KENYA PHARMACEUTICAL SECTOR DEVELOPMENT STRATEGY

UNITED NATIONS
INDUSTRIAL DEVELOPMENT ORGANIZATION

Kenya Pharmaceutical Sector Development Strategy

Global UNIDO Project:
Strengthening the local production of essential medicines in least developed and developing countries

In collaboration with
Ministry of Industrialization
Ministry of Medical Services
Pharmacy and Poisons Board
National Quality Control Laboratory
Federation of Kenya Pharmaceutical Manufacturers

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FOREWORD FROM THE PERMANENT SECRETARY OF THE MINISTRY OF MEDICAL SERVICES

The overall goal of the Ministry of Health (Ministry of Medical Services and Ministry of Public Health and Sanitation) is defined in the National Health Policy (2012-2030) which aligns the goals of the health sector and the Constitution of Kenya, 2010 and coordinates the delivery of the health mandate. Its main functions shall be to:

i. Develop national policy and legislation, standard setting, national reporting supervision, sector coordination and resource mobilization

ii. Offer technical support with emphasis on planning, development and monitoring of health services and delivery standards throughout the country

iii. Monitor the quality and standards of performance of the County Governments and community organizations in the provision of health services

iv. Provide guidelines on tariffs chargeable for the provision of health services

v. Conduct studies required for administrative or management purposes

The delivery of pharmaceutical services is part of the broad policy mechanisms as stipulated in the Kenya National Pharmaceutical Policy (KNPP). This states that pharmaceuticals are critical to the economic and social development of Kenya. Medicines treat diseases, save lives and promote health. They are also a core component of the Right to Health, the key objective being universal access to quality essential medicines, essential health technologies and pharmaceutical services in Kenya. One of the objectives of the KNPP is to **"Promote local production, research and innovations of essential health products and technologies"**. The Policy ideal of self sufficiency in quality medicines requires the enabling regulatory framework which will facilitate recognition by stringent inspection agencies.

Access to essential medicines will be an avenue for the country to meet the Millennium Development Goals to reduce the child mortality rate and to combat HIV, Malaria and other diseases, as well as helping to establish public/private partnerships to ensure economic development as envisaged in Vision 2030.

Kenya is currently the hub of the pharmaceutical manufacturing sector in the East African region and it benefits greatly from initiatives on pharmaceutical development. The East African Community Regional Pharmaceutical Manufacturing Plan of Action (2012-2016) recommends improvement of the business environment and the strengthening of regulatory capacity and human resources. The plan of action is in harmony with the Kenya Pharmaceutical Sector Development Strategy (KPSDS) which is the main vehicle for implementing the KNPP component concerned with local pharmaceutical production. The seven Strategy Components of the KPSDS envisage ambitious solutions to the core challenges to the pharmaceutical sector in Kenya, as outlined in the Kenya Pharmaceutical Profile.

Of particular interest is the plan to define the Kenya GMP roadmap as a stepwise approach to industrialization to international standards within a given period. It is an adjunct

to keeping abreast with international standards proposed in Vision 2030. This recognizes the regulatory requirements in the manufacture of pharmaceuticals, their marketing authorization and distribution chain. It means that, with appropriate controls on importation and exportation licensing, the country would largely be free of the widespread problem of substandard medicines as well as the counterfeits which occasionally infiltrate the pharmaceutical market. The national quality assurance scheme within the distribution chain is monitored through the pharmacovigilance activities and technical analysis at the National Quality Control Laboratory. Support and enhancement of this regulatory capacity will address these shortcomings.

As much as the Strategy Components address human capital issues and infrastructure, it is equally important that the sector should review policies and identify avenues for access to finance. The pharmaceutical industry faces complex requirements which involve meeting product quality in conformance to GMP standards. In order to spur local pharmaceutical production, the need for the establishment of supportive structures for common use cannot be over emphasized. The costs of carrying out certain tests prior to marketing authorization can be prohibitive, especially for less well established manufacturers. Whereas such needs may be beyond immediate reach, nonetheless, they represent another opportunity for investment in clinical research to establish bio-equivalences. Other important areas include metrology to ensure compliance of machinery, equipment and instruments and there are many more.

The Ministry of Health has the responsibility of implementing the Constitution with regard to the right to health and access to quality essential medicines by providing the oversight policies to promote pharmaceutical manufacturing. We welcome the UNIDO global project on strengthening the local production of essential medicines as critical at this time in Kenya. We look forward to working with UNIDO to ensure that the Kenya Pharmaceutical Sector Development Strategy is implemented. The Government will provide the enabling environment for successful implementation of the strategy.

M.W.NGARI (MS), CBS
PERMANENT SECRETARY
MINISTRY OF MEDICAL SERVICES

FOREWORD FROM THE PERMANENT SECRETARY OF THE MINISTRY OF INDUSTRIALIZATION

The Ministry of Industrialization (MOI) in Kenya is the partner Government Ministry to the United Nations Industrial Development Organization (UNIDO). It is involved in the formulation of the National Industrialization Policy Framework for Kenya which seeks to establish harmony between environmental conservation and the development of sustainable industries and to attract investment in line with Kenya Vision 2030. The mission of the Ministry is to facilitate and expand a globally competitive and innovative industrial sector by creating an enabling environment. This will be achieved through the formulation of an Industrial Development Policy; quality control and standardization; intellectual property rights policy and the settlement of intellectual property rights disputes; industrial training and capacity building; attracting local and foreign direct investment; promotion of industrial research and development, together with innovation and technology transfer; cement production; industrial tooling and machining; finance and venture capital for industrial development; provision of market linkages and access to finance for micro, small and medium industries; and training, infrastructure and business development services for micro, small and medium industries.

