

REPUBLIC OF RWANDA



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National Pharmacy Policy

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Foreword

In Rwanda, medicine, health supplies, and technology each play an important role in the healthcare services provided to the population as well as the credibility of healthcare facilities. Making quality and safe medicines, health commodities, and technologies available and accessible to the people has always been a concern of the Government of Rwanda. Thus, since 1996, the Government has undertaken a series of quality improvement interventions and has held numerous discussions on how to meet and uphold the standards to make essential, high-quality health commodities and technologies accessible to all Rwandans, in accordance with the national health policy.

Although the analysis of the current pharmaceutical sector reveals that significant results have been achieved thus far, additional effort is still needed to achieve national public health goals. To fulfill its mission to provide quality healthcare for all its people, the Government has always taken bold steps in its health policy, such as the Alma Ata Declaration of 1978 and the Bamako Initiative of 1987. By adopting the National List of Essential Medicines, creating a pharmaceutical service unit within the Ministry of Health, and establishing a central medical store for essential medicines, commodities, and technologies and allowing exemption from entry duties on these items, Rwanda is boldly moving forward to develop its pharmaceutical sector so that quality healthcare can be available to its people.

The Pharmacy Policy as an integral part of the National Health Policy's aim to provide and continually improve upon the equitable availability of essential and affordable medications, health commodities and technologies that are of high quality and effective for patients. Through sustainable management systems, this policy will guide the proper use of these medicines, commodities, and technologies by healthcare providers and consumers in order to improve the health of the population.

The Pharmacy Policy represents the written expression of the Government of Rwanda's determination and commitment to improve the pharmaceutical sector. The policy also serves as a guide for national planning within the pharmaceutical sector and as a reference for all sector stakeholders and investors.

I call upon all stakeholders from government institutions, the private sector, and development partners involved in the pharmaceutical sector to align their interventions to the Pharmaceutical Policy in order to support Rwanda's continued steps in health development.


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Acronyms and Abbreviation

AIDS	Acquired Immunodeficiency Syndrome
ARI	Acute Respiratory Infection
ARV	Anti-Retro-Viral
BUFMAR	Bureau des Formations Medicales Agréées du Rwanda
CBHI	Community based health insurances
CPD	Continuous Professional Development
DPs	District Pharmacies
EAC	East African Community
EDPRS	Second Economic Development and Poverty Reduction Strategy
e-LMIS	Electronic Logistics Management Information System
FIP	Federation Internationale des Pharmaciens
GDP (PIB)	Gross Domestic Product (Produit Interne Brut)
HIV	Human Immunodeficiency Virus
HMIS	Health Management Information System
HR	Human Resources
ICT	Information Communication Technology
IDHS	Intermediate Demographic Health Survey
IEC	Information, Education and Communication
INN	International Non-proprietary Name
LMIS	Logistics Management Information System
MA	Market Authorization
MDGs	Millennium Development Goals
MI	Medicine Information
MINALOC	Ministry of Local Governance
MINEAC	Ministry of East African Affairs
MINECOFIN	Ministry of Finance and Economic Planning
MINEDUC	Ministry of Education
MINICOM	Ministry of Industry and Trade
MMI	Military Medical Insurance
MOH	Ministry of Health
MoH/CS	Directorate of Clinical Services in Ministry of Health
MPPD	Medical Production and Procurement Division
MSH	Management Science for Health
MTCs	Medicines and Therapeutics Committees
MYICT	Ministry of Youth and Information Communication Technology
NEML	National Essential Medicine List
NEPAD	The New Partnership for Africa's Development
NF	National Formulary

NMTC	National Medicines and Therapeutics Committee
NPC	National Pharmacy Council of Rwanda
NPMIC	National Pharmacovigilance and Medicine Information
NRA	National Regulatory Authority
OI	Opportunistic Infection
PICs	The Pharmaceutical Inspection Convention/Co-operation
PTF	Pharmacy Task Force
PV	Pharmacovigilance
R&D	Research and Development
RSB	Rwanda Standard Board
RDB	Rwanda development Board
RDHS	Rwanda Demographic Health Survey
RFMA	Rwanda Food and Medicine Authority
RMU	Rational Medicine Use
RNEC	Rwanda National Ethic Committee
RNP	Rwanda National Police
RSSB	Rwanda Social Security Board
SCMS	Supply Chain Management System
SPIU	Single Project Implementation Unit
SSFFC	Spurious, Substandard, Falsified False Labelled and Counterfeit, WHO program
STG	Standard Treatment Guidelines
TWG	Technical Working Group
AU	African Union
UMC	WHO Collaborating Centre for International Drug Monitoring
UNFPA	United Nations Population Fund
UR	University of Rwanda
USD	United State Dollars
USG	United State Government
WB	World Bank
WHO	World Health Organization

1. Introduction

The national pharmaceutical policy aligns itself to the Government vision for development of the health sector, as defined in Vision 2020, the Millennium Development Goals and the Economic Development for Poverty Reduction Strategy and the National Health Policy.

Significant efforts have been made to ensure availability and accessibility of quality of medicines, health commodities and technologies to prevent, detect and treat diseases. The government of Rwanda has put in place strategies to promote the management of health care delivery by strengthening the supply chain of medicines, health commodities and technologies, establishment of quality control capacities and good procurement practices, development of medicines registration procedures so as to achieve good control of pharmaceutical standards, promotion of research and development of alternative and herbal medicines, regulation of the pharmaceutical establishments, manufacture, imports, trade, sale of medicines, other health commodities and technologies.

The pharmacy policy will address among other challenges, the establishment of functional National Medicines Regulatory Authority that will implement all the regulatory functions, lack of local manufacturing facilities, lack of pricing policy of health commodities and technologies in private sector.

This policy is based on the following key priorities: the Quality assurance, accessibility and the rational use of medicines, other health commodities and technologies.

1.1 Country context

a) Demographic and geographic situation.

Rwanda is a landlocked country located in central- East Africa, in the Great Lakes region. Its area is 26,338 square kilometres. According to the National statistical Institute of Rwanda, in 2012, the Rwandan population was estimated at 10,537,222 inhabitants with a density of 416 inhabitants per square kilometre, one of the highest in Africa. The index of population growth is 2.6. The population is predominantly rural (83%) and 52% is less than twenty years old. Women were 52% and 48% men of the total population¹. The country is divided administratively into 5 provinces, 30 districts, 416 sectors and 2148 cells. The illiteracy rate declined from 34 percent to 15.5 percent among women and from 24 percent to 10.3 percent among men between 2005 and 2010².

¹ Rwanda National Census 2012, NISR

² Rwanda Demographic Health Survey (RDHS) 2005 and 2010

b) Socio-economic

On the socio-economic, according to the EDPRS II, Gross Domestic Product (GDP) of Rwanda was USD 644 per capita in 2012. Annual growth rate was 8.2 during the period of 2008-2012. In 2012, the service sector accounts for the largest share of Rwanda's Gross Domestic Product (GDP), 46 percent, followed by agriculture with 32 percent and industry with 22 percent¹. The percentage of people living below the poverty line was 44.9% in 2010-11, down from 56.7% in 2005-06³. Access to education has improved with the implementation of the nine year basic education program while completion rates have also increased significantly for both boys (79%) and girls (82%) by 2012. The percentage of people having access to safe drinking water was 74.2% and it was 10.8% for people having access to electricity for lighting⁴.

c) Health context

Rwanda is on the way to reach the Millennium Development Goals (MDGs) target in terms of Maternal and child mortality. The infant mortality ratio has decreased from 86 per 1000 live births in 2004 to 50 per 1000 live births in 2010, and the under-five mortality ratio declined from 152 to 76 per 1000 live births over the same period. The maternal mortality rate has decreased also from 750 per 100,000 live births to 476 per 100,000 but still short of the MDG target of 325 per 100,000 live births. Even though the above achievements have been assessed, neonatal mortality remains a concern, as it slowly decreased from 28/1000 live births (IDHS 2007-08) to 27/1000 live births (RDHS 2010). The vaccination coverage for children aged 12 to 23 months has grown up to 90% in 2010 from 75% in 2005.

The RDHS 2010 also indicates the decrease in malaria prevalence by almost half since 2007-08 (from 2.6 percent to 1.4 percent among children aged 6-59 months and from 1.4 percent to 0.7 percent among women aged 15-49 years)².

Considerable progress has been made in combating HIV/AIDS, as the HIV prevalence in Rwanda was 3% in 2010, one of the lowest in Sub-Saharan Africa². The prevalence of acute respiratory infection (ARI) also decreased significantly (the percentage of children who reported ARI in the two weeks preceding the survey was 17% in 2005 and 4% in 2010). However, diarrhea hardly decreased (the percentage of children who reported diarrhea in the two weeks preceding the survey was 14% in 2005 and 13% in 2010).

In the span of five years, the modern contraceptive prevalence rate more than quadrupled from 10% (RDHS 2005) to 45% in 2010. The total fertility rate decreased from 6.1% in 2005 (RDHS 2005) to 4.6% in 2010 (RDHS 2010), underlining the role of family planning in addressing population growth. In terms of Human Resource, Rwanda still has a challenge of shortage of

³ Enquête Intégrale sur les conditions de vie de ménages/The third Integrated household living conditions surveys (EICV) 2012.

⁴ Economic Development for Poverty Reduction Strategy II, 2012.

Human resources for health: 1/16001 per population ratio, Physician 1 / 30565 Pharmacist, 1/1,291⁵ Nurses and 1/10626 Lab technician

1.2 Situation of the Pharmaceutical sector

a) Quality assurance

Quality assurance of medicines refers to all the necessary measures taken to ensure that products quality is maintained from the point of production to the point of use. Rwanda has established quality assurance systems to ensure that health commodities and technologies circulating in the supply chain meet national and international standards of quality, safety and efficacy. Despite all these efforts, the quality assurance framework has limited capacity in terms of infrastructure, human and financial resources.

b) Legislation

Pharmaceutical laws and Ministerial orders have been initiated, developed and gazetted to ensure that pharmaceutical services are properly regulated. The following documents have been put in place:

1. Law determining “The Art of Healing”
2. Law relating to the regulation and inspection of food and pharmaceutical products
3. Law governing narcotic drugs, psychotropic substances and precursors in Rwanda
4. Law establishing Rwanda Food and Medicines Authority and determining its mission, organization and functioning
5. Law on organisation, functioning and competence of the Council of Pharmacists

c) Regulation

In Rwanda Pharmacy sector is regulated at two levels: medicines, other health commodities and technologies and Pharmacy professionals.

- Currently, the Pharmacy department in the Ministry of health combines both the responsibilities of policy formulation and regulatory activities to provide minimum services related to product evaluation and registration, import and export control, licensing and inspection of pharmaceutical establishment, supply chain monitoring, pharmacovigilance and post-marketing surveillance, pharmaceutical products advertisement and promotion.
- A National Pharmacy Council (NPC) was established by the law n° 45/2012 of 14/01/2013 to regulate the pharmacy profession.

4 Annual Report of the Ministry of Health 2012.

d) Rational use of Medicines, Health commodities and technologies

Rational use of medicines (RUM), is when patients receive medications appropriate to their clinical needs in doses that meet their requirements, for an adequate period of time and at the lowest possible cost. It includes medicines information, prescribing and dispensing.

Rwanda has established various mechanisms to promote medicines information, prescribing and dispensing; including the development of treatment guidelines and protocols, the national formulary, a national essential medicine list, with their subsequent periodic reviews.

In addition, pharmacovigilance systems have been established at different levels.

Despite of these initiatives, Rwanda faces a number of challenges, including limited adherence to good prescribing and dispensing practices, and low reporting of adverse reactions. Also, there is inadequate awareness among the community on rational use of medicines, and inadequate reference materials at the health facilities.

e) Selection

Selection of medicines is a process of identifying medicines to satisfy the health care needs of the majority of the population.

The choice of medicines depends on many factors such as the prevailing diseases, treatments guidelines, level of healthcare delivery and financial resources.

Rwanda encounters challenges in medicines and therapeutic committees not performing optimally due to limited capacity and competences in pharmaceutical management.

f) Procurement, storage and distribution

Procurement, storage and distribution of health commodities are key pillars of an effective healthcare system. In Rwanda, procurement functions are mainly fulfilled by Central Medical Store “currently Medical Production and Procurement Division” (MPPD), Referral Hospitals, BUFMAR and private pharmacy wholesalers.

The Coordinated Procurement and Distribution System (CPDS) has improved the availability of HIV related Health commodities and technologies.

For public procurement of Health commodities and technologies, an international competitive bidding is used. The national procurement regulation law and stringent regulations adopted by partners are used for the procurement processes.

The overall storage infrastructure and equipment for Health commodities and technologies need improvement in terms of capacity, design, maintenance and security, transport and information management systems.

g) Local Manufacturers of Medicines

Despite difficulties in the development of local capacity for the production of essential medicines, Rwanda has made some efforts to create a comprehensive environment for investment. Rwanda must continue to work through the national investment authorities in providing guidance and incentives to create manufacturing capacity for specific investments in pharmaceutical industry. Rwanda has only one pharmaceutical factory that produces some essential medicines.

h) Affordability

Currently there is no Pharmaceutical Pricing Policy both in public and private sector; hence this may render the prices of Health commodities and technologies to be generally high and less affordable to the majority of the population. However, in the absence of the pricing policy, the Ministry of Health in collaboration with stakeholders established tariffs of services rendered in public health facilities.

i) Health product Financing

The Government guarantee and commitment to an appropriate level of sustainable financing is an essential element in the success of the entire health sector and in particular, the pharmaceutical sub sector.

In Rwanda Health commodities and technologies are financed through fiscal budgetary allocations, development partners, insurance schemes, private sector and out of pocket expenditure.

The population covered by any health insurance scheme in Rwanda is 96 % (Rwanda health insurance indicators: progress 2010(DHS & EICV) sector performance indicators HSSPII & III trends 2000 to 2010 (baseline) and target for MDG (2015).

j) Pharmaceutical Research and Development

Research and development play a major role in industrial transformation and economic growth, as well as in healthcare delivery. Pharmaceutical R&D is driven by current developments in disease control and treatment, in particular the need for enhanced use of diagnostics; early onset of treatment and use of newer, safer, more efficacious and age-appropriate medicines.

The Pharmaceutical services in the Ministry of Health regulate clinical trials, in collaboration with the Rwanda National Ethics committee (RNEC).

The School of Pharmacy at the University of Rwanda and other research institutes have been undertaking various forms of research on medicines and treatment, including clinical trials and product development.

Rwanda is endowed with many medicinal flora and fauna, but there is limited investment to exploit this endowment in making products for use in healthcare. In cases where research has shown the presence of pharmacological activity in plants, the research ends in only publications, but not in products development.

There is a need to increase and prioritize funding for pharmaceutical research and development activities that address local needs and attract investment.

k) Information and Communication Technology (ICT)

There have been numerous advances in the field of ICT, and many of these have been embraced in various facets of the pharmaceutical sector. ICT use in pharmaceuticals includes technological advancements in design and automation of processes, including procurement and logistics management (e-LMIS), dispensing of health commodities (EMR), online reporting on medicines safety and quality monitoring (WHO/UMC & SSFFC), availability and consumption of Health commodities and technologies (HMIS).

The country has made significant strides towards narrowing the digital divide within and the rest of the world, through infrastructure expansion and upgrading; and through an enabling legal and institutional framework. However, there remain some gaps in infrastructural and HR capacity for the full application of ICT in the pharmaceutical sector.

Challenges relating to ICT in the pharmaceutical sector include:

- a) Insufficient infrastructure, equipment, and skilled human resource in ICT for improved efficiency and effectiveness of pharmaceutical services.
- b) Absence of ICT in regulatory functions (e.g. electronic submission of dossiers for registration of medicines, importation licenses, licensing of pharmacies), hindering adoption of best practices.

To address the challenges of information technology in pharmaceutical sector, the Government is investing in ICT infrastructure for effective operation of public pharmaceutical services, including procurement, distribution, regulation and quality control. This is also evidenced in the regional initiatives for the pharmaceutical regulatory harmonization and integration.

l) Human Resource for the Pharmaceutical Sector

Rwanda recognizes the insufficient numbers of appropriately trained human resources in the sector. The existing gaps are increasing as the demand increases.

The pharmaceutical work force in Rwanda includes pharmacists and pharmacy technicians and of the available 500 pharmacists, but only 39% are serving in the public sector. 40% of Pharmacists employed in the public sector are in Kigali City while 60% are in other provinces. On the other hand pharmacists employed in the private sector, 75% are in Kigali City while 25% are in other provinces.

m) Pharmaceutical Human Resource Development

The current training content and mechanisms for deployment of pharmaceutical personnel have been identified as major constraints to their utilization. Pharmacy training is largely oriented towards clinical practice and academic knowledge, with minimal emphasis on other skills required to handle pharmaceutical sector functions, like procurement and supply, manufacturing and trade.

2. Policy orientation

2.1 Vision and Mission

Vision

Rwandan population's health is improved through sustainable provision and rational use of equitably accessible and affordable essential quality Health commodities and technologies .

Mission

The mission of the Rwandan Pharmaceutical sector policy is to provide and continually improve equitable availability of essential and affordable quality, safe and effective Health commodities and technologies through a sustainable management systems and ensuring proper use by healthcare providers and consumers for improved health of the population.

2.2 Values and guiding principles

The Policy is based on the following guiding principles and values:

1. **The Right to Health:** Access to essential medicines is an integral part of the fundamental right to health enshrined in the Constitution. The Policy provides for strategies to ensure equitable access to essential medicines for all citizens.
2. **People-centered services:** The pharmacy policy ensures universal demand and access to affordable quality and safe Health commodities and technologies; it is focused on the well-being of individuals and communities.
3. **Essential Medicines:** defined as those that satisfy the priority health care needs of the population; selected with due regard to public health relevance, evidence on efficacy and safety and comparative cost-effectiveness. Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford.
4. **Good Governance:** The medicines supply chain and pharmaceutical regulation are vulnerable to inefficiency and unethical practices, with adverse consequences for Government, individuals and healthcare providers. Good Governance in the pharmaceutical sector entails efficiency, transparency, accountability, institutional

integrity and moral leadership. Checks and balances are required at each step in the pharmaceutical supply chain.

5. **Regulation:** The process by which consumers obtain pharmaceuticals is complex. It involves several intermediaries and has inherent moral hazards and information asymmetries. Pharmaceutical systems do not always guarantee rational decision making that primarily benefits the consumer. Therefore, strong regulatory enforcement is required to safeguard the interests of the consumer.
6. **Multi-Sector and International Collaboration:** The pharmaceutical sector is a distinct economic entity with linkages across several sectors and operating in a highly globalized and interconnected manner. Multi-sector and international collaboration and cooperation are essential to comprehensively address pharmaceutical sector issues and to safeguard public health and safety.
7. **Effective Partnerships:** The Policy affirms the importance of stakeholder involvement and coordination; aligns partnership coordination in the pharmaceutical sector with the current health sector coordinating framework and outlines key roles and obligations of stakeholders, as well as a framework for measuring progress in policy implementation.

2.3 Policy Objectives

To achieve its mission, the pharmacy policy has identified the following objectives:

1. To build a Quality Assurance systems to ensure safety, effectiveness and efficacy of health commodities and technologies from the manufacturers to consumers
2. To promote the Rational Use of Health commodities and technologies by both healthcare providers and the consumers.
3. To strengthen health product information and pharmacovigilance system.
4. To ensure adequate availability and equitable accessibility of assured quality of essential Health commodities and technologies at affordable cost to an individual and the community in both public and private sector.
5. To strengthen the national health commodities and technologies supply system in order to ensure regular supply of essential health commodities and technologies at all times in sufficient quantities to all health facilities.
6. To promote investment in local manufacturing of health commodities and technologies .
7. Strengthen the pharmaceutical sector operational capacities in order to enhance performance and sustainability.

2.4 Policy direction

Objective 1: To build Quality Assurance systems to ensure safety, effectiveness and efficacy of Health commodities and technologies from the manufacturers to consumers.

Strategies to address this objective are below:

- 1) Operationalize Competent Medicines Regulatory Authority;
- 2) Reinforce regulation of Health commodities and technologies supply chain, pharmaceutical practices and pharmacy professionals;
- 3) Ensure the development and compliance to Quality Assurance standards
- 4) Ensure quality and safety of health product through all regulatory functions (licensing of premises and practitioners; health product evaluation and registration, inspections, surveillance and quality control testing, control of promotion and advertisement, import and export controls)
- 5) Regularly review the legislation and implementing guidelines to respond the emerging situation
- 6) Establish regulations for online sale of health commodities and technologies and implement strategies that encourage consumers to buy medications from licensed pharmaceutical outlets.

Objective 2: To promote the Rational Use of Health commodities and technologies by both healthcare providers and the consumers.

Strategies to address this objective are below:

- 1) Ensure the principles of rational use of Health commodities and technologies are incorporated in the curricula of all institutions involved in the training of health professionals.
- 2) Establish and implement a systematic and comprehensive programme of in-service training and other suitable continuing education activities on rational medicine use.
- 3) Carry out regular review of Standard Treatment Guidelines, National Formulary and National Essential Medicines list and ensure their application at various level of health system.
- 4) Develop and monitor implementation of Pharmaceutical Best Practices.
- 5) Establish mechanisms to enforce good prescribing practices
- 6) Putting a mechanism for monitoring rational use of Health commodities and technologies .
- 7) Establish a National Medicines and Therapeutic Committee and reinforce existing hospital Medicines and Therapeutics Committees.

Objectives 3: To strengthen Pharmacotherapeutic information and Pharmacovigilance system.

Strategies to address this objective are below:

- 1) Collaborate with other stakeholders to integrate basic information on rational Health commodities and technologies use into the educational curricula and community sensitization.
- 2) Undertake comprehensive and sustainable Information, Education and Communication (IEC) programme to educate the general public on rational Health commodities and technologies use.
- 3) Strengthen the National Pharmacovigilance and Medicines Information Center (NPMIC) with collaborative efforts of all stakeholders.

Objectives 4: To ensure adequate availability and equitable accessibility of assured quality of essential Health commodities and technologies at affordable cost to an individual and the community in both public and private sector .

Strategies to address this objective are below:

- 1) Regularly review the national Essential medicines list according to pre-defined guideline and monitor its implementation
- 2) Improve national procurement planning of Health commodities and technologies based on country needs
- 3) Establish mechanisms to ensure that the health commodities and technologies are affordable
- 4) Streamline procurement processes to provide a timely, responsive and efficient procurement services while complying with applicable regulation and guidelines
- 5) Develop and regularly review a pricing policy and ensure its implementation
- 6) Encourage the equitable distribution of pharmacy services both in rural and urban areas

Objectives 5: To strengthen the national Health commodities and technologies supply system in order to ensure regular supply of essential Health commodities and technologies at all times in sufficient quantities to all health facilities.

Strategies to address this objective are below:

- 1) Put in place an effective and efficient distribution system of Health commodities and technologies
- 2) Ensure the selection and quantification processes are adequately coordinated to take in to account of the needs of particular level of health care delivery

- 3) Ensure that private sector is part of national supply system to provide health product of assured quality and within price control framework.
- 4) Encourage the private sector to avail essential Health commodities and technologies in country
- 5) All health product supply establishments in the private sector shall have to comply with all the rules and prescribed requirements of registration, licensing, import, transport, storage and distribution.
- 6) Ensure adequate capacity in Health commodities and technologies management in order to improve stock management and prevent losses through expiries and pilferage.
- 7) Improve storage infrastructure and equipment for Health commodities and technologies needs in terms of capacity, design, maintenance and security to meet applicable standards.

Objectives 6: To promote investment in local manufacturing of Health commodities and technologies .

Strategies to address this objective are below:

- 1) Provide the required technical support and incentives to the private sector for the promotion of local manufacturing of Health commodities and technologies.
- 2) Develop and implement the policies, regulations and plans for the local manufacture of essential Health commodities and technologies.
- 3) Attract global pharmaceutical companies to establish pharmaceutical manufacturing facilities in Rwanda or invest in joint ventures with local investors.

Objective7: Strengthen the pharmaceutical sector operational capacities in order to enhance performance and sustainability.

Strategies to address this objective are below:

a) For Human Resources:

1. To develop and standardize scope of pharmaceutical services performed at all level of healthcare system
2. Review and implement pharmaceutical schemes of service to attract and retain appropriate HR for the pharmaceutical services.
3. Develop and implement a national pharmaceutical human resources development plan to train, attract and retain personnel, as an integral part of the overall national human resources for health development plan.

4. Strengthen collaboration and cooperation with training institutions in the training of sufficient competent pharmacy professionals.
5. Ensure a sustainable equitable distribution of pharmaceutical professionals.
6. Institutionalize the CPD for all pharmacy practitioners in all institutions.
7. Enact legislation to recognize pharmaceutical specializations
8. Expand the variety and scope of postgraduate courses to meet the growing requirements for pharmacy specialists in Rwanda and the sub-region.
9. Through the Pharmacy Council foster multilateral collaboration to enable mutual recognition of pharmaceutical personnel in the context of regional integration and international cooperation.
10. Encourage and support the review, harmonization and regulation of pharmaceutical training curricula and standards to align with defined needs of sector.

b) Financing:

1. Explore areas where public private sector engagement will be optimized to benefit the long term financing of the pharmaceutical sector.
2. Establish a financial strategy for self-sustainability and improvement of pharmaceutical sector
3. Promote collaboration with the private sector and development partners in strengthening pharmaceutical sector.

c) Research and development

1. Build capacity of the country in conducting research in the pharmaceutical sector.
2. Promote collaboration and partnership with national, regional and international research institutions and other stakeholders.
3. Identify and regularly update priority areas for research in pharmaceutical sector and mobilize different stakeholders to invest in this research agenda
4. Increase support for pharmaceutical research (including operational research) and utilize research findings to further develop health policies and practices.
5. Encourage, motivate and support health institutions and professionals to conduct R&D on medicines including Traditional Medicine.

6. Encourage pharmaceutical drug and device research and development (R&D) by creating regulations that ensure robust development programs. Regulate preclinical testing, phase 1 type clinical trials (absorption, distribution, metabolism and excretion), phase-2 and phase-3 type clinical trials establishing safety and efficacy, and post-marketing Phase 4-type clinical trials including those to support new indications and meet post-approval commitments to the Competent Regulatory Authority.
7. Encourage the appropriate use of current and the development of new methods to characterize the safety, efficacy and effectiveness of drugs and medical devices. This includes the use of pragmatic clinical trials and observational studies using data obtained from various sources including post-marketing safety surveillance reports, insurance claims and real world study designs.
8. Encourage and support the establishment of clinical trials and bioequivalence testing centres for pharmaceutical research.

d) Infrastructure

1. Establish standard for infrastructures and equipment for pharmaceutical services at different levels of health system.
2. Avail adequate infrastructures and equipment for effective pharmaceutical services and ensure adherence to established standards.

3. Governance framework

3.1. Organization and management of pharmacy sector

The organization of the Pharmaceutical sector in Rwanda is in line with the Health system framework. In this specific area, there is both public and private sector involvement in the provision of Health commodities and technologies and pharmaceutical services in general.

The Ministry of health through pharmaceutical department does the coordination of the pharmaceutical sector, which is in charge of the policy, regulation and accessibility to Health commodities and technologies interventions.

The pharmaceutical supply chain system is organized into different levels with different stakeholders:

- At national level, Central Medical Store (currently MPPD) and faith based medical store (BUFMAR) supply district pharmacies and public health programmes as well as referral hospitals;
- The private wholesalers supply retail pharmacies and district pharmacies together with referral hospitals in case needed;

- At decentralized level, there are district pharmacies that supply public health facilities (hospitals, health centres and post) and the community level. Most of Health commodities and technologies used in Rwanda are imported as the local pharmaceutical production is not fully developed to produce for the national needs.

3.2. Partnership and coordination

The pharmaceutical sector is a distinct economic entity with linkages across several sectors and operating in a highly globalized and interconnected manner. Therefore efforts have been made to connect Rwanda Pharmacy sector with other partners (national, regional and international).

- National level: different ministries and other entities intervene in pharmaceutical sector, with the following responsibility:
 - MoH is responsible of policies formulation and coordination of their implementation.
 - MINECOFIN is responsible of financing the pharmacy sector and facilitate accessibility to Health commodities and technologies through tax exemptions
 - RSSB and other Health Insurances contribute to increase financial accessibility to Medicines, other Health commodities and new technologies.
 - MINICOM is responsible of regulation of trade and investment including health product related
 - MINEDUC, responsible for development of policies and strategies for the education of pharmacy professionals among others.
 - MINALOC contribute in management of district health facilities including pharmacies
 - RNP contribute to the mitigation of illicit circulation (importation, exportation, distribution and dispensation) of drugs and health related commodities and technologies and fight against their use
 - MYICT responsible for laying strategies that addresses the illicit use and abuse of drugs in younger generation especially the youth.
 - RSB establish quality standard of Health medicines and other health related commodities and new emerging technologies
 - RDB responsible for encouraging, promoting and facilitate investment in pharmaceutical sector
 - National Pharmacy Council will be responsible for regulating pharmacy professionals and accreditation of quality education
 - Development Partners provide both financial and technical support to the pharmaceutical sector

- Regional level:
 - EAC secretariat coordinate harmonization of pharmacy regulation and development of policies, legislation , resource mobilization and capacity building
 - NEPAD, support the harmonization of pharmaceutical regulation within Africa
 - AU, support the harmonization of pharmaceutical regulation within Africa
 - UMC/Africa: responsible for coordinating medicine safety monitoring in Africa
 - World Health Organization (WHO)
- International:
 - World Health Organization (WHO)
 - PICs: lead the international development, implementation and maintenance of harmonised GMP standards and quality systems of inspectorates in the field of medicinal products.
 - International Federation of Pharmacist, as forum of pharmacy councils and association
 - Collaboration with other countries National Medicines Regulatory Authorities
 - Collaboration with donors to support the pharmaceutical sector financing

3.2. Monitoring and Evaluation

Performance of the National Pharmaceutical Policy needs regular monitoring and periodic evaluation. These activities will help identify necessary corrective measures both during the implementation and the review status of the policy. It enables the government to keep track of the performance of the different players in the implementation of the policy. In view of the above, the Government through the Ministry of Health will ensure the establishment of strong monitoring and evaluation systems to facilitate improvements in the Pharmaceutical Policy implementation.

The monitoring and evaluation will be done through following strategies:

1. Develop and reinforce systems to monitor pharmaceutical sector including the necessary tools and appropriate performance indicators and allocate adequate resources.
2. Define indicators for the monitoring and evaluation for the implementation of this Policy.
3. Establish mechanisms for support, monitoring and evaluation of performances and sanctions under laws at all levels.
4. Institutionalize monitoring and evaluation of the policy through regular review, assessment and survey.
5. Ensure the effectively utilization of the results of monitoring and evaluation for the improvement of further planning and implementation of pharmaceutical policy

4. References

1. Annual Report of the Ministry of Health 2012
2. Economic Development for Poverty Reduction Strategy II, 2012
3. Enquête Intégrale sur les conditions de vie de ménages/The third Integrated household living conditions surveys (EICV) 2012
4. Progress Rwanda health indicators June 2012
5. How to develop and Implement a National Drug Policy, WHO, Geneva, second edition 1998
6. INTERNATIONAL STANDARD ISO 9000 third edition, 2005
7. Kenya National Pharmaceutical Policy, 2008
8. National Supply Chain Assessment August 2013
9. Rwanda Demographic Health Survey (RDHS) 2005 and 2010
10. Rwanda National Census 2012, NISR
11. The Fourth Rwanda Population and Housing Census 2012, National Institute of Statistic of Rwanda, 2014
12. Third Health Sector Strategic Plan, July 2012 – June 2018, Government of Rwanda, Ministry of Health 2012
13. WHO Data Collection Tool for the Review of Drug Regulatory Systems, WHO Geneva 2007