointly with the Philippine Information Agency and the Department of Interior and Local Government and in coordination with Non-Governmental Organizations shall conduct a continuous information and education campaign for the public. The Commission on Higher Education and the Department of Education, in coordination with DOH, shall conduct training for the medical and allied medical professions on drugs with generic names as an alternative of equal efficacy to the more expensive branded drugs. *(40, n)*

Rule 48. Content of Information and Education Drive. Such educational campaign shall include information on the illnesses or symptoms which each generically named drug is supposed to cure or alleviate, as well as its contraindications. *(40, n)*

Rule 49. Curriculum Update. The DOH shall collaborate with the Commission on Higher Education and the Professional Regulations Commission, in order to update the curriculum on Pharmacy, Medical and Allied Professions Education. *(n)*

CHAPTER X
PHARMACY LAW

Rule 50. Sale of Prescription Medicines, PharmaceutIcals, Drugs and Devices. No medicine, pharmaceutical, or drug, except for those which are non-prescription or over the counter, of whatever nature and kind or device shall be compounded, dispensed, sold or resold, or otherwise be made available to the consuming public except through a prescription drugstore or hospital pharmacy, duly established in accordance with the provisions of this Act. *(43, n)*

Rule 51. Packaging of Over-the-Counter Drugs. Non-prescription or over-the-counter drugs may be sold in their original packages, bottles and containers to the consuming public through super-

markets, convenience stores and other retail establishments. Only solid dosage forms with individual original and primary packaging as, approved by BFAD, like blisters packs, foils packs, and other similar individual packaging, may be sold in smaller quantities. No other repackaging shall be allowed. Any new packaging shall require BFAD approval. BFAD shall issue appropriate guidelines on proper packaging of OTC drugs. *(43, n)*

Rule 52. Sale of Over-the-Counter Pharmaceutical Products in Non-traditional Outlets. Pharmaceutical, drug or biological manufacturing establishments, importers and wholesalers of drugs, medicines, or biological products shall not sell their products for re-sale except to retail drug outlets, hospital pharmacies or other drug wholesalers under the supervision of a registered pharmacist, and supermarkets, convenience stores, other retail establishments only for over-the-counter drugs, duly licensed by the BFAD. *(43)*

Rule 53. Single Drug Classification. In order to promote rational drug use, any drugs and medicines in prepared multiple dosage strength shall only be under one classification as determined by BFAD. *(n)*

Rule 54. Licensing of Non-traditional Outlets. The BFAD shall issue the appropriate implementing guidelines for the requirements in licensing non-traditional outlets and similar establishments. To ensure public safety, the requirements for License to Operate (LTO) for non-traditional outlets shall include BFAD training/seminar on OTC medicines on procurement, proper storage and handling, safety and quality for outlet personnel as well as having a supervising pharmacist. *(n)*

Rule 55. Botika ng Barangay. Botika ng Barangays (BnBs) are drug outlets with special licenses to operate issued in compliance with the DOH and BFAD guidelines that serve to improve access to essential drugs and the general healthcare of the population, especially the poor. In support of this intent, BnBs shall be allowed to carry a selected list of prescription, over-the-counter, and other such drugs and medicines as deemed necessary to address the pressing health needs of an area. The DOH shall issue in a separate document the approved list of drugs and medicines that may be carried by BnBs. The list should be reviewed regularly and amended as necessary. BnBs shall be manned by DOH-BFAD trained operators and shall have a supervising pharmacist. *(n)*

CHAPTER XI
POWER TO DEPUTIZE GOVERNMENT ENTITIES

Rule 56. Power to Deputize Government Entities. The Secretary of Health shall have the power to call upon and deputize any official, agent, employee, agency, or instrumentality of the national and local government for any assistance that it may deem necessary to carry out the purposes of the rules on drugs and medicines price regulation. *(19E)*

Rule 57. Deputizing Health Attaches/Philippine Missions. The Secretary of Health may appoint or designate health attaches for detection of international drug prices for monitoring. *(n)*

In the absence of health attaches, the Secretary of Health may seek the assistance of Philippine Missions abroad or their attached agencies, thru their respective Department or Agency heads, to accomplish the objectives of the Act. *(n)*

Rule 58. Authorizing the PPI. The PPI or its equivalent agency is hereby authorized to establish a common facility for pooled procurement in compliance with RA 9184. *(n)*

Rule 59. Deputizing the Bureau of Customs (BOC), Securities and Exchange Commission (SEC) and Bureau of Internal Revenue (BIR). The Secretary of Health shall call upon the BOC, SEC, and the BIR for assistance in determining the cost incurred and the profits earned by the industry and in order to ultimately determine the actual prices of drugs and medicines. Further, the Secretary of Health shall deputize the Bureau of Internal Revenue in obtaining and validating the documents that he may so require as described in Section 19F of the Act. *(n)*

Rule 60. Deputizing the LGUs. The Secretary of Health shall deputize the local government units (LGUs) to monitor prices of drugs and medicines in their area of jurisdiction and report all suspected violations as covered by the Act. LGUs shall also be deputized to enforce provisions of non-discriminatory clause pursuant to rules jointly put in place by the DOH and LGUs. *(n)*

Rule 61. Deputizing other Government Agencies. The Secretary of Health may deputize any other official, agent, employee, agency, or instrumentality of government as appropriate to implement drugs and medicines price regulations. *(n)*

CHAPTER XII
REPORTING AND SURVEYS

Rule 62. Reports from Local Government Units (LGUs) and the Department of Trade and Industry (DTI). All local government units and the DTI shall help ensure the implementation of pricing policies provided under the Act and these Implementing Rules and Regulations by submitting quarterly price monitoring reports to the Secretary of Health of drugs and medicines identified by the latter, and any and all necessary information that the Secretary of Health may require. *(27)*

Rule 63. System and Standards. The system and standards for reporting shall be issued by the DOH. *(n)*

Rule 64. Scope of Price Monitoring Function of DTI. Monitoring of prices of drugs and medicines to be conducted by DTI shall be limited to drugstores operating within the territorial limits of the city or municipality where the provincial office of DTI is located. The list of drugs and medicines the prices of which are to be monitored by DTI on a quarterly basis shall be agreed upon by the Secretary of Health and the Secretary of Trade and Industry. Such list shall be subject to an annual review and revision, if necessary. *(n)*

Rule 65. Scope of Price Monitoring Function of LGUs. The monitoring of prices of drugs and medicines to be conducted by the LGUs shall be limited to drugstores operating within the territorial limits of their respective city or municipality, except the city or municipality where the provincial office of DTI is located. The list of drugs and medicines the prices of which are to be monitored by the LGUs on a quarterly basis shall be agreed upon by the Secretary of Health and the Secretary of Interior and Local Government. Such list shall be subject to an annual review and revision, if necessary. *(n)*

Rule 66. Role of the Department of Health (DOH) and the Department of Trade and Industry (DTI). The DOH and the DTI shall conduct independent periodic surveys and studies of the selling prices of all drugs and medicines all over the country as well as their share or effect on the family income of the different economic groups in the country for purposes of serving as data base for government efforts to promote access to more affordable medicines, as well as evaluating the effectivity of the measures undertaken. The DTI shall always officially provide the Secretary of Health copies of these independent reports. *(28)*

Rule 67. Monitoring Reports. The Secretary of Health shall submit a biannual Monitoring Report of its performance on the implementation of the Act to the Office of the President. This report shall be published in a newspaper of general circulation within thirty (30) days upon submission. *(30a)*

Rule 68. Monitoring of Progress. The DOH with the assistance of the Department of Interior and Local Government and the Philippine Information Agency shall monitor the progress of the education drive, and shall submit regular reports to Congress. *(40)*

Rule 69. Performance Report. The Secretary of Health shall also submit an annual performance report regarding the implementation of the Act to both Houses of Congress, within fifteen (15) days from the opening of the regular session. He shall also regularly report to and immediately comply with any order of the Congressional Oversight Committee. *(30b)*

CHAPTER XIII
BFAD STRENGTHENING

Rule 70. Retention of Income. For a more effective and expeditious implementation of the Act, the Director or the Head of BFAD shall be authorized to retain, without need of a separate approval from any government agency, and subject only to existing accounting and auditing rules and regulations, all the fees, fines, royalties and other charges, collected by the BFAD under the Act and other laws that it is mandated to administer based on the immediately prior year of operations, for use in its operations, like upgrading of facilities, equipment outlay, human resource development and expansion, and the acquisition of the appropriate office space, among others, to improve the delivery of its services to the public. This amount, which shall be in addition to the annual budget of BFAD, shall be deposited and maintained in a separate account or fund, which may be used or disbursed directly by the Director or Head. *(31a)*

Rule 71. Budgetary Support. After five (5) years from the coming into force of the Act, the Director or Head of the BFAD shall, subject to the approval of the Secretary of Health, determine if the fees and charges, mentioned in Section 1 hereof, are sufficient to meet its budgetary requirements. If so, it shall retain all the fees and charges it shall collect under the same conditions indicated in said Section 1 but shall forthwith, cease to receive any funds from the annual budget of the National Government; if not, the provisions of Section 1 shall continue to apply until such time when the Director or Head of the BFAD, subject to the approval of the Secretary of Health, certifies that the above stated fees and charges the BFAD shall collect are enough to fund its operations. *(31b)*

Rule 72. Review of Fees and Charges. In relation to the above rule, the fees and charges shall be periodically reviewed by BFAD in consultation with relevant stakeholders. *(n)*

Rule 73. Performance Report. The BFAD shall submit a yearly performance report to the Quality Affordable Medicines Oversight Committee. The report shall itemize the use of such retained funds in the past year up to the present and the budgeted use of the same in the succeeding periods. *(31c)*

Rule 74. Quality Assurance of Drugs. The BFAD shall take the necessary steps to ensure that all drugs authorized for marketing in the country shall conform to international standards for the content, purity and quality of pharmaceutical products as established in the International Pharmacopoeia: *Provided,* That imported products in finished dosage forms, should be certified under the World Health Organization (WHO) certification scheme on the quality of pharmaceutical products moving in international commerce: *Provided, further*, That the registration for multi-source pharmaceutical products should conform to the WHO guidelines on registration equirements to establish interchangeability. *(32)*

CHAPTER XIII
BFAD STRENGTHENING

Rule 75. General Penalties. The Secretary of Health shall have the authority to impose administrative sanctions such as, but not limited to, suspension, or revocation of license to operate; suspension or revocation of Certificate of Product Registration, product recall; or recommend suspension or revocation of license to practice profession to the Professional Regulation Commission as the case may be for the violation of the Act and these Implementing Rules and Regulations. *(41C)*

Rule 76. Administrative Sanctions. Unless otherwise provided herein, the following administrative sanctions shall be imposed upon any person, juridical or natural, found to have violated the provisions of the Act and these Implementing Rules and Regulations:

a. 1st violation – Warning
b. 2nd violation – Administrative fine of a minimum of Ten Thousand (P10, 000.00) to Fifty Thousand (P 50,000.00) Pesos depending on the gravity and extent of the violation, including the recall of the offending product when applicable;
c. 3rd violation – Administrative fine of minimum of Sixty Thousand (P60, 000.00) to One Hundred Fifty Thousand (P150, 000.00) Pesos, depending on the gravity and extent of the violation, and in addition thereto, the recall of the offending product, and suspension of the Certificate of Product Registration (CPR) when applicable;
d. 4th violation – Administrative fine of a minimum of Two Hundred Thousand (P200,000.00) to Five Hundred Thousand (P500, 000.00) Pesos, depending on the gravity and extent of the violation, and in addition thereto, the recall of the offending product, revocation of the CPR, suspension of the License to Operate (LTO) and or License to Import and Distribute, when applicable, for a period of one year;

e. 5th and succeeding repeated violations – Administrative fine of One Million (P1,000,000.00) Pesos, and, when applicable, the recall of the offending product, revocation of the CPR, revocation of the License to Operate (LTO) and or License to Import and Distribute of the company concerned, including the blacklisting of the company to be furnished the Government Procurement Policy Board (GPPB) and the Department of Trade and Industry (DTI);
f. An additional penalty of Two Thousand Five Hundred (P 2,500.00) Pesos per day shall be made for every day the violation continues after having received the order from the DOH or other such appropriate body, notifying and penalizing the offending person or company for the infraction.

Rule 77. Repeated Violations. For purposes of determining whether or not there is "repeated" violation for companies, each product violation belonging or owned by a company, including those of their subsidiaries, are deemed to be violations of such concerned person or entity and shall not be based on the specific violating product alone.

Rule 78. Fees, Charges and Fines. All fees collected, charges imposed and administrative fines that have accrued as a consequence of the implementation of the Act and these Implementing Rules and Regulations shall be for the account and income of the BFAD.

Rule 79. Government Depositary Bank. All such fees and fines shall be deposited in an Authorized Government Depositary Bank (AGDB).

Rule 80. Erring Public Employees. In accordance with the Administrative Code and pertinent Civil Service laws, rules and regulations, erring government employees found to be liable, and depending on the gravity of the said violation, shall be imposed the appropriate penalty by the disciplining authority.

Rule 81. Liability of Manufacturers/Distributors. Manufacturers and Distributors of the products covered by the Law shall be directly liable for any violation of the provisions of the Law and its IRR. Should the offense be committed by a juridical person, the Chairman of the Board of Directors, the president, general manager, or the partners and/or the persons directly responsible therefore, shall be made accountable.

Agents/Representatives of the Manufacturer or Distributor of the products within the scope of the Law, who commit any violation of the provisions of the Law and its implementing rules and regulations shall jointly and solidarily liable with the said manufacturers and distributors.

All those found responsible after the investigation shall be jointly and solidarily liable.

Rule 82. Penalty for Violations of the Maximum Retail Price. After due notice and hearing, the Secretary of Health shall have the power to impose administrative fines against any person, manufacturer, importer, trader, distributor, wholesaler, retailer, or any other entity, in such amount as it may deem reasonable, which in no case shall be less than **Fifty thousand pesos (Php50,000.00) nor more than Five million pesos (Php5,000,000.00)** for violations of the maximum retail price approved by the President of the Philippines pursuant to the provisions of this Chapter. *(19D)*

Rule 83. Penalty for Illegal Acts of Price Manipulation. Any person or entity who commits any act of illegal price manipulation of any drug and medicine subject to price regulation shall suffer the penalty of not less than five (5) years but not more than fifteen (15) years of imprisonment, or shall be imposed a fine of **not less than One hundred thousand pesos (Php100,000.00) but not more than Ten million pesos (Php10,000,000.00)**, at the discretion of the court. The court may also order the suspension or revocation of its **license to operate (LTO), professional or business license**.

Whenever any act of illegal price manipulation of any drug and medicine subject to price regulation is committed by a juridical person, its officials or employees, or in case of a foreign corporation or association, its agent or representative in the Philippines who is responsible for the violation, shall be held liable therefore. *(25)*

Rule 84. Penalties for Violations under the Non-discriminatory Clause. Any person or entity who shall refuse to carry or sell drugs and medicines pursuant to the provisions of these Rules and Regulations shall be punished with a fine of **not less than One hundred thousand pesos (Php100,000.00) but not more than Five hundred thousand pesos (Php500,000.00)**, at the discretion of the court. For the succeeding offense, the penalties shall **not be less than Five hundred thousand pesos (Php500,000.00) but not more than One million pesos (Php1,000,000.00)**, at the discretion of the court, and suspension or revocation of its **license to operate (LTO), business or professional license**, as the case may be. *(35)*

Rule 85. Penalties for Violation of Generics Act Amendments.

a. Any person who violate Sections 2(a), 2(b), 2(c) of the Generics Law amendments as reflected in this Implementing Rules and Regulations shall suffer the penalty graduated hereunder, *viz* :
   1. For the first conviction, he shall suffer the penalty of reprimand which shall be officially recorded in the appropriate books of the Professional Regulation Commission.
   2. For the second conviction, the penalty of fine in the amount of not less than Ten thousand pesos (Php10,000.00) but not exceeding Twenty-five thousand pesos (Php25,000.00), at the discretion of the court.
   3. For the third conviction, the penalty of fine in the amount of not less than Twenty-five thousand pesos (Php25,000.00) but not exceeding Fifty thousand pesos (Php50,000.00) and suspension of his license to practice his profession for sixty (60) days at the discretion of the court.
   4. For the fourth and subsequent convictions, the penalty of fine of not less than One hundred thousand pesos (Php100,000.00) and suspension of his license to practice his profession for one (1) year or longer at the discretion of the court. *(41)*

b. Any juridical person who violates Sections 2(d), 2(e), and 4 of the Generics Law amendments of this implementing rules and regulations as well as Section 7 of Republic Act No. 6675 otherwise known as the Generics Act of the Philippines shall suffer the penalty of a fine of **not less than One hundred thousand pesos (Php100,000.00)** and suspension or revocation of license to operate such drug establishment or drug outlet at

the discretion of the court: *Provided,* That its officers directly responsible for the violation shall suffer the penalty of fine of at least **Forty thousand pesos (Php40,000.00)** and suspension or revocation of license to practice profession, if applicable, and by imprisonment of not less than six(6) months nor more than one (1) year or both fine and imprisonment at the discretion of the court: and, *Provided, further,* That if the guilty party is an alien, he shall be ipso facto deported after service of sentence without need of further proceedings. *(41 B)*

CHAPTER XV
MISCELLANEOUS PROVISIONS

Rule 86. Amendments.

Section 1. Amendments to the Implementing Rules and Regulations. The DOH, DTI, IPO, and BFAD, either collectively or individually, may initiate the amendment of the IRR. Prior to the conduct of any public hearing for the proposed amendment, the initiating party shall first inform the other parties of the same at least 30 days prior to the date of the first public consultation.

Section 2. Issuance of Appropriate Guidelines. The DOH, DTI, IPO, and BFAD may issue appropriate guidelines that may be deemed necessary to address existing and emerging situation for the purpose of effectively implementing the intentions and objectives of the Act.

Section 3. Publication of Amendments. Any amendments to these Implementing Rules and Regulation shall take effect fifteen (15) days after its publication in at least two (2) national papers of general circulation and upon filing at the UP Law Center as accorded by Law. *(n)*

Section 4. Review of IRR. After two (2) years from the effectivity of these Implementing Rules and Regulations and every two (2) years thereafter, the DOH, DTI, IPO and BFAD shall jointly review these Implementing Rules and Regulations.

Rule 87. Transitory Provisions

Section 1. Submission of Prices and Inventory. Within 30 days from the effectivity of the Law, and every December 31st of every year thereafter, every manufacturer, importer, trader, distributor, wholesaler, and retailer of a drug and medicine whether included in or excluded from the list of drugs and medicines that are subject to price regulation shall furnish the Secretary of Health a list, containing on the minimum the corresponding prices and inventory, of all drugs and medicines it manufactures, imports, trades, distributes, wholesales, or retails, data pertaining to the factors enumerated under Section 19A2 of the Law and any and all necessary information that the Secretary of Health may require. *(19F)*

Section 2. Undertake the Study to Determine the MRP. Subject to the relevant provisions of these Rules and Regulations, in order that affordable prices of drugs and medicines shall be made available to the public, the Secretary of Health shall immediately undertake a study on the prevailing prices of drugs and medicines which he/she will prioritize to be subject to price regulation and shall provide this initial list of drugs and medicines, with its recommended MRP to the President of the Philippines. *(19A3)*

Rule 88. Separability Clause. Any portion or provision of the Act or of these Rules that may be declared unconstitutional or invalid shall not have the effect of nullifying other portions and provisions hereof as long as such remaining portion or provision can still subsist and be given effect in their entirety. *(47)*

Rule 89. Repealing Clause. All administrative issuances or parts thereof inconsistent herewith are hereby repealed or modified accordingly. *(48)*

Rule 90. Effectivity Clause. This Implementing Rules and Regulation shall take effect fifteen (15) days after its publication in at least two (2) national papers of general circulation and upon filing at the UP Law Center as accorded by Law. *(n)*

ANNEX "A"

The TRIPS Protocol. Unless otherwise amended by the IP Code and these IRR, the Protocol Amending the TRIPS Agreement (ref: WT/L/641) is reproduced below:

1. For the purposes of Article 31*bis* and this Annex:
   a. "eligible importing Member" means any least-developed country Member, and any other Member that has made a notification to the Council for TRIPS Agreement of its intention to use the system set out in Article 31*bis* and this Annex ("system") as an importer, it being understood that a Member may notify at any time that it will use the system in whole or in a limited way, for example only in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. It is noted that some Members will not use the system as importing Members and that some other Members have stated that, if they use the system, it would be in no more than situations of national emergency or other circumstances of extreme urgency;
   b. "Exporting Member" means a Member using the system to produce pharmaceutical products for, and export them to, an eligible importing Member.
2. The terms referred to in paragraph 1 above are that:
   a. The eligible importing Member(s) has made a notification to the Council for TRIPS Agreement, that:
      (i) Specifies the names and expected quantities of the product(s) needed;
      (ii) Confirms that the eligible importing Member in question, other than a least-developed country Member, has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question in one of the ways set out in the Appendix to this Annex; and
      (iii) Confirms that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory license in accordance with Articles 31 and 31*bis* of this Agreement and the provisions of this Annex;
   b. The special compulsory license issued by the exporting Member under the system shall contain the following conditions:

(i) Only the amount necessary to meet the needs of the eligible importing Member(s) may be manufactured under the license and the entirety of this production shall be exported to the Member(s) which has notified its needs to the Council for TRIPS Agreement;

(ii) Products produced under the license shall be clearly identified as being produced under the system through specific labeling or marking. Suppliers should distinguish such products through special packaging and/or special colouring/shaping of the products themselves, provided that such distinction is feasible and does not have a significant impact on price; and

(iii) Before shipment begins, the licensee shall post on a website the following information:

- The quantities being supplied to each destination as referred to in indent (i) above; and
- The distinguishing features of the product(s) referred to in indent (ii) above;

c. The exporting Member shall notify the Council for TRIPS Agreement of the grant of the license, including the conditions attached to it. The information provided shall include the name and address of the licensee, the product(s) for which the license has been granted, the quantity(ies) for which it has been granted, the country(ies) to which the product(s) is (are) to be supplied and the duration of the license. The notification shall also indicate the address of the website referred to in subparagraph (b) (iii) above.

3. In order to ensure that the products imported under the system are used for the public health purposes underlying their importation, eligible importing Members shall take reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion to prevent re-exportation of the products that have actually been imported into their territories under the system. In the event that an eligible importing Member that is a developing country Member or a least-developed country Member experiences difficulty in implementing this provision, developed country Members shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in order to facilitate its implementation.

4. Members shall ensure the availability of effective legal means to prevent the importation into, and sale in, their territories of products produced under the system and diverted to their markets inconsistently with its provisions, using the means already required to be available under this Agreement. If any Member considers that such measures are proving insufficient for this purpose, the matter may be reviewed in the Council for TRIPS Agreement at the request of that Member.

5. With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products, it is recognized that the development of systems providing for the grant of regional patents to be applicable in the Members described in paragraph 3 of Article 31*bis* should be promoted. To this end, developed country Members undertake to provide technical co-

operation in accordance with Article 67 of this Agreement, including in conjunction with other relevant intergovernmental organizations.

6. Members recognize the desirability of promoting the transfer of technology and capacity building in the pharmaceutical sector in order to overcome the problem faced by Members with insufficient or no manufacturing capacities in the pharmaceutical sector. To this end, eligible importing Members and exporting Members are encouraged to use the system in a way which would promote this objective. Members undertake to cooperate in paying special attention to the transfer of technology and capacity building in the pharmaceutical sector in the work to be undertaken pursuant to Article 66.2 of this Agreement, paragraph 7 of the Declaration on the TRIPS Agreement and Public Health and any other relevant work of the Council for TRIPS Agreement.

7. The Council for TRIPS Agreement shall review annually the functioning of the system with a view to ensuring its effective operation and shall annually report on its operation to the General Council. *(n)*

NOW, THEREFORE, the parties have herein below affixed their signatures to the Joint DOH-DTI-IPO-BFAD Administrative Order No. 2008-01 this 4th day of November 2008.

Signed
FRANCISCO T. DUQUE III, MD, MSc.
Secretary
Department of Health

Signed
PETER B. FAVILA
Secretary
Department of Trade and Industry

Signed
ADRIAN S. CRISTOBAL, JR.
Director General
Intellectual Property Office

Signed
LETICIA BARBARA B. GUTIERREZ, MSc.
Director IV
Bureau of Food and Drugs

APPENDIX AA

Philippine National Drug Formulary

Essential Medicines List for PRIMARY CARE MEDICINES

Volume I
7th Edition
2008

SYMBOLS, ABBREVIATIONS AND SYSTEM OF MEASUREMENT

LEGEND :

★	—	Not available in Philippine market
■	—	Based on the requirement of Recommended Energy and Nutrient Intakes **(RENI)**
(A2)	—	Drug Preparations Containing Controlled Chemicals to be dispensed and prescribed through a **Personalized Prescription** issued by a prescribing physician with the **S2 license #**, among others, indicated therein. Only one (1) drug preparation shall be prescribed in one single prescription form. Partial filling allowed. **STRICTLY NO REFILL**. (*see* Appendix K)
B	—	List B Medicines requiring *in-vivo* bioequivalence studies (*see* Appendix I)
DPI	—	Dry Powder Inhaler
g	—	Gram
(IM)	—	Intramuscular Injection
Inj.	—	Injection
IU	—	International Unit/s
(IV)	—	Intravenous Injection
L	—	Liter
MDI	—	Metered Dose Inhaler
mg	—	Milligram
mL	—	Milliliter
mmol	—	Millimole
MR	—	Modified Release (includes Controlled Release (**CR**), Extended Release **(ER),** Sustained Release **(SR),** Long Acting **(LA),** etc.)
RE	—	Retinol Equivalent
Resp. Soln.	—	Respiratory Solution
(SC)	—	Subcutaneous Injection
Soln.	—	Solution
Category A	—	Primary Care Medicines for all Rural Health Units (RHUs)
Category B	—	Primary Care Medicines for RHUs with physicians and other health workers

MEASUREMENTS :

1 grain = 60 mg

1/2 grain = 30 mg

Quantities of 1 gram or more are written as 1 g, etc.

Quantities less than 1 gram are written in milligram/s, e.g., 500 mg, not 0.5 g.

Quantities less than 1 milligram are written in microgram/s, e.g., 100 microgram/s, not 0.1 mg

When decimals are unavoidable, a zero is written before the decimal point where there is no other figure, e.g. 0.5 mL, not .5 mL.

The term milliliter (mL) is used and not cubic centimeter or cc.

I N T R O D U C T I O N

This list of essential medicines has been derived from the Philippine National Drug Formulary (PNDF) Vol. I, 7th edition (2008) and is intended for use in the Rural Health Units (RHUs). These drugs are useful in meeting the immediate health needs of the great majority of the population for commonly encountered ailments all over the country. They are generally safe and do not require special expertise and equipment for proper use.

There are a total of ninety eight (98) medicines in this list which have been grouped under two categories, viz., those used for all RHUs (30 medicines) and those for RHUs with physicians in addition to other health workers (68 medicines). The medicines are further classified as vital (V), essential (E) and less essential (L) based on the following criteria: (1) frequency of occurence of target condition/s; (2) severity of target condition/s; (3) therapeutic effects of the drug, whether preventive, curative or just symptomatic relief; and (4) cost of therapy. Such classification is useful in prioritizing procurement of medicines especially in resource poor areas.

This list of essential primary care medicines, is a dynamic list just like the PNDF, which needs periodic review and updating in the light of new developments and experiences and the prevailing health needs of our population. We welcome reactions, suggestions and recommendations from the end users of this list to make it truly relevant.

PROF. ESTRELLA B. PAJE-VILLAR, MD
Chairperson, National Formulary Committee

GUIDELINES FOR MEDICINE CLASSIFICATION

Characteristic of Individual Medicine	Vital (V)	Essential (E)	Less Essential (L)
1 — Occurrence of Target Condition(s)			
Persons affected (0% of population)	> 5%	1 - 5%	< 1%
Persons diagnosed (cases/100,000 pop/yr)	> 100	50 - 100	< 50
Persons treated (frequency of target condition seen by health worker)	Moderate	Low	Very low
2 — Severity of Target Condition(s)			
Life threatening (likely to cause death if untreated)	Possibly	Infrequently	Rarely
Chronic (likely to cause recurrence, relapse, continued disease if untreated)	Possibly	Infrequently	Rarely
Disabling (likely to cause permanent disability if untreated)	Possibly	Infrequently	Rarely
Restricting (likely to cause loss of working and housekeeping time)	Frequently	Occasionally	Infrequently
3 — Therapeutic Effect(s)			
Drug Action	Prevention of disease Cure of disease Prevention of complication	Cure of disease Prevention or treatment of complication	Relief and/or mitigation of self-limited disease Palliative treatment of minor symptoms/ complication
4 — Cost			
Average cost of a single course of therapy (acute therapy)	Low	Moderate	High
Average yearly cost of therapy (chronic therapy)	Low	Moderate	High

PRIMARY CARE MEDICINES
(2008 Edition)

CATEGORY A : PRIMARY CARE MEDICINES FOR ALL RURAL HEALTH UNITS (RHUs)	V	E	L
1. ANALGESICS / ANTIPYRETICS			
Paracetamol			x
Oral: 300 mg (325 mg) and 500 mg tablet			
120 mg (125 mg)/5 mL syrup/suspension, 60 mL (alcohol-free)			
250 mg/5 mL syrup/suspension, 60 mL (alcohol-free preferred)			
100 mg/mL drops, 15 mL (alcohol-free)			
Yerba Buena *[Mentha cordifolia Opiz (* Fam. Labiatae*)]*			x
Oral: 250 mg and 500 mg tablet			
2. ANTACID			
Aluminum hydroxide + Magnesium hydroxide			x
Oral: 225 mg aluminum hydroxide + 200 mg magnesium hydroxide, per 5 mL suspension, 120 mL			
3. ANTIALLERGY			
Hydroxyzine	x		
10 mg and 25 mg tablet (as dihydrochloride)			
2 mg/mL syrup, 60 mL (as dihydrochloride or as hydrochloride)			
4. ANTHELMINTIC			
Mebendazole	x		
Oral: 100 mg and 500 mg tablet			
20 mg/mL suspension, 30 mL			
50 mg/mL suspension, 10 mL			
5. ANTIANEMIC			
Ferrous Salt	x		
Oral: tablet, equiv. to 60 mg elemental iron			
solution, 15 mg elemental iron/0.6 mL drops, 15 mL			
solution, 15 mg elemental iron/0.6 mL drops, 30 mL			
30 mg elemental iron/5 mL syrup, 60 mL			
N.B. The elemental iron content of a ferrous salt depends on the type of preparation as follows:			

	V	E	L
Ferrous fumarate — 33%			
Ferrous gluconate — 12%			
Ferrous lactate — 19%			
Ferrous sulfate, hydrated — 20%			
Ferrous sulfate, dessicated — 32%			
6. FOR COUGH			
Lagundi *[Vitex negundo L. (* Fam. Verbenaceae*)]*			x
Oral: 300 mg and 600 mg tablet			
300 mg/5 mL syrup, 60 mL			
7. ANTIDOTE (general)			
Activated Charcoal	x		
Oral: powder, USP grade given as slurry			
8. ANTI-EMETIC			
Meclozine (meclizine)			x
Oral: 12.5 mg chewable tablet (as hydrochloride)			
25 mg tablet (as hydrochloride)			
9. ANTIRHEUMATICS (ANTI-INFLAMMATORY)			
Aspirin		x	
Oral: 300 mg (325 mg) tablet			
Ibuprofen		x	
Oral: 200 mg and 400 mg tablet			
100 mg/5 mL suspension, 60 mL			
10. ANTISEPTICS / DISINFECTANTS			
Alcohol, Ethyl		x	
Solution: 70%, 480 mL bottle			
Povidone-Iodine		x	
Solution: 10%, 60 mL and 120 mL			
11. ANTISPASMODICS			
Dicycloverine (dicyclomine)			x
Oral: 10 mg tablet (as hydrochloride)			
10 mg/5 mL syrup, 30 mL (as hydrochloride)			
Tsaang Gubat *[Carmona retusa (Vahl) Masam (* Fam. Boraginaceae*)]*			x
Oral: 250 mg tablet			

	V	E	L
12. ANTI-SCABIES, ANTI-LICE AND ANTIFUNGALS			
★ Akapulko *[Cassia alata L. (* Fam. Leguminosaea*)]* Lotion: 60 mL bottle		x	
Benzyl Benzoate Lotion: 25%, 120 mL bottle		x	
Crotamiton Lotion: 10%, 60 mL bottle 10%, 120 mL bottle Cream: 10%, 10 g tube		x	
Sulfur Ointment: 10%, 30 g tube			x
13. DIURETIC			
Sambong *[Blumea balsamifera L. DC (* Fam. Compositae*)]* Oral: 250 mg and 500 mg tablet		x	
14. ANTIBACTERIAL EYE PREPARATIONS			
Gentamicin Eye Drops Solution 0.3%, 5 mL bottle (as sulfate) Eye Ointment: 0.3%, 3.5 g tube (as sulfate)	x		
Erythromycin Eye Ointment: 0.5%, 3.5 g tube	x		
15. FLUIDS AND ELECTROLYTES			
Oral Rehydration Salts (ORS 75-replacement) Oral: Composition of reduced osmolarity ORS per liter of water (WHO recommended):	x		

Sodium chloride	—	2.6 g
Trisodium citrate dihydrate	—	2.9 g
Potassium chloride	—	1.5 g
Glucose anyhdrous	—	13.5 g
Total Weight	—	20.5 g
Reduced osmolarity ORS Equivalent in mmol/L:		
Sodium	—	75
Chloride	—	65
Potassium	—	20

	V	E	L
Citrate — 10 Glucose anhydrous — 75 Total osmolarity — 245 N.B. Reconstitute with clean potable water Unused reconstituted solution shall be discarded after 24 hours.			
16. VITAMINS			
Ascorbic acid (vitamin C) Oral: 500 mg tablet 100 mg/5 mL syrup, 120 mL 100 mg/mL drops, 15 mL		**x**	
Multivitamins Oral:		**x**	

	<u>for Infants per 1 mL drops</u>	<u>for Children per 5 mL syrup</u>	<u>for Adults per tablet/capsule</u>
vitamin A	325 micrograms RE	350-400 micrograms RE	425-525 microgram RE
vitamin B1	0.3-0.4 mg	0.7-0.9 mg	0.7-1.3 mg
	▪ 0.1-0.3 mg	**▪ 0.5-1 mg**	**▪ 1.3-1.7 mg**
vitamin B2	0.3-0.4 mg	0.7-0.9 mg	0.7-1.3 mg
vitamin B6	0.3-0.6 mg	0.9-1.6 mg	1.6-2 mg
vitamin B12	0.5-1.5 micrograms	2-3 micrograms	3-5 microgram
	▪ 0.3-0.4 micrograms	**▪ 0.9-1.8 micrograms**	**▪ 2.4 microgram**
vitamin C	30 mg	35-55 mg	65-80 mg
vitamin D	400 IU	400 IU	400 IU
	▪ 5 micrograms	**▪ 5 micrograms**	**▪ 5-15 microgram**
vitamin E	3-4 mg	5-7 mg	6-10 mg
	▪ 3.4 mg	**▪ 5-7 mg**	**▪ 10-12 mg**
folic acid	20-30 micrograms	40-80 micrograms	100-170 microgram
niacin	5-8 mg	13-17 mg	13-23 mg

Pyridoxine (vitamin B6) Oral: 25 mg tablet (as hydrochloride)	**x**		
Retinol (vitamin A) Oral: 10,000 IU, 25,000 IU, and 50,000 IU soft gel capsule (as palmitate) 100,000 IU soft gel capsule with nipple (as palmitate) (only for DOH program) 200,000 IU soft gel capsule with nipple (as palmitate) (only for DOH program) **(B)**	**x**		
Vitamin B1 B6 B12 Oral: 100 mg B1 + 5 mg B6 + 50 B12 microgram per tablet		**x**	

17. VITAMINS AND MINERALS

	V	E	L
Ferrous Salt + Folic Acid (nutritional supplement during pregnancy)	x		
Oral: 60 mg elemental iron + 250 microgram folic acid per tablet/capsule			
Zinc	x		
Oral: chewable tablet, (equiv. to 10 mg elemental zinc) (as gluconate)			
tablet, (equiv. to 30 mg elemental zinc) (as gluconate trihydrate)			
solution, (equiv. to 10 mg elemental zinc/mL) drops, 15 mL, (as sulfate monohydrate)			
solution, (equiv. to 20 mg elemental zinc/5 mL) syrup, 60 mL (as sulfate monohydrate)			

CATEGORY B : PRIMARY CARE MEDICINES FOR RHUs WITH PHYSICIANS AND OTHER HEALTH WORKERS - THE FOLLOWING MEDICINES MAY BE ADDED TO THE ABOVE CATEGORY A LIST:	V	E	L
1. ADRENERGIC			
Epinephrine (adrenaline) Inj.: 1 mg/mL ampul (IM, SC) (as hydrochloride)	x		
2. ANTI-ANGINAL			
Glyceryl Trinitrate (nitroglycerin) Sublingual: 400 microgram tablet Ointment: 2%, 30 g tube	x		
3. ANTIDOTES			
Atropine (for organophosphate and carbamate insecticide poisoning) Oral: 600 microgram tablet (as sulfate) Inj.: 1 mg/mL ampul (IM, IV) (as sulfate)	x		
Cobra Antivenin Inj.: 800 IU/5 mL ampul (IM, IV)	x		
4. ANTIALLERGY			
Diphenhydramine Oral: 25 mg and 50 mg capsule (as hydrochloride) Inj.: 50 mg/mL, 1 mL ampul (IM, IV) (as hydrochloride)	x		
Hydroxyzine Oral: 10 mg and 25 mg tablet (as dihydrochloride) Inj.: 50 mg/mL, 1 mL vial (IM, IV)	x		
5. ANTIHYPERTENSIVES			
Amlodipine Oral: 5 mg and 10 mg tablet (as besilate/camsylate)	x		
Enalapril Oral: 5 mg and 10 mg tablet (as maleate)	x		
Hydrochlorothiazide Oral: 25 mg and 50 mg tablet	x		
Metoprolol Oral: 50 mg tablet	x		

	V	E	L
Nifedipine **(B)** Oral: 5 mg and 10 mg capsule (restricted use for acute hypertensive emergencies in patients less than 18 years old with extreme caution due to rapid and prolonged fall in blood pressure)	x		
Propranolol Oral: 10 mg and 40 mg tablet (as hydrochloride)	x		
6. ANTI-INFECTIVES			
6.1 Antibacterials			
Amoxicillin Oral: 250 mg and 500 mg capsule (as trihydrate) 100 mg/mL granules/powder for drops (suspension), 10 mL (as trihydrate) 125 mg/5 mL, 250 mg/5 mL granules/powder for suspension, 60 mL (as trihydrate)	x		
Ciprofloxacin Oral: 250 mg and 500 mg tablet (as hydrochloride)	x		
Cotrimoxazole (sulfamethoxazole + trimethoprim) Oral: 400 mg sulfamethoxazole + 80 mg trimethoprim tablet/capsule **(B)** 800 mg sulfamethoxazole + 160 mg trimethoprim tablet **(B)** 200 mg sulfamethoxazole + 40 mg trimethoprim/ 5 mL suspension	x		
Erythromycin Oral: 250 mg tablet (as stearate) **(B)** 200 mg/5 mL granules/powder for suspension, 60 mL (as ethyl succinate)	x		
Penicillin G Benzathine (benzathine benzylpenicillin) Inj.: 1,200,000 units vial (MR) (IM)	x		
Penicillin G Crystalline (benzylpenicillin) Oral: 500,000 and 1,000,000 units (IM, IV) (as sodium or potassium salt)	x		
Phenoxymethylpenicillin (penicillin V) Oral: 250 mg and 500 mg tablet/capsule (as potassium salt) 125 mg/5 mL granules/powder for syrup/ suspension, 60 mL (as potassium)	x		

	V	E	L
250 mg/5 mL granules/powder for syrup/ suspension, 60 mL (as potassium salt) 50,000 units/mL granules/powder for drops (syrup/ suspension), 30 mL (as potassium salt)			
6.2 Antiprotozoals			
6.2.1 Amebecide			
★ Diloxanide Oral: 500 mg tablet (as furoate) **(B)** 125 mg/5 mL syrup/suspension, 60 mL (as furoate)	x		
Metronidazole (also for *G. lamblia, T. vaginalis* and anaerobic bacteria) Oral: 250 mg and 500 mg base tablet 125 mg base/5 mL (200 mg/5 mL as benzoate) suspension, 60 mL	x		
6.2.2 Antimalarials (under Malaria Control Program)			
Artemether + Lumefantrin **(B)** Oral: 20 mg artemether + 120 mg lumefantrin tablet	x		
Chloroquine Oral: 250 mg (150 mg base) tablet (as phosphate/diphosphate)	x		
Primaquine Oral: 26.3 mg (15 mg base) tablet (as diphosphate)	x		
Quinine Oral: 325 mg (300 mg) tablet (as sulfate)	x		
Sulfadoxine + Pyrimethamine (not for prophylaxis; only for clinical suppression) **(B)** Oral: 500 mg sulfadoxine + 25 mg pyrimethamine per tablet	x		
6.3 Antituberculosis Medicines (under National TB Program)			
Ethambutol (caution in children less than 6 yrs. old) Oral: 200 mg and 400 mg tablet (as hydrochloride)	x		
Isoniazid Oral: 100 mg, 300 mg and 400 mg tablet 200 mg/5 mL syrup, 60 mL 200 mg/5 mL syrup, 120 mL	x		

	V	E	L
Isoniazid + Ethambutol	x		
Oral: ★ 150 mg isoniazid + 400 mg ethambutol per tablet			
★ 200 mg isoniazid + 500 mg ethambutol per tablet			
Isoniazid + Rifampicin **(B)**	x		
Oral: ★ 30 mg + 60 mg tablet (pediatric)			
60 mg + 60 mg tablet (pediatric) (for intermittent use three times weekly)			
75 mg + 150 mg tablet			
★ 150 mg + 150 mg tablet (for intermittent use three times weekly)			
100 mg + 150 mg tablet			
150 mg + 300 mg tablet			
★ 200 mg + 225 mg tablet			
300 mg + 450 mg tablet			
400 mg + 450 mg tablet			
★ 600 mg + 400 mg tablet/film coated tablet			
Isoniazid + Rifampicin + Pyrazinamide **(B)**	x		
Oral: ★ 30 mg + 60 mg + 150 mg tablet (pediatric) (for intermittent use three times weekly)			
75 mg + 150 mg + 400 mg tablet			
★ 150 mg + 150 mg + 500 mg tablet			
300 mg + 450 mg + 500 mg tablet			
Isoniazid + Rifampicin + Pyrazinamide + Ethambutol **(B)**	x		
Oral: 60 mg + 120 mg + 300 mg + 225 mg tablet			
75 mg + 150 mg + 400 mg + 275 mg tablet			
200 mg + 450 mg + 500 mg + 400 mg tablet (restricted for 60 days use only)			
Pyrazinamide	x		
Oral: 500 mg tablet			
250 mg/5 mL suspension, 60 mL			
250 mg/5 mL suspension, 120 mL			
Rifampicin **(B)**	x		
Oral: 150 mg, 300 mg, 450 mg and 600 mg tablet/capsule			
100 mg/5 mL suspension, 30 mL			
100 mg/5 mL and 200 mg/5 mL suspension, 60 mL			
Streptomycin	x		
Inj.: 1 g vial (IM) (as sulfate)			
6.4 Urinary Antiseptic			
Nitrofurantoin **(B)**	x		
Oral: 50 mg and 100 mg capsule (as macrocrystals)			

	V	E	L
7. ANTIPEPTIC ULCER DISEASE			
Famotidine	x		
Oral: 10 mg, 20 mg and 40 mg tablet			
20 mg/5 mL powder for suspension, 60 mL			
Inj.: 10 mg/mL, 2 mL ampul/vial (IM, IV)			
lyophilized powder, 20 mg vial (IV)			
Ranitidine	x		
Oral: 150 mg and 300 mg tablet (as base and as hydrochloride)			
150 mg and 300 mg effervescent tablet (as hydrochloride)			
75 mg tablet (as base and as hydrochloride)			
75 mg/5 mL syrup, 60 mL and 150 mL (as hydrochloride)			
Inj.: 25 mg/mL, 2 mL ampul (IM, IV, IV infusion) (as hydrochloride)			
8. ANTIPSYCHOSIS			
Chlorpromazine	x		
Oral: 50 mg, 100 mg and 200 mg tablet			
Inj.: 25 mg/mL, 1 mL ampul (IM, IV) (as hydrochloride)			
9. BRONCHODILATORS			
Epinephrine (adrenaline)	x		
Inj.: 1 mg/mL, 1 mL ampul (IM, SC) (as hydrochloride)			
Salbutamol	x		
Oral: 2 mg tablet (as sulfate)			
4 mg MR and 8 mg MR tablet (as sulfate)			
2 mg/5 mL syrup, 60 mL (as sulfate)			
Inhalation:			
Metered Dose Inhaler (MDI):			
100 micrograms/dose x 200 doses (as sulfate) (spacer recommended)			
Breath Actuated MDI (autohaler):			
100 micrograms/dose x 400 doses (as sulfate)			
Resp. Soln.: (for nebulization)			
1 mg/mL, 2.5 mL unit dose (as sulfate)			
5 mg/mL, 10 mL multidose (as sulfate)			
5 mg/mL, 20 mL multidose (as sulfate)			
OR			
Terbutaline	x		
Oral: 2 mg, 2.5 mg and 5 mg tablet (as sulfate)			
1.5 mg/5 mL syrup, 60 mL (as sulfate)			

	V	E	L
Inhalation:			
MDI: 250 micrograms/dose x 200 doses (as sulfate)			
Dry Powder Inhaler:			
500 micrograms/dose x 100 doses (as sulfate)			
Resp. Soln.: (for nebulization)			
2.5 mg/mL, 2 mL unit dose (as sulfate)			
2.5 mg/mL, 30 mL multidose (as sulfate)			
Theophylline (anhydrous)	x		
Oral: 125 mg and 200 mg MR tablet			
250 mg and 300 mg MR tablet			
25 mg/5 mL (26.7 mg/5 mL) syrup, 60 mL			
10. CARDIOTONIC (Inotropic)			
Digoxin	x		
Oral: 250 microgram tablet			
50 micrograms/mL elixir, 60 mL			
11. CORTICOSTEROIDS			
Hydrocortisone	x		
Topical: 1%, ointment or cream, 5 g tube			
Prednisolone	x		
Oral: 5 mg and 20 mg tablet			
15 mg/5 mL syrup, 60 mL (as sodium phosphate)			
20 mg/5 mL syrup, 60 mL (as sodium phosphate)			
Prednisone	x		
Oral: 5 mg tablet			
10 mg tablet			
20 mg tablet			
10 mg/5 mL suspension, 60 mL			
12. BLOOD COAGULANT			
Phytomenadione (phytonadion, vitamin K1)	x		
Inj.: 10 mg/mL, 1 ampul (IM, IV, SC) (as aqueous colloidal solution with benzyl alcohol)			
10 mg/mL, 1 mL ampul (IM, IV, SC) (as mixed micelle)			
13. DIURETICS			
Hydrochlorothiazide	x		
Oral: 25 mg and 50 mg tablet			

	V	E	L
Furosemide	x		
Oral: 40 mg tablet **(B)**			
Inj.: 10 mg/mL, 2 mL ampul (IM, IV)			

14. FLUIDS AND ELECTROLYTES

Balanced Multiple Replacement Solution	x		
Inj.: 500 mL and 1 L bottle/bag (IV infusion)			
Composition:			
Na^+ — 140 mmol/L			
K^+ — 5 mmol/L			
Mg^{++} — 3 mmol/L			
Cl^- — 98 mmol/L			
Acetate — 50 mmol/L			
plus 5% dextrose			
5% Dextrose in 0.3% Sodium Chloride	x		
Inj.: 500 mL bottle/bag (IV infusion)			
Composition:			
Dextrose — 50 g/L			
Na^+ — 51 mmol/L			
Cl^- — 154 mmol/L			
5% Dextrose in 0.9% Sodium Chloride	x		
Inj.: 500 mL and 1 L bottle/bag (IV infusion)			
Composition:			
Dextrose — 50 g/L			
Na^+ — 154 mmol/L			
Cl^- — 154 mmol/L			
5% Dextrose in Water		x	
Inj.: 250 mL bottle/bag (IV infusion and as vehicle for IV medications)			
★ Acetated Ringer's Solution	x		
Inj.: 500 mL and 1 L bottle/bag (IV infusion)			
Composition:			
Na^+ — 130 mmol/L			
K^+ — 4 mmol/L			
Ca^{++} — 3 mmol/L			
Cl^- — 109 mmol/L			
Acetate — 28 mmol/L			

	V	E	L
Lactated Ringer's Solution (Ringer's lactate) Inj.: 500 mL and 1 L bottle/bag (IV infusion) Composition: Na^+ — 130 mmol/L K^+ — 4 mmol/L Ca^{++} — 3 mmol/L Cl^- — 109 mmol/L Lactate — 28 mmol/L	x		
15. LOCAL ANESTHETIC			
Lidocaine Inj.: 2%, 10 mL and 20 mL vial (local infiltration) (as hydrochloride)		x	
16. ORAL HYPOGLYCEMICS (for Diabetes Mellitus Type 2)			
Glibenclamide Oral: 5 mg tablet **(B)**	x		
Metformin Oral: 500 mg tablet/film coated tablet (as hydrochloride)	x		
17. OXYTOCIC			
Methylergometrine (methylergonovine) (A2) Oral: 125 microgram tablet (as hydrogen maleate or maleate) Inj.: 200 micrograms/mL, 1 mL ampul (IM, IV) (as hydrogen maleate or maleate)		x	
18. THYROID HORMONE AND ANTITHYROIDS			
Aqueous Iodine Solution (Lugol's solution) Oral; 5% iodine, 10% potassium iodide (total iodine-130 mg/mL), 30 mL bottle	x		
Levothyroxine Oral: 25, 50, 75, 100, 125, and 150 microgram tablet	x		
Propylthiouracil Oral: 50 mg tablet	x		
19. FAMILY PLANNING MEDICINES			
Ethinylestradiol + Levonorgestrel Oral: 30 microgram ethinylestradiol + 150 microgram levonorgestrel per tablet			x

	V	E	L
Medroxyprogesterone Inj.: 50 mg/mL, 3 mL vial + syringe (IM) (as acetate) (N.B. Use one (1) inch long needle)			x
20. INFUSION SETS			
IV infusion Sets Adult with Gauge 19 and 21 Needles Airvent and Y injection site	x		
IV infusion Sets Pedia with Gauge 23 and 25 Needles Airvent and Y injection site	x		
21. NEBULIZER for administration of inhalational bronchodilators	x		

I. Vital Medicines (V)

	Category
Acetated Ringer's Solution	B
Activated Charcoal	A
Amlodipine	B
Amoxicillin	B
Aqueous Iodine Solution (Lugol's Solution)	B
Artemeter + Lumefantrin	B
Atropine	B
Balanced Multiple Replacement Solution	B
Chloroquine	B
Chlorpromazine	B
Ciprofloxacin	B
Cobra Antivenin	B
Cotrimoxazole	B
5% Dextrose in 0.3% Sodium Chloride	B
5% Dextrose in 0.9% Sodium Chloride	B
Digoxin	B
Diloxanide	B
Diphenhydramine	B
Enalapril	B
Epinephrine (adrenaline)	B
Erythromycin	A/B
Ethambutol	B
Famotidine	B
Ferrous Salt	A
Ferrous Salt + Folic Acid	A
Furosemide	B
Gentamicin	A
Glibenclamide	B
Glyceryl Trinitrate (nitroglycerin)	B
Hydrochlorothiazide	B
Hydrocortisone	B
Hydoxyzine	A/B
Isoniazid	B
Isoniazid + Ethambutol	B
Isoniazid + Rifampicin	B
Isoniazid + Rifampicin + Pyrazinamide	B
Isoniazid + Rifampicin + Pyrazinamide + Ethambutol	B
Lactated Ringer's Solution (Ringer's Lactate)	B
Levothyroxine	B
Mebendazole	A
Metformin	B
Methylergometrine (methylergonovine) inj.	B
Metoprolol	B

	Category
Metronidazole	B
Nifedipine	B
Nitrofurantoin	B
Oral Rehydration Salts (ORS-75 replacement)	A
Penicillin G Benzathine (benzathine benzylpenicillin)	B
Penicillin G Crystalline (benzylpenicillin)	B
Phenoxymethylpenicillin (penicillin V)	B
Phytomenadione (phytonadion, vitamin K1)	B
Prednisolone	B
Prednisone	B
Primaquine	B
Propranolol	B
Propylthiouracil	B
Pyrazinamide	B
Pyridoxine (Vitamin B6)	A
Quinine	B
Ranitidine	B
Retinol (Vitamin A)	A
Rifampicin	B
Salbutamol	B
Streptomycin	B
Sulfadoxine + Pyrimethamine	B
Terbutaline	B
Theophylline (anhydrous)	B
Zinc	A

II. Essential Medicines (E)

Akapulko	A
Alcohol, Ethyl	A
Ascorbic Acid	A
Aspirin	A
Benzyl Benzoate	A
Crotamiton	A
5% Dextrose in Water	B
Ibuprofen	A
Lidocaine	B
Methylergometrine (methylergonovine) oral	B
Multivitamins (infants/children)	A
Povidone Iodine	A
Sambong	A
Vitamin B1 B6 B12	A

III. Less Essential Medicines (L)

Aluminum Hydroxide + Magnesium Hydroxide	A
Dicycloverine (dicyclomine)	A
Ethinylestradiol + Levonorgestrel	B

	Category
Lagundi	A
Meclozine (meclizine)	A
Medroxyprogesterone	B
Paracetamol	A
Sulfur	A
Tsaang Gubat	A
Yerba Buena	A

LIST OF DOH RETAINED HOSPITALS

Center for Health Development (CHD) I - Ilocos Region

Ilocos Training & Regional Medical Center
Parian, San Fernando City, La Union 2500

Mariano Marcos Memorial Hospital & Medical Center
Batac, Ilocos Norte 2906

Region I Medical Center (Gov. Teofilo Sison Memorial Medical Center)
Arellano St., Dagupan City, Pangasinan 2400

CHD II - Cagayan Valley

Cagayan Valley Medical Center
Carig, Tuguegarao City, Cagayan 3500

Veterans Regional Hospital
Bayombong, Nueva Vizcaya 3700

CHD III - Central Luzon

Bataan General Hospital
Tenejero, Balanga City, Bataan 2100

Dr. Paulino J. Garcia Memorial Research & Medical Center
Mabini St., Cabanatuan City, Nueva Ecija 3100

Jose B. Lingad Memorial General Hospital
Dolores, San Fernando City, Pampanga 2000

Mariveles Mental Hospital
Mariveles, Bataan 2105

Southern Isabela General Hospital
Santiago, Isabela 3311

Talavera Extension Hospital
Talavera, Nueva Ecija 3114

CHD IV-A - CALABARZON

Batangas Regional Hospital
Kumintang Ibaba, Batangas City, Batangas 4200

CHD IV-B - MIMAROPA

Culion Sanitarium & Balala Hospital
Culion, Palawan 5315

Ospital ng Palawan
Puerto Princesa City, Palawan 5300

CHD V - Bicol Region

Bicol Medical Center (Don Susano Memorial Medical Center)
Naga City, Camarines Sur 4400

Bicol Regional Training & Teaching Hospital (Albay Provincial Hospital)
Rizal St., Legaspi City, Albay 4500

Bicol Sanitarium
Cabusao, Camarines Sur 4406

CHD VI - Western Visayas

Corazon Locsin Montelibano Memorial Regional Hospital
Lacson St., Bacolod City, Negros Occidental 6100

Western Visayas Medical Center
Mandurriao, Iloilo City, Iloilo 5000

Western Visayas Regional Hospital
Lacson St., Bacolod City, Negros Occidental 6100

Western Visayas Sanitarium
Sta. Barbara, Iloilo 5002

CHD VII - Central Visayas

Don Emilio Del Valle Memorial Hospital
Bood, Ubay, Bohol 6316

Don Jose S. Monfort Medical Center Extension Hospital (Western Visayas Medical Center)
Tabucan, Barotac Nuevo, Iloilo 5007

Eversley Childs Sanitarium
Jagobiao, Mandaue City, Cebu 6014

Gov. Celestino Gallares Memorial Hospital
M. Parras St., Tagbilaran City, Bohol 6300

St. Anthony Mother & Child Hospital
Basac, San Nicolas, Cebu City, Cebu 6000

Talisay District Hospital
San Isidro, Talisay, Cebu 6045

Vicente Sotto Sr. Memorial Medical Center
B. Rodriguez St., Cebu City, Cebu 6000

CHD VIII - Eastern Visayas

Eastern Visayas Regional Medical Center
Magsaysay Blvd., Tacloban City, Leyte 6500

Schistosomiasis Control & Research Hospital
Palo, Leyte 6501

CHD IX - Zamboanga Peninsula

Basilan General Hospital
Isabela City, Basilan 7300

Dr. Jose Rizal Memorial Hospital
Lawa-an, Dapitan City, Zamboanga del Norte 7101

Labuan Public Hospital (Zamboanga City Medical Center)
Labuan, Zamboanga City, Zamboanga del Sur 7000

Margosatubig Regional Hospital
Margosatubig, Zamboanga del Sur 7035

Mindanao Central Sanitarium
Pasobolong, Zamboanga City, Zamboanga del Sur 7000

Sulu Sanitarium
Jolo, Sulu 7400

Zamboanga City Medical Center
Dr. Evangelista St., Sta. Catalina, Zamboanga City, Zamboanga del Sur 7000

CHD X - Northern Mindanao

Camiguin General Hospital
Mambajao, Camiguin 9100

Mayor Hilarion Ramiro Sr. Regional Training & Teaching Hospital
Mindog, Maningcol, Ozamiz City, Misamis Occidental 7200

Northern Mindanao Medical Center
Capitol Cmpd., Cagayan de Oro City 9000

CHD XI - Davao Region

Davao Medical Center
Bajada, Davao City, Davao del Sur 8000

Davao Regional Hospital
Apokon Road, Tagum City, Davao del Norte 8100

CHD XII - Central Mindanao

Amai Pakpak Medical Center
Marawi City, Lanao del Sur 9700

Cotabato Regional & Medical Center
Sinsuat Ave., Cotabato City, Maguindanao 9600

Cotabato Sanitarium
Pinaring, Sultan Kudarat, Maguindanao Province 9605

CHD - Autonomous Region in Muslim Mindanao (ARMM)

Buluan District Hospital
Buluan, Maguindanao Province 9616

Dr. Serapio B. Montañer Jr. Al Haj Memorial Hospital
Lumpong, Malabang, Lanao del Sur 9300

Maguindanao Provincial Hospital
Limpongo, Shariff Aguak, Maganoy, Maguindanao Province 9608

CHD - Cordillera Administrative Region (CAR)

Baguio General Hospital & Medical Center
Governor Pack Road, Baguio City, Benguet 2600

Conner District Hospital
Conner, Kalinga-Apayao 3807

Far North Luzon General Hospital & Training Center
Luna, Apayao 3813

Luis Hora Memorial Regional Hospital
Abatan, Bauko, Mountain Province 2621

CHD - Caraga

Adela Serra Ty Memorial Medical Center
Capitol Hills, Tandag, Surigao del Sur 8300

Caraga Regional Hospital
Surigao City, Surigao del Norte 8400

CHD - National Capital Region (NCR)

Amang Rodriguez Medical Center
Sumulong Highway, Marikina, M.M.

Batanes General Hospital
Basco, Batanes 3900

Dr. Jose Fabella Memorial Hospital
Lope De Vega St., Sta. Cruz, Manila, M.M.

Dr. Jose N. Rodriguez Memorial Hospital
Tala, Caloocan City, M.M.

East Avenue Medical Center
East Avenue, Quezon City, M.M.

Jose R. Reyes Memorial Medical Center
Rizal Ave., Sta. Cruz, Manila, M.M.

Las Piñas General Hospital & Satellite Trauma Center
Bernabe Cmpd., Pulang Lupa, Las Piñas City, M.M.

Lung Center of the Philippines
Quezon Avenue, Quezon City, M.M.

National Center for Mental Health
Nueve de Pebrero St., Mandaluyong City, M.M.

National Children's Hospital
266 E. Rodriguez Sr. Ave., Quezon City, M.M.

National Kidney & Transplant Institute
Quezon Avenue, Quezon City, M.M.

Philippine Children's Medical Center
Quezon Avenue, Quezon City, M.M.

Philippine Orthopedic Hospital
Maria Clara St., Quezon City, M.M.

Philippine Heart Center
East Avenue, Quezon City, M.M.

Quirino Memorial Medical Center
Project 4, Quezon City, M.M.

Research Institute for Tropical Medicine
Filinvest Corporate City, Alabang, Muntinlupa City, M.M.

Rizal Medical Center
Shaw Blvd., Pasig City, M.M.

San Lazaro Hospital
Quiricada St., Sta. Cruz, Manila, M.M.

San Lorenzo Ruiz Women's Hospital
O. Reyes St., Santulan, Malabon, M.M.

Tondo Medical Center
Balut, Tondo, Manila, M.M.

Valenzuela Medical Center
Padrigal St., Karuhatan, Valenzuela City, M.M.

INDEX

Ampicillin + Sulbactam	Comp.	3.1.10	19
Anti-D Immunoglobulin (human anti-D immunoglobulin)	Comp.	4.2	29
Antilymphocyte Immunoglobulin (ALG) (equine)	Comp.	9.3.2	62
Antithymocyte Immunoglobulin (ATG) (equine)	Comp.	9.3.2	62
Anti-rabies serum (equine)	Comp.	4.2	29
Anti-tetanus serum (equine)	Comp.	4.2	29
Artemether + Lumefantrin	Core	3.3.2	26
Ascorbic Acid (vitamin C)	Core	12.2	68
	Core	21.1	109
Asparaginase	Core	9.5	63
Aspirin	Comp.	2.4.1	12
	Core	5.1.3	36
	Core	5.1.4	37
	Core	5.6	44
	Core	10.4	66
Atenolol	Core	5.1.2	35
	Core	5.1.3	37
	Core	5.1.4	37
	Core	5.1.5	38
	Core	5.2.2	40
Atracurium	Core	2.5.2	14
Atropine	Core	1.1.2	2
	Core	5.5	44
	Core	12.2	68
	Core	13.1	72
	Core	19.7	105
Azathioprine	Comp.	2.3	12
	Core	9.3.2	62
Azithromycin	Comp.	3.1.8	18

B

Bacitracin + Neomycin + Polymixin B	Comp.	20.4	107
Baclofen	Core	2.5.1	13
Balanced Multiple Maintenance Solution	Core	16.1.2	85
Balanced Multiple Replacement Solution	Core	16.1.2	85
Balanced Multiple Replacement Solution w/ pH 7.4	Core	16.1.2	85
Barium Sulfate	Core	17.2	96
Basiliximab	Comp.	9.1.2	60
BCG Vaccine	Core	4.3	30
Beclomethasone	Comp.	7.1.2	50
Benzoic Acid + Salicylic Acid	Core	18.1.2	97
	Core	18.4	99
Benzoyl Peroxide	Core	18.4	100
Benzyl Benzoate	Comp.	18.1.3	98
Beractant	Comp.	7.5	54
Betahistine	Comp.	1.6	6
Betamethasone	Comp.	14.1	76
	Comp.	18.2	98
Betaxolol	Comp.	19.5.2	104
Biperiden	Core	1.4.2	5

C

Cefadroxil	Comp.	3.1.4	16
Cefalexin	Core	3.1.4	15
Cefazolin	Core	3.1.4	16
Cefepime	Core	3.1.4	17
Cefixime	Core	3.1.4	16
Cefotaxime	Core	3.1.4	16
Cefoxitin	Core	3.1.4	16
Ceftaxidime	Core	3.1.4	17
Ceftriaxone	Core	3.1.4	17
Cefuroxime	Core	3.1.4	16
Celecoxib	Core	2.4.2	13
Cetirizine	Comp.	8.1	55
Chick Embryo Cell (purified, inactivated)	Core	4.3	32
Chloral Hydrate	Comp.	1.11.4	10
Chlorambucil	Core	9.1.2	59
Chloramphenicol	Core	3.1.5	17
	Core	19.2	102
	Core	20.3	107
Chlorhexidine	Core	22	114
	Core	18.3	99
Chloroquine	Comp.	3.3.2	26
	Core	3.3.2	26
Chlorphenamine (Chlopheniramine)	Comp.	8.1	55
Chlorpheniramine (see Chlorphenamine)			
Chlorpromazine	Core	1.11.2	9
Chlorpropamide	Comp.	14.8.2	82
Ciclosporin	Core	9.3.2	62
	Comp.	19.8	106
Cilostazol	Core	5.6	45
Cinnarizine	Comp.	1.6	6
Ciprofloxacin	Comp.	3.1.11	20
Cisplatin	Core	9.1.2	60
Clarithromycin	Comp.	3.1.8	18
	Core	3.1.14	21
Clindamycin	Comp.	3.1.7	17
Clobetasol	Comp.	18.2	98
Clofazimine	Core	3.1.15	22
Clomifene	Comp.	14.5	79
Clonazepam	Core	1.2	4
	Comp.	1.11.3	9
Clonidine	Comp.	5.2.2	41
Clopidogrel	Comp.	5.1.3	36
	Comp.	5.6	45
	Comp.	10.4	66
Cloxacillin	Core	3.1.10	19
Clozapine	Comp.	1.11.2	9
Coal Tar	Core	18.4	100
	Core	18.5	100
Co-Amoxiclav (amoxicillin + potassium clavulanate)	Comp.	3.1.10	20
Cobra Antivenin	Core	4.2	29
	Core	12.2	69

Codeine	Core	1.8.2	7
Colchicine	Core	2.1	11
Colestyramine	Comp.	13.5	74
Combined Glucose-Amino Acid Solutions	Core	16.4	91
Conjugated Equine Estrogen	Comp.	2.2.1	11
	Comp.	14.5	80
Conjugated Equine Estrogen +	Comp.	2.2.1	11
Medroxyprogesterone Acetate	Comp.	14.5	80
Conjugated Estrogen	Core	14.5	79
Cotrimoxazole (sulfamethazole + trimethoprim)	Core	3.1.12	21
Crotamiton	Comp.	18.1.3	98
Cyclophosphamide	Comp.	2.3	12
	Core	9.1.2	60
Cyproterone	Comp.	9.2	61
	Comp.	14.5	78
Cytarabine	Core	9.1.1	58

D

Dacarbazine	Core	9.1.2	60
Dactinomycin	Core	9.1.2	60
Dalteparin	Comp.	10.3	65
Danazol	Core	14.5	78
Dantrolene	Core	2.5.1	13
	Core	12.2	69
Dapsone	Core	3.1.15	22
Daunorobicin	Comp.	9.1.2	60
Deferiprone	Comp.	12.2	71
Deferoxamine	Core	12.2	69
Desflurane	Comp.	1.1.1	1
Desmopressin	Core	14.3	78
Dexamethasone	Core	1.9	8
	Core	14.1	76
	Comp.	19.3.1	103
Dextran, High Molecular Weight (Dextran 70)	Comp.	11.1	67
Dextran, Low Molecular Weight (Dextran 40)	Core	11.1	67
Dextromethorphan	Comp.	7.3	53
5% Dextrose in 0.3% Sodium Chloride	Core	16.1.2	86
5% Dextrose in 0.45% Sodium Chloride	Core	16.1.2	86
5% Dextrose in 0.9% Sodium Chloride	Core	16.1.2	86
5% Dextrose in Lactated Ringers	Core	16.1.2	86
5% Dextrose in Water	Core	16.1.2	86
10% Dextrose in Water	Core	16.1.2	86
Diazepam	Core	1.1.2	2
	Core	1.2	4
	Core	1.11.3	9
	Core	2.5.1	13
Diclofenac	Comp.	1.1.2	1
	Comp.	2.4.1	13
Dicyclomine (see Dicycloverine)			
Dicycloverine (Dicyclomine)	Core	13.1	72

E

F

G

H

I

Idarubicin	Comp.	9.1.2	60
Ifosfamide	Core	9.1.2	60
Imatinib	Comp.	9.5	63
Imidazoles (topical)	Core	18.1.2	97
Imipramine	Comp.	1.7	6
	Comp.	1.8.3	8
	Comp.	1.11.1	8
Immunoglobulin Normal, Human (IGIM)	Core	4.2	29
Immunoglobulin Normal, Human (IGIV)	Comp.	4.2	30
Indapamide	Comp.	5.2.1	40
Indinavir	Comp.	3.4.3	27
Indomethacin	Comp.	2.4.1	13
Influenza Polyvalent Vaccine	Core	4.3	31
Insulin Zinc Suspension, Human	Comp.	14.8.1	82
Interferon Alfa 2A (human)	Core	9.3.1	61
Interferon Alfa 2B (human)	Core	9.3.1	61
Intraocular Irrigating Solution (balanced salt solution)	Comp.	19.1	102
Iodamide	Comp.	17.2	94
Iodine	Core	22	114
	Core	14.7.2	81
Iodized Oil Fluid	Core	21.2	112
Iohexol	Core	17.2	95
Iopamidol	Core	17.2	95
Iopromide	Core	17.2	95
Iothalamate	Core	17.2	94
Ioversol	Core	17.2	95
Ioxithalamic Acid	Comp.	17.2	94
Ipratropium	Comp.	7.1.1	48
Ipratropium + Fenoteral	Comp.	7.2.1	52
Ipratropium + Salbutamol	Comp.	7.2.1	53
Irbesartan	Comp.	5.1.4	37
	Comp.	5.2.6	42
Irbesartan + Hydrochlorothiazide	Comp.	5.2.6	42
Irinotecan	Comp.	9.1.1	59
Iron Dextran	Comp.	21.2	113
Isoflurane	Core	1.1.1	1
Isoniazid	Comp.	3.1.16	22
Isoniazid + Ethambutol	Core	3.1.16	22
Isoniazid + Rifampicin	Core	3.1.16	22
Isoniazid + Rifampicin + Ethambutol	Core	3.1.16	23
Isoniazid + Rifampicin + Pyrazinamide	Core	3.1.16	23
Isoniazid + Rifampicin + Pyrazinamide + Ethambutol	Core	3.1.16	23
Isoniazid + Thiacetazone	Core	3.1.16	23
Isophane Insulin Human (recombinant DNA)	Core	14.8.1	81
Isosorbide Dinitrate	Core	5.1.2	35
Isosorbide-5-Mononitrate	Core	5.1.2	35
Isoxsuprine	Comp.	15.2	83
Itraconazole	Comp.	3.2	24
Ivermectin	Comp.	3.3.1	25

K - L

Kanamycin	Comp.	3.1.16	23
Ketamine	Core	1.1.1	1
Ketoconazole	Core	3.2	24
Ketoprofen	Comp.	1.1.2	2
	Comp.	2.4.1	13
Ketorolac	Comp.	1.1.2	2
Lactated Ringer's Solution (Ringer's Lactate)	Core	16.1.2	87
Lactulose	Comp.	13.9	74
Lagundi	Comp.	7.1.1	48
	Comp.	7.1.2	49
Lamivudine	Comp.	3.4.3	27
Lansoprazole	Comp.	13.4	73
Latanoprost	Core	19.5.4	104
Leucovorin Calcium (see Calcium Folinate)			
Leuproreline	Comp.	9.2	61
	Comp.	14.4	78
Levodopa + Carbidopa	Core	1.4.1	5
Levofloxacin	Comp.	3.1.11	21
	Comp.	3.1.16	23
Levothyroxine	Core	14.7.1	80
Lidocaine	Core	1.1.3	3
	Core	5.1.5	38
	Core	19.6	105
	Core	20.2	107
Lipids	Core	16.4	90
Lithium Carbonate	Core	1.11.5	10
Live Attenuated Measles Vaccine	Core	4.3	32
Live Attenuated Measles, Mumps and Rubella (MMR)	Core	4.3	32
Live Attenuated Mumps Vaccine	Core	4.3	32
Live Attenuated Rubella Vaccine	Core	4.3	32
Live Attenuated Trivalent Oral Polio Vaccine	Core	4.3	32
Live Attenuated Varicella Vaccine	Core	4.3	32
Lomustine	Core	9.1.2	60
Loperamide	Comp.	13.3	72
Loratadine	Comp.	8.1	55
Lorazepam	Core	1.2	4
	Core	12.1	68
Losartan	Comp.	5.1.4	38
	Comp.	5.2.6	42
Losartan + Hydrochlorothiazide	Comp.	5.2.6	42
Lynestrenol	Comp.	14.5	79

M

Magnesium Sulfate	Core	1.2	4
	Comp.	5.1.5	38
	Comp.	15.2	83
	Core	16.2	87

Mannitol	Core	1.9	8
	Core	6.0	46
	Core	19.5.6	105
Mebendazole	Core	3.3.1	25
Mebeverine	Comp.	13.8	74
Meclozine (meclizine)	Comp.	1.6	6
Mecobalamin	Comp.	21.1	110
	Comp.	10.1	64
Medroxyprogesterone	Comp.	2.2.1	11
	Comp.	14.5	79
	Comp.	14.5	80
Mefenamic Acid	Comp.	2.4.1	13
Mefloquine	Comp.	3.3.2	26
Megestrol	Core	9.2	61
Melphalan	Core	9.1.2	60
Meningococcal polysaccharide (Neisseria meningitidis) Vaccine	Comp.	4.3	33
Mercaptopurine	Core	9.1.1	58
Meropenem	Comp.	3.1.3	15
Mesalazine	Comp.	13.7	74
Mesna (sodium-2-mercaptoethane sulphonate)	Comp.	9.6	63
Metformin	Core	14.8.2	82
Methotrexate	Comp.	2.3	12
	Core	9.1.1	58
Methyldopa	Comp.	5.2.2	41
Methylene Blue	Core	12.2	70
Methylergometrine (methylergonovine)	Core	15.1	83
Methylergonovine (see Methylergometrine)			
Methylphenidate	Comp.	1.7	6
Methylprednisolone	Comp.	7.1.1	49
	Comp.	7.1.2	51
	Comp.	8.3	56
	Comp.	14.1	76
Metoclopramide	Comp.	13.10	75
Metoprolol	Core	5.1.2	35
	Core	5.1.3	37
	Core	5.1.4	37
	Core	5.1.5	38
	Core	5.1.6	40
	Core	5.2.2	40
Metronidazole	Core	3.1.9	18
	Core	3.1.14	21
	Core	3.3.2	26
Midazolam	Core	1.1.2	2
	Comp.	1.2	4
	Comp.	1.11.4	10
Minocycline	Comp.	3.1.15	22
Mitoxantrone	Comp.	9.1.2	60
Modified Fluid Gelatin (polymerisate of degraded succinylated gelatin	Comp.	11.1	67

Molgramostin (GM-CSF)	Comp.	10.2	65
Monobasic/Dibasic Sodium Phosphate	Comp.	13.9	74
Montelukast	Comp.	7.1.2	52
Morphine	Core	1.8.2	7
	Core	5.1.3	37
Multivitamins	Comp.	21.1	110
Mupirocin	Core	18.1.1	97
Mycophenolate Mofetil	Comp.	9.3.2	62
Mycophenolic Acid (as Mycophenolate Sodium)	Comp.	9.3.2	62

N

N-acetyl Penicillamine	Core	12.2	70
Nadroparin	Comp.	10.3	65
Nalbuphine	Core	1.8.2	7
Nalidixic Acid	Core	3.1.11	20
	Core	3.1.17	24
Naloxone	Core	12.2	70
Naltrexone	Core	12.2	70
Naproxen	Core	2.4.1	12
Nelfinavir	Comp.	3.4.3	28
Neomycin + Polymixin B + Fluocinolone Acetonide	Comp.	20.5	107
Neostigmine	Core	1.1.2	2
Nepafenac	Comp.	19.3.2	103
Netilmicin	Comp.	3.1.1	15
Nevirapine	Comp.	3.4.3	27
Nicardipine	Comp.	5.2.4	41
Nicotinamide (vitamin B3)	Core	21.1	109
Nifedipine	Core	5.2.4	41
	Comp.	5.2.4	41
Nimodipine	Comp.	5.2.4	41
Nitrofurantoin	Core	3.1.17	24
Nitroglycerin (see Glyceryl Trinitrate)			
Nitrous Oxide	Core	1.1.1	1
Norepinephrine	Core	5.1.1	34
	Core	5.4.2	44
Norethisterone	Comp.	14.5	79
Norfloxacin	Comp.	3.1.17	24
Nystatin	Core	3.2	24
	Comp.	18.1.2	97

O

Octreotide	Comp.	13.11	75
Ofloxacin	Comp.	3.1.11	20
	Comp.	3.1.16	24
	Comp.	19.2	103
	Core	20.3	107
Olanzapine	Comp.	1.11.2	9
Omeprazole	Core	13.4	73
Ondansetron	Comp.	9.6	63
	Comp.	13.2	72

Oral Rehydration Salts (ORS 75-replacement)	Core	16.1.1	84
Oseltamivir	Comp.	3.4.4	28
Oxacillin	Core	3.1.10	19
Oxantel + Pyrantel	Core	3.3.1	25
Oxiplatin	Comp.	9.1.2	60
Oxycodone	Comp.	1.8.2	7
Oxygen	Core	1.1.2	3
Oxymetazoline	Core	20.7	108
Oxytocin (synthetic)	Core	14.3	78
	Core	15.1	83

P

Paclitaxel	Core	9.1.1	59
Pancuronium	Core	2.5.2	14
Paracetamol	Comp.	1.3	5
	Core	1.5	5
Peginterferon Alfa 2A	Core	9.3.1	62
Penicillin G Benzathine (benzathine benzylpenicillin)	Core	3.1.10	19
Penicillin G Crystalline (benyzylpenicillin)	Core	3.1.10	19
	Core	12.2	70
Peritoneal Dialysis Solution	Core	16.5	91
Permethrin	Core	18.1.3	98
Pethidine (meperidine)	Core	1.8.2	7
Petrolatum/Petroleum	Comp.	18.6	101
Phenobarbital	Core	1.2	4
Phenoxymethyl Penicillin (penicillin V)	Core	3.1.10	19
Phenylephrine	Core	19.7	106
Phenytoin	Core	1.2	4
Physostigmine	Core	12.2	70
Phytomenadione (phytonadione, vitamin K1)	Core	12.2	70
	Core	21.1	109
Pilocarpine	Core	19.5.1	104
Piperacillin + Tazobactam	Comp.	3.1.10	20
Piribedil	Comp.	1.4.1	5
Pneumococcal Conjugate Vaccine	Core	4.3	32
Pneumococcal Polyvalent Vaccine	Core	4.3	32
Polygeline	Comp.	11.1	67
Potassium	Core	16.1.1	84
Potassium Chloride	Core	16.2	87
Potassium Free Dialysate Acetate-Based Containing	Core	16.6	92
Potassium Free Dialysate Bicarbonate-Based Containing	Core	16.6	92
Potassium Permanganate	Core	18.3	99
Potassium Phosphate	Core	16.2	87
Povidone Iodine	Core	18.3	99
	Comp.	19.2	103
	Core	22.0	114
Pralidoxime Chloride	Core	12.2	70
Praziquantel	Core	3.3.1	25
Prednisolone	Core	7.1.1	48
	Comp.	7.1.2	51
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Q - R

S

Salicylic Acid	Core	18.4	100
	Core	18.5	100
Sambong	Comp.	6.0	46
Saquinavir	Comp.	3.4.3	28
Selegiline	Comp.	1.4.1	5
Selenium Sulfide	Comp.	18.1.2	98
Sertraline	Core	1.11.1	8
Sevoflurane	Comp.	1.1.1	1
Silver Nitrate	Comp.	18.4	100
	Core	20.1	107
Silver Sulfadiazine	Core	18.1.1	97
Simvastatin	Core	5.3	43
Sirolimus	Comp.	9.3.2	62
Sodium Bicarbonate	Core	16.2	88
Sodium Calcium Edetate	Core	12.2	71
Sodium Chloride	Core	16.2	88
0.9% Sodium Chloride	Core	16.1.2	87
Sodium Dichloroisocyanurate	Comp.	22	114
Sodium Hyaluronate	Comp.	19.8	106
Sodium Hypochlorite	Comp.	18.3	99
	Comp.	22	114
Sodium Iodide 1311	Core	9.4	63
	Core	14.7.2	81
Sodium Nitrate	Core	12.2	71
Sodium Nitroprusside	Core	5.2.3	41
Sodium Sulfate	Core	12.1	68
Sodium Thiosulfate	Core	12.2	71
	Core	18.1.2	97
Somatostatin	Comp.	13.11	75
Spectinomycin	Comp.	3.1.2	15
Spironolactone (K-sparer)	Core	5.1.6	39
	Comp.	6.0	46
Standard Senna Concentrate	Comp.	13.9	74
Stavudine	Comp.	3.4.3	27
Sterile Water for Injection	Core	16.1.2	87
Streptokinase	Core	5.1.3	36
	Core	10.5	66
Streptomycin	Core	3.1.16	22
Succimer	Core	12.2	71
Sucralfate	Core	13.4	73
Sulfacetamide	Comp.	19.2	103
Sulfacetamide + Prednisolone	Comp.	19.2	103
Sulfadoxine + Pyrimethamine	Core	3.3.2	26
Sulfamethoxazole + Trimethoprim (see Cotrimoxazole)			
Sulfur	Comp.	18.1.3	98
Suxamethonium (succinylcholine)	Core	2.5.2	13

T

Tacrolimus	Core	9.3.2	62
Tamoxifen	Core	9.2	61

Tamsulosin	Comp.	14.6	80
Tegafur + Uracil	Comp.	9.1.1	59
Telmisartan	Comp.	5.1.4	38
	Comp.	5.2.6	42
Telmisartan + Hydrochlorothiazide	Comp.	5.2.6	42
Terbinafine	Comp.	18.1.2	98
Terbutaline	Core	7.1.1	47
	Comp.	7.1.2	49
	Core	15.2	83
Terizodone	Comp.	3.1.16	24
Testosterone	Core	14.5	78
Tetanus Immunoglobulin (human)	Core	4.2	29
Tetanus Toxoid	Core	4.3	33
Tetracaine	Core	1.1.3	3
Tetracosactide (cosyntropin)	Comp.	14.2	77
Tetracycline	Comp.	3.1.13	21
	Core	3.3.2	26
Theophylline (anhydrous)	Comp.	7.1.1	48
	Comp.	7.1.2	49
	Comp.	7.2.2	53
Thiacetazone	Comp.	3.1.16	24
Thiamazole (methimazole)	Core	14.7.2	81
Thiamine	Core	21.1	110
	Core	12.2	71
Thiopental Sodium	Core	1.1.1	1
	Comp.	1.2	4
Timolol	Core	19.5.2	104
Tinzaparin	Comp.	10.3	65
Tiotropium	Comp.	7.2.2	53
Tobramycin	Comp.	19.2	103
Tobramycin + Dexamethasone	Comp.	19.2	103
Topiramate	Comp.	1.2	4
Tramadol	Comp.	1.8.2	7
Tranexamic Acid	Comp.	10.6	66
Trastuzumab	Comp.	9.5	63
Travoprost	Comp.	19.5.4	105
Triamcinolone	Comp.	14.1	77
Trichloracetic Acid	Core	20.1	107
Trimetazidine	Comp.	5.1.2	36
Tropicamide	Comp.	19.7	106
Tsaang Gubat	Comp.	13.3	72
Tuberculin Purified Protein Derivative (PPD)	Core	4.1	29
Typhoid Vaccine	Core	4.3	33

U - V

Ursodeoxycholic Acid	Core	13.6	74
Valaciclovir	Comp.	3.4.1	27
Valproate Disodium / Valproic Acid	Core	1.2	4
	Comp.	1.11.5	10
Valsartan	Comp.	5.1.4	38
	Comp.	5.2.6	42

Valsartan + Hydrochlorothiazide	Comp.	5.2.6	42
Vancomycin	Comp.	3.1.6	17
Varicella Zoster Immunoglobulin (VZIG)	Comp.	4.2	30
Vasopressin	Comp.	14.3	78
Vecuronium	Core	2.5.2	14
Verapamil	Comp.	5.1.2	35
	Comp.	5.1.5	39
Vero Cell (purified)	Core	4.3	32
Vinblastine	Core	9.1.1	59
Vincristine	Core	9.1.1	59
Vitamin A (see Retinol)			
Vitamin B1 B6 B12	Comp.	21.1	111
Vitamin B12 (see Hydroxocobalamin)			
Vitamin B2 (see Riboflavin)			
Vitamin B3 (see Nicotinamide)			
Vitamin B6 (see Pyridoxine)			
Vitamin C (see Ascorbic Acid)			
Vitamin D2 (see Ergocalciferol)			
Vitamin E (see Alpha-Tocopherol)			
Vitamin Intravenous, Fat-Soluble	Core	16.2	88
Vitamin Intravenous, Trace Elements	Core	16.2	88
Vitamin Intravenous, Water-Soluble	Core	16.2	88
Vitamin K1 (see Phytomenadione)			

W - Y - Z

Warfarin	Core	5.1.3	36
	Core	5.6	45
	Core	5.7	45
	Core	10.3	66
Yellow Fever Vaccine	Core	4.3	33
Yerba Buena	Comp.	1.8.1	6
Zalcitabine	Comp.	3.4.3	27
Zidovudine	Comp.	3.4.3	27
Zinc	Core	21.2	112
Zolmitriptan	Comp.	1.3	5
Zolpidem	Comp.	1.11.4	10

National Formulary Committee

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