The socio-economic goals to which Kenya Vision 2030 aspires focus on addressing the Millennium Development Goals which promise a prosperous nation through job creation as a result of industrialization, thus improving income and reducing poverty; and through provision of quality medicines to improve treatment of diseases by ensuring access to essential medicines that will lower the incidence of disease, child mortality and improve maternal health.

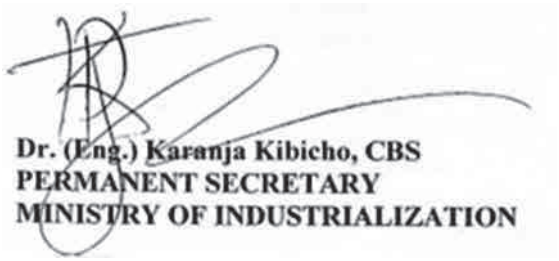
The hub of the pharmaceutical manufacturing industry in the region is based in Kenya. Kenya Vision 2030 anticipates overall growth in market share and the East Africa Community Industrialization Policy and the Kenya Industrialization Framework identify pharmaceutical manufacturing as a priority industry amongst agro-processing; fertilizers and agro chemicals; pharmaceuticals; petro-chemical and gas processing; iron ore and other mineral processing industries, as well as energy and bio-fuels. In particular, the Kenya Industrialization Policy emphasizes industrial growth and international benchmarking.

The Ministry of Industrialization and the Ministry of Medical Services have recognized the important role of the local pharmaceutical industry in the manufacture of essential generic medicines from both a health and an economic development perspective. Kenya is a country with undoubted potential and this initiative has already identified the challenges that the sector faces which inhibit rapid growth and the ability to contribute to improved health, as well as the economic development of the country. The findings from these investigations were documented in a “Pharmaceutical Sector Profile” in 2010.

One main underlying factor is that the pharmaceutical industry is a complex one with many stakeholders involved. Following the publication of the Profile, UNIDO, together with members of the Working Group, formulated the sector development strategy which was presented and endorsed by stakeholders in a Round Table forum on 27 August 2011. The inputs of the stakeholders have since been incorporated in the draft document. The draft KPSDS also took into consideration the aspirations of Kenya Vision 2030, the Kenya

National Pharmaceutical Policy and the National Industrialization Policy. The draft was further circulated amongst Government Ministries and their input was incorporated.

The development of a Good Manufacturing Practice (GMP) roadmap to enable local industry to achieve higher standards is a sure means of growth across the board that enables all consumers, prescribers and the business community to trust the quality of medicines manufactured in Kenya. In developing the Sector Development Strategy, it is considered critical to focus on both quality and affordability in order to improve access to essential medicines. In this regard, the successful implementation of the strategy will require high level Government support as well as that of all other stakeholders.



Dr. (Eng.) Karanja Kibicho, CBS
PERMANENT SECRETARY
MINISTRY OF INDUSTRIALIZATION

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ACRONYMS

ACA	Anti-Counterfeit Agency
AMRHI	African Medicines Regulatory Harmonization Initiative
API	Active Pharmaceutical Ingredient
ARV	Anti-Retroviral
AU	African Union
CAGR	Compound Annual Growth Rate
CAMI	Conference of African Ministers of Industry
cGMP	Current Good Manufacturing Practice
COMESA	Common Market for East and Southern Africa
CROs	Clinical Research Organizations
DFI	Development Finance Institution
DoMC	Division of Malaria Control
EAC	East African Community
FKPM	Federation of Kenya Pharmaceutical Manufacturers
GDP	Good Distribution Practice
GMP	Good Manufacturing Practice
ISO	International Organization for Standardization
KEMSA	Kenya Medical Supplies Agency
KENINVEST	Kenya Investment Authority
KIP	Kenya Industrial Policy
KNASP	Kenya National AIDS Strategic Plan
KNPP	Kenya National Pharmaceutical Policy
KPSDS	Kenya Pharmaceutical Sector Development Strategy
LPP	Local Production of Pharmaceuticals
MDGs	Millennium Development Goals
MEDS	Missions for Essential Drugs and Supplies
MoI	Ministry of Industrialization
MoMS	Ministry of Medical Services
NQAP	National Quality Assurance Programme
NQCL	National Quality Control Laboratory
OI	Opportunistic Infections
PEPFAR	President's Emergency Plan for AIDS Relief
PIC/S	The Pharmaceutical Inspection Convention and Pharmaceutical Inspection
PMPA	Pharmaceutical Manufacturing Plan of Action (of the African Union)
PMS	Post-Market Surveillance
PPB	Pharmacy and Poisons Board
PQ	WHO Pre-Qualification
R&D	Research and Development
RHF	Rural Health Facilities
SC	Strategy Component
SDS	Sector Development Strategy
SME	Small and Medium-Sized Enterprise
SOPs	Standard Operating Procedures
UNIDO	United Nations Industrial Development Organization
WHO	World Health Organization

I. INTRODUCTION

The Ministry of Industrialization and the Ministry of Medical Services recognize the importance of the role of the local pharmaceutical industry in the manufacture of essential generic medicines from both a health and an economic development perspective. However, the industry is currently operating at less than its full potential and there is a need to strengthen it. The United Nations Industrial Development Organization (UNIDO) has an ongoing project to strengthen local manufacturing of essential generic medicines in developing and least developed countries and has been working with the Ministry of Industrialization (MoI) and the Ministry of Medical Services (MoMS) and with key stakeholders in the sector, including the Pharmacy and Poisons Board (PPB) and the Federation of Kenya Pharmaceutical Manufacturers (FKPM). These entities have worked to develop this Kenya Pharmaceutical Sector Development Strategy (KPSDS) document, which sets out an approach that will enable Kenya to develop a strong pharmaceutical industry providing high quality medicines at internationally competitive prices for its population as well as in the wider sub-region and beyond.

Access to high quality medicines is critical to the health of the population and strong national regulatory systems are critical to ensuring the quality, safety and efficacy of products in the domestic market. Whilst international quality assurance systems have been established to ensure that the medicines procured with international resources against the pandemic diseases (i.e. malaria, HIV/AIDS, and TB) are safe and effective, these systems only apply to selected products. It is not feasible for such an international QA system to be implemented across all categories of medicines in the domestic market. In view of this, it falls to the national regulatory bodies to protect the consumer against substandard and counterfeit products in home markets.

Bearing in mind the large number of products and product sources that currently supply pharmaceuticals to Kenya and the limited resources available to the regulatory bodies, the Pharmacy and Poisons Board (PPB) and the National Quality Control Laboratory (NQCL), regulatory control of all products with the necessary rigour is a formidable task. For example, data available on antimalarial products indicates a total of 187 unique products found in the market, originating from 113 different manufacturers, in 20 countries across four continents[1]. Recent results of a WHO survey on the quality of antimalarial medicines in Kenya suggest that the system has performed well and that both locally produced and imported products were of comparably good quality. However, evidence across the complete range of medicines is not available and it is believed that developing local sources of products which meet established manufacturing standards would further enable the regulatory bodies to both reduce the number of substandard products and cut acquisition costs of essential medicines.

In addition to public health benefits, a strengthened pharmaceutical industry will contribute to the economic development of the country through growth in exports; import substitution; by being a driver of employment in the wider economy; and by ultimately increasing government revenues.

The pharmaceutical industry is a complex one with many stakeholders involved. Quality is a key issue given the implications for public health of substandard products as is the issue of affordability. In developing a Sector Development Strategy - and if access to medicines is to be improved - it is critical to focus on maintaining both quality and affordability. Furthermore, given the nature of the sector, any strategy must be founded on a firm understanding of the situation on the ground and should involve inputs from a number of key stakeholders.

1 *Antimalarial Medicines in Kenya: availability, quality and registration status. Ministry of Health, PPB and the Division of Malaria Control (DoMC), 2007*

The first phase of this work included gathering information on the status of the pharmaceutical sector in Kenya. This information served to develop an initial understanding of the structure of the industry and to begin to identify the challenges faced in further enhancing its ability to contribute to both improved public health and the economic development of the country. The findings from these investigations were documented in a 'Pharmaceutical Sector Profile'[2] for Kenya circulated to a group of key stakeholders[3] in June 2010. Following incorporation of further inputs from the stakeholders, the 'Pharmaceutical Sector Profile: Kenya' was completed and made available for general circulation in November 2010.

Following some initial research, a working group (WG) of key stakeholders was convened, with representation from the Ministry of Industrialization (MoI), Ministry of Medical Services (MoMS), the Pharmacy and Poisons Board (PPB), the National Quality Control Laboratory (NQCL), and the Federation of Kenya Pharmaceutical Manufacturers (FKPM). As work on the formulation of the Strategy proceeded, the WG was the primary forum for consideration and validation. On a preliminary basis, and as a template for discussion with stakeholders, UNIDO proposed a development strategy for the sector based on seven key Strategy Components (SCs), with particular strategic objectives and outcomes for each of these.

Feedback and inputs on the SCs were sought from the main stakeholders, particularly from major departments of the PPB - including the Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP) Inspectorates, Registration, and Pharmacovigilance - along with the NQCL, and FKPM. These inputs were clarified and refined over successive consultations and were finally incorporated into the Strategy presented in this document. The draft Kenya Pharmaceutical Sector Development Strategy (KPSDS) was presented and endorsed in a Round Table forum held on 26 August 2011 and inputs from that meeting have been incorporated in the document

The development process of this Strategy has taken into account regional, continental, and international efforts to make affordable and quality essential medicines available, namely the African Union Pharmaceutical Manufacturing Plan of Action (PMPA) and the East African Community (EAC) Regional Pharmaceutical Manufacturing Plan of Action. There have been several other forums in recent times addressing similar issues, including Roll Back Malaria 2010, the Conference of African Ministers of Industry (CAMI), the Round Table on Pharmaceutical Industries (Algiers, March 2011), the International Conference on Local Pharmaceutical Production (Cape Town, April 2011), and the Friends of ALMA Manufacturers' Forum (Nairobi, May 2011). A common feature of these meetings has been the outlining of the challenges faced by domestic pharmaceutical manufacturers, which demonstrates the need to develop a clear and comprehensive approach to allow the development of the local industry.

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2 *http://www.unido.org/fileadmin/user_media/Services/PSD/BEP/Kenya_Pharma%20Sector%20profile_TEGLO05015_Ebook.pdf*

3 *The Ministry of Medical Services (MoMS); Ministry of Industrialization (MoI); the Pharmacy and Poisons Board (PPB), the regulating body for the pharmaceutical sector; the National Quality Control Laboratory (NQCL); and the Federation of Kenya Pharmaceutical Manufacturers (FKPM)*

1. Situation Analysis

Some key findings from the Pharmaceutical Sector Profile: Kenya* formulated in 2010 are cited below:

1.1 Kenya has a significant, and growing, domestic pharmaceutical market

The value of the Kenyan pharmaceutical market was estimated at US$ 417 million in 2010[4] and it is expected to grow at a Compound Annual Growth Rate (CAGR) of 15.9% between 2009 and 2019 in US dollar terms.

1.2 Kenya is dependent on foreign sources for a substantial proportion of its essential medicines

In the case of medicines for the pandemic diseases (HIV/AIDS, malaria and TB), Kenya is highly dependent on donor funding. However, local pharmaceutical firms do not participate in this type of procurement which has stringent requirements including WHO prequalification of products. Since only one locally produced product in Kenya is prequalified by WHO, the domestic industry is effectively locked out[5]. Figures on actual donor funds spent on medicines annually are difficult to ascertain but some indicative numbers are available. These illustrate the large-scale spending on the pandemic medicines. According to the Kenya National AIDS Strategic Plan (KNASP), of the expected contributions to the total budget of US$ 629.3 million for HIV/AIDS control in 2009/10, the Government of Kenya provided only 5.4%. The rest came from donors. The largest contributor, the US Government's PEPFAR (President's Emergency Plan for AIDS Relief) alone spent US$ 60 million on antiretrovirals (ARVs) during that year. An additional amount was spent on medicines for opportunistic infections (OI) in HIV/AIDS patients. According to the World Malaria Report 2009, of total malaria funding of US$ 61.7 million for Kenya in 2008, the Government provided only 0.5%.

A significant portion of the Kenyan Government's public procurement of medicines is also sourced outside Kenya. The Kenya Medical Supplies Agency (KEMSA)'s 2010/2011 government budget for the procurement of essential medicines was US$ 49.5 million. Of this, about 60% was for Rural Health Facilities (RHF). There is some indication that local pharmaceutical companies supply KEMSA with some of the medicines for RHF but it is not possible to know their share exactly since the agency does not distinguish between local pharmaceutical producers and local distributors of imported products in its information gathering and reporting. It is clear, however, that a significant proportion of KEMSA's purchases are also imported. For purposes of strategic direction, KEMSA could develop a mechanism to indicate a comparative percentage of products procured and/or manufactured locally, provided that a local supplier could supply equivalent products to those imported.

This situation means that, overall, the domestic pharmaceutical market is dominated by imports. Excluding donor-funded spending on the pandemic medicines, local manufacturers

* *updated, where possible*

4 *Kenya Pharmaceuticals and Healthcare Report, Q1 2011, Business Monitor International*

5 *Universal Corporation received WHO prequalification for its Lamivudine/Zidovudine antiretroviral product (October 2011).*

supply less than 30% of the domestic market[6]. Clearly, if donor-funded procurement were to be taken into account, the market share of local manufacturers would be substantially lower.

1.3 Kenya exports a significant proportion of its pharmaceutical production but there is still potential for expansion

Kenya's exports of all pharmaceutical products, including medicines, almost doubled from US$ 30.3 million in 2004 to US$ 59.4 million in 2008 in spite of the global economic slowdown in that year. About half of these exports were to its immediate neighbours, Tanzania and Uganda, and the strong growth in the sector represented an impressive Compound Annual Growth Rate (CAGR) of 18.3%. There is potential for Kenya to establish itself as a major source of pharmaceutical products in the region. For example, South Sudan and the Democratic Republic of Congo (DRC) are emerging as important markets and there may be considerable scope in the future for sales to Somalia. A study[7] of the African suppliers of 30 main pharmaceutical products to the Common Market for East and Southern Africa (COMESA) also indicated the potential in that broader market. While Kenya's exports to COMESA of the selected principal pharmaceutical products have been on an upward trend, in 2008 they still amounted to only 56% of the value of exports from South Africa to COMESA of these same products. This clearly shows that there is considerable room for Kenyan exports to grow.

1.4 Ensuring uniform product quality of thousands of medicines, most of them imported, requires enhancement of regulatory capacity

As of mid-2010, there were 13,000 medicines from 1,250 manufacturers registered with the regulatory authority, the Pharmacy and Poisons Board. About 30 new applications for new drug registrations were being received per week, more than two-thirds of which were from foreign suppliers. Effective regulatory control requires initial plant inspections (both domestic and foreign sites), periodic post-registration inspections, product testing for registration renewal, plus continuous and effective post-marketing surveillance (PMS). These requirements apply to all products in the market and this situation conveys some sense of the regulatory burden.

Relative to the task at hand, PPB is working with inadequate resources. For instance, the GMP Inspectorate, which employs six officers, is responsible for carrying out GMP audits of over 40 local and over 1,000 foreign manufacturers supplying medicines to the Kenyan market. There are 57 inspectors at the GDP Inspectorate and they are expected to monitor all wholesale and retail establishments, including hospitals, in the entire country. One effect of these understaffed Inspectorates is the risk of substandard and counterfeit medicines in the marketplace. Although there have been no systematic studies to determine the general level of substandard and counterfeit medicines in Kenya, and while there is some indication that the quality problem may be less acute in Kenya than in other sub-Saharan countries[8], it

6 *Pharmaceutical Sector Profile: Kenya; 2010, UNIDO*

7 *Market Analysis & Research, International Trade Centre (ITC)*

8 *The WHO 'Survey of the Quality of Selected Anti-Malarial Medicines circulating in Six Countries of Sub-Saharan Africa', January 2011, showed failure rates of 5% in Kenya compared with 63.9% in worst case Nigeria.*

is also apparent that this is a problem that needs careful and detailed attention[9], particularly given its negative impact on health.

Defective medicines in the market manifest themselves in various forms, each with its own regulatory implications. PMS activities need to be able to distinguish between the different types of defective medicines that could be in the market in order to guide effective regulatory or administrative action. Defects can range from the deliberately spurious, such as falsely labelled products with no active ingredient, to the poorly-made, such as those with insufficient active ingredients due to poor quality assurance in the manufacturing process, or products which are improperly labelled. They also include degraded medicines - for example, products which have been subject to unsuitable storage. In other words, problems are very diverse and can span from substandard medicines through to fraudulent actions such as the deliberate manufacture and sale of counterfeit drugs.

Because quality can only be built into a medicine during production, GMP inspection is a critical function in regulation. For the welfare of consumers, a basic challenge is the verification of the quality of the medicine at source. Medicines regulation is consequently costly and costs more in the case of imported than of locally-produced pharmaceuticals.

1.5 Import dependence also makes consumers' access to medicines more difficult

Procurement of imported medicines, particularly in the case of public procurement through KEMSA, involves long lead times. This, in turn, increases the need for adequate planning, accurate forecasting, budgeting, and efficient execution and, when any of these processes breaks down, the result is stockouts of essential medicines. Such stockouts can then lead to a scramble to undertake emergency procurement measures which bypass usual tendering mechanisms and result in higher costs as well as interrupted access to drugs. In the case of disasters and emergencies, rapid response, including swift acquisition of life-saving products, is also a critical issue. Logistical problems, too, are more likely to arise and more difficult to manage in the case of imports than in local sourcing. There is, therefore, a greater risk of interruptions in supply with imports.

2. Inter-related Problems

As the Kenyan market for medicines grows, a series of inter-related problems are becoming more evident with local manufacturers finding it difficult to increase market share because of a number of constraints:

2.1 Common product lines

Local companies mostly produce generics and they have similar product portfolios which address relatively narrow market segments. This results in intense competition in these

9 *In the baseline survey of 'Anti-Malarial Medicines in Kenya' conducted by PPB and the Division of Malaria Control in November 2007, 42% of the 187 antimalarial products found in the market were not registered.*

product categories, giving rise to lower margins. There are no restrictions on imports of even those medicines which local companies can supply. In addition, many local companies lack the technological capacity and financial strength to invest in new product formulations. Finally, local pharmaceutical companies are shut out of certain market segments, such as donor-funded products, due to stringent quality requirements.

2.2 Unequal competition from a quality perspective

Local pharmaceutical companies face competition on two fronts: they compete with each other; and, collectively, they face stiff competition from imports.

A few firms have already made the investment needed in plant and equipment to meet World Health Organization (WHO) Good Manufacturing Practice (GMP) standards. Other pharma firms fall considerably below the required GMP standards. They need to upgrade but generally lack access to technical assistance and adequate finance, or both, to achieve the necessary standards. Therefore, the standard to which local companies manufacture varies significantly.

Similarly, quality variations exist with imported medicine. Foreign medicines are relatively easy to register in Kenya and there are no import tariffs. Consequently, the domestic market is flooded with imports of cheap generics, some of whose quality may not be proven. As mentioned elsewhere in this document, the number of foreign companies registered to market medicines in Kenya is quite large and regulatory resources are limited. Controlling large volumes of imported medicines consequently creates a considerable regulatory burden.

Implementing higher GMP standards is capital intensive because of the technology and infrastructure required and it also increases operational costs. Consequently, local manufacturers interested in maintaining or enhancing quality have to consider the balance between this objective and market competitiveness. Companies will not be strongly incentivised to improve quality standards unless the regulating bodies enforce stringent GMP and product quality standards uniformly on all local and foreign medicines.

2.3 Low capacity utilization and the need for greater production efficiencies

Most local companies are running their production lines at only between 50% and 66% of their installed capacity. Operating at less-than-optimum capacity utilization naturally results in relatively higher production costs and makes it harder for local producers to compete with imports. A major factor in the dominance of imported generics, particularly those from India and China, in the domestic market is that they undercut the price of locally-produced medicines.

2.4 Inadequate access to finance

Whilst the need to undertake upgrading of facility infrastructure is well understood in many pharma companies, the range of financing options is less well known. Moreover, financial institutions often do not understand the specific needs of the pharmaceutical sector for longer-term investment in plant and equipment and the training of personnel. The conventional financing mechanism - loans from commercial banks - is expensive because of high

interest rates. Thus, companies need to start considering different financing instruments such as more innovative combinations of debt/equity funding. They should also seek time-limited assistance from the Government in the form of incentives to address this problem.

2.5 Shortage of qualified personnel

The number of trained pharmacists in Kenya has been increasing with time but is still insufficient relative to the population. There is currently only one pharmacist for every 8,710 persons, or approximately 0.1 per 1,000 persons. Pharmacists trained locally are more clinically focused and lack the adequate orientation in industrial, regulatory and policy skills, all of which are critical for the development of local pharmaceutical production.

2.6 Unfavourable business environment

Neither the policy framework nor the legal environment are conducive to the growth of the pharmaceutical sector. Moreover, the Industrialization policy and the Kenya National Pharmaceutical Policy (KNPP) are inconsonant. The Pharmacy and Poisons Act is outdated and requires urgent revision to incorporate acceptable practice norms and standards, and governance.

The constraints faced by local pharmaceutical firms and some options for actions which could strengthen local pharma production capabilities are discussed in greater detail in the Pharmaceutical Sector Profile for Kenya.

3. The Benefits of Local Production of Pharmaceuticals (LPP)

Local Production of Pharmaceuticals (LPP) can reduce import dependence and related problems of regulatory load and access. It can also provide other economic benefits such as job creation; skills upgrading of nationals working in the sector; reduced expenditure of foreign exchange on imported medicines; and the opening up of avenues for exports of pharmaceuticals and increased foreign exchange earnings. Moreover, an increase in local production of pharmaceuticals should lead to improved quality and more cost effective regulatory oversight. It is, of course, easier for a local regulator to carry out regular GMP inspections of a local plant than it is for a foreign regulator. Traceability of product to local manufacturers is easier when carrying out Post-Marketing Surveillance and, in general, a regulator is expected to have greater overall leverage over the activities of local suppliers than those of foreign producers. With shorter lead times, local manufacturers should also be in a better position to contribute to more reliable supplies of essential medicines and thus to greater access for consumers.

Another important benefit of LPP and one which is often overlooked, is national drug security. Import dependence and donor dependence both represent risks in terms of national drug security. Moreover, since the continuation of donor funding appears more uncertain in coming years, LPP offers a measure of protection against interruptions in supply of essential medicines to Kenyans.

3.1 Regional Initiatives

Regional initiatives have already highlighted the important role that the pharmaceutical sector can play in promoting industrial development. Kenya is a member of the East African Community (EAC) of nations and the EAC's Industrialization Policy[10] suggests the targeting of high-technology and high value-added production that would accelerate regional industrialization. The Policy document specifically mentions pharmaceuticals as one of the "key industries that offer the highest opportunity for accelerated growth in the region".

The domestic pharmaceutical sector in Kenya has much to offer in this respect. It is the most well-established pharmaceutical manufacturing industry in the region. It has the largest number of established pharmaceutical manufacturers which already produce the main formulations (tablets/capsules, parenterals, ointments/creams, liquids/syrups/suspensions). There is local capacity to manufacture most of the essential medicines, including antimalarials, as well as medication for treating HIV/AIDS and TB. At least two firms have voluntary licensing to manufacture ARVs and one firm was granted WHO prequalification status in October 2011 for Lamivudine/ Zidovudine as a fixed dose combination drug.

Kenya's regulatory bodies are well-positioned to develop and provide the oversight which the industry requires. The National Quality Control Laboratory (NQCL) is WHO-prequalified and capable of expanding its scope to meet the demands of a growing local and regional pharma industry. The Pharmacy and Poisons Board (PPB) has established the necessary range of functions for overseeing the industry[11] and has been enhancing its technical capacity through various interventions by WHO and other agencies. In particular, PPB is participating in an ongoing project on harmonization of medicines regulation among the EAC Partner States, under the auspices of the African Medicines Regulatory Harmonization Initiative (AMRHI). However, as mentioned earlier, PPB's legal mandate is inadequate and its resources are stretched. This severely limits its effectiveness as an independent regulator.

4. Challenges

The pharmaceutical sector faces some significant challenges if the potential benefits of LPP are to be realized. The quality of production varies between different manufacturers. A number of companies have been certified through the Pharmaceutical Inspection Convention and Pharmaceutical Inspection scheme (PIC/S) but others have yet to reach such a level, with some falling well below established standards. This has a number of implications, including increased risk of substandard products and the lack of a level playing field, since some companies with higher standards will inevitably incur higher costs.

Moreover, achieving Good Manufacturing Practice (GMP) standards is no small matter. Requirements include investment in facilities, well-trained staff, a 'Quality' culture within the company, validation of equipment and processes, and Standard Operating Procedures (SOPs). Given the financial and technical considerations, concerns among companies that reaching GMP standards is not achievable are therefore understandable. In view of this, a strategy that incorporates required quality standards and provides assistance to companies in order to achieve them is necessary.

10 *East African Community Industrialisation Policy, Draft Final Report, LOG Associates, May 2010*

11 *WHO assessment of the medicines regulatory system in Kenya, 2006*

Apart from technical and financial considerations, upgrading of manufacturing plants (where necessary) will take time. In view of this, the Strategy will need to set out a pragmatic timeline for the sector's development. It will also need to include a clear and time-limited roadmap for strengthening the medicines regulatory framework as regulatory capacity in Kenya is severely constrained by inadequate resources and legal frameworks.

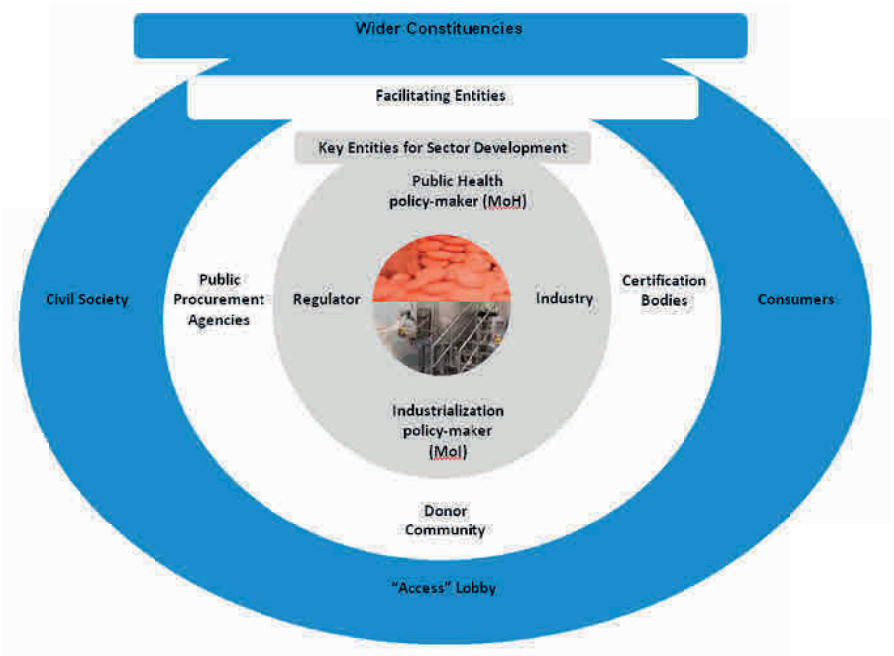
All these challenges have to be met in conjunction with, and in the context of, efforts to harmonize policies within the EAC, such as the Community's Medicines Regulation Harmonization Project. At the moment, the varying capacity levels of the regulatory bodies and different technological levels among pharmaceutical manufacturers within the EAC region pose difficulties that will have to be addressed in order to achieve harmonization.

5. A holistic Sector Development Strategy

A Development Strategy for the pharmaceutical sector must be based on the principle that, although the pharmaceutical industry must be competitive and profitable, if it is to be sustainable, public health concerns are also paramount. Investment to achieve quality initially means additional costs. However, through an understanding of the economics of medicine production, the industry can be helped to restructure so that, in the long term, it will be sustainable whilst producing universally high quality products. Achieving the goal of competitive high quality local production will require policymakers to support the industry in its transition stage with a package of support that includes fiscal incentives as well as other components such as facilitating access to know-how, a prerequisite to enhanced quality standards.

The complexity of the environment in which the pharmaceutical sector operates and the multi-faceted challenges that it faces may be illustrated by considering the different stakeholders in the pharma sector at various levels, as shown in Figure 1.

Figure 1: Many stakeholders influence the pharmaceutical manufacturing environment



The core stakeholders are industry, the regulator, and the policy-making bodies for health and industrial development respectively (the Ministry of Medical Services and the Ministry of Industrialization, in Kenya's case). However, facilitating entities such as the certification bodies (e.g. WHO), public procurement agencies such as KEMSA, and the donor community are important stakeholders as well. In the wider circle of stakeholders, groups involved in access, advocacy, civil society, and - ultimately - the consuming public are interested parties in any directions to be set for, and developments within, the pharmaceutical sector.

Different stakeholders naturally have varying interests. Even within the core group of stakeholders, each is likely to have different priorities, as shown in Table 1.

Table 1: Stakeholder priorities

Stakeholder	***Major Issues***
Regulator	• *enhancing quality standards* • *enforcing standards* • *market surveillance* • *monitoring and control, including:* – *authorization to market (registration)* – *licensing* – *inspections*
Industry	• *maintaining competitiveness* • *"level playing field" for all market suppliers* • *accessing capital needed for investments* • *increased domestic market share and exports* • *special incentives from Government* • *profit*
Health Policymaker	• *safe, quality, and effective medicines* • *affordability* • *availability* • *minimum procurement cost*
Industrial Policymaker	• *sector growth* • *job creation* • *technology transfer*

As Table 1 shows, stakeholder interests are linked and cannot be achieved in isolation. It is not possible, for example, to have job creation in the sector without the industry remaining competitive against alternative suppliers. Similarly, the health policy objective of quality (safe and effective) medicines in the market has to be supported by the regulator through market surveillance.

For the formulation of a Sector Development Strategy (SDS) and its effective implementation, cooperation and coordination among at least this core group of stakeholders is a critical success factor. Each stakeholder must perceive a 'gain' from the implementation of one or more Components. Only a holistic approach balancing the different stakeholder interests is likely to be successful. Consequently, this is the approach that has been adopted to formulate this SDS.

6. Achieving higher GMP standards

Taking cognizance of the fact that there is a mix of GMP levels amongst licensed manufacturers, with very few achieving international recognition to-date (one company has achieved WHO-PQ), it is important that the strategy acknowledges the need to move all manufacturing facilities to WHO-GMP standards in a stepwise approach.

Figure 2: Higher quality standards and competitiveness: factors to enable the transition

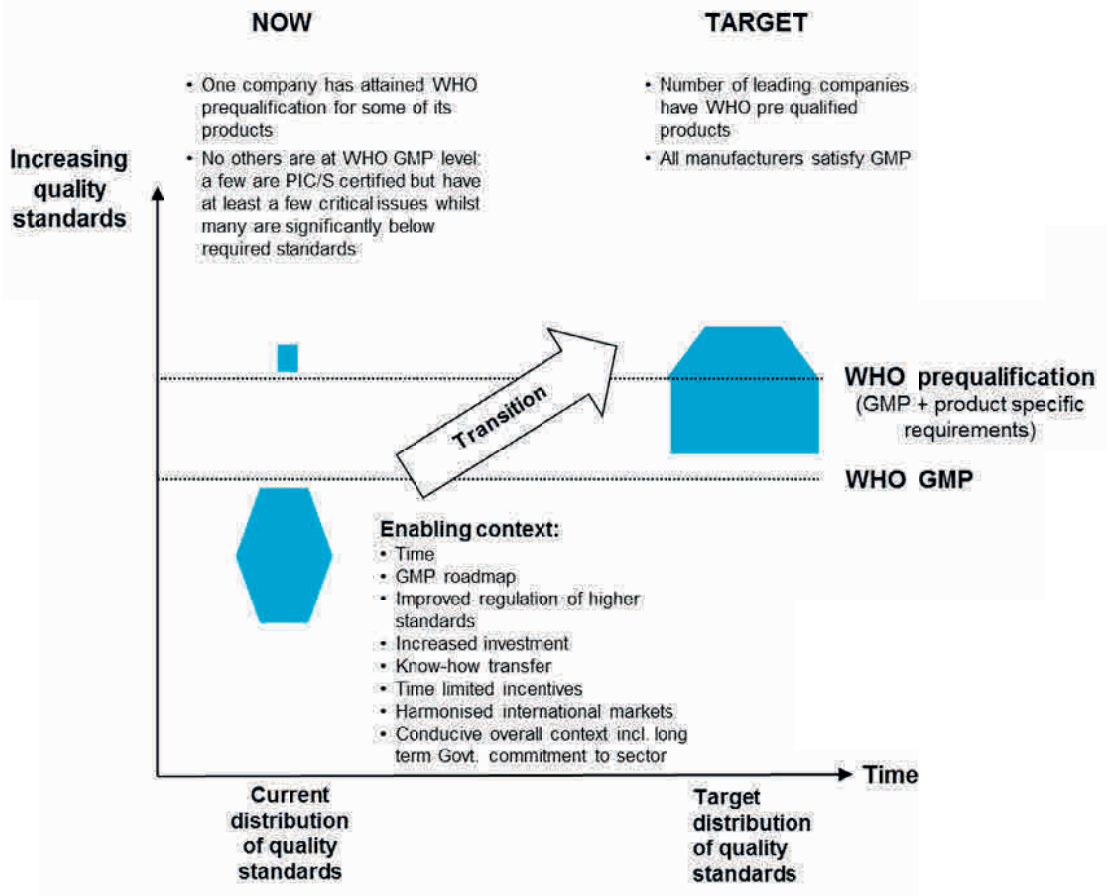


Figure 2 above illustrates the approach to higher standards whilst maintaining competitiveness, a combination of outcomes that should enable the growth of the industry and the realization of valuable public health improvements.

7. Approach / Methodology

The development of the pharmaceutical industry is a complex undertaking with many moving parts and numerous stakeholders. Fundamentally, it is only through conducting a consultative process with the various stakeholders that these complexities can be considered in context and solutions reached. For this reason, the Working Group was established. Further refinement of this Strategy was achieved through incorporating input from the broader range of stakeholders.

It should also be recognized that a Sector Development Strategy (SDS) cannot include every possible improvement that could potentially benefit the sector. Priorities have to be set. Nonetheless, since we are here seeking a holistic strategy, a necessary and sufficient set of critical elements must be part of the SDS to ensure that it makes strategic sense as a whole.

In general, the formulation of the SDS was an interactive, iterative process with and between principal stakeholders in a position of influence with regard to each element of a Development Strategy. Ongoing leadership from the MoI, MoMS and other key stakeholders will be critical for developing and implementing an action plan for this Strategy. As already pointed out, achieving the goal of universal high quality, competitive local pharmaceutical production will require time and involves many stakeholders. In view of this, sustained high-level government support and political will is necessary over a period of several years.

II. SECTOR DEVELOPMENT STRATEGY

The objective of this document is to present a clear and concise Strategy for the development of the pharmaceutical sector that addresses the central needs and concerns of the principal stakeholders and points the way for the pharmaceutical manufacturing sector in Kenya to move forward.

Based on the inputs of the Working Group, the Sector Development Strategy now comprises seven Strategy Components (SCs):

1. Setting out a roadmap for industry to achieve GMP Standards
2. Strengthening mechanisms for quality assurance of medicines in the distribution chain
3. Strengthening regulatory capacity
4. Accessing necessary financing for investment in the sector
5. Devising time-limited incentives for industry
6. Developing necessary human resources
7. Developing common support services for the local pharma industry

These seven components are outlined below:

Strategy Component 1: Setting out a roadmap for industry to achieve GMP standards

Companies in the Kenyan pharma industry are at different levels of GMP status. Some fall well short of GMP requirements while other manufacturers are voluntarily pursuing international GMP standards, such as PIC/S and WHO prequalification. One company achieved WHO prequalification status in October 2011. Central to the concept of strengthening local production is the overall progression of the sector to comply with GMP. This will primarily ensure the quality, safety, and efficacy of the medicines manufactured in premises that are technically suitable.

As pointed out above, the Kenyan pharma sector is largely unable to participate in donor-funded procurement of the pandemic disease drugs. This is because donors typically require medicine suppliers to meet stringent quality standards (WHO GMP certification) and only one Kenyan pharmaceutical manufacturer is currently prequalified. The Pharmacy and Poisons Act[12] requires compliance with good manufacturing practices prescribed by the Board. However, to date, there is no definition of which GMP standards local pharma producers

12 *Pharmacy and Poisons Act (Cap 244): 35 B Every person who is granted a manufacturing licence under Section 35 A shall comply with the good manufacturing practices prescribed by the Board*

are expected to meet. The ideal situation would be compliance with internationally-recognized GMP standards by all manufacturers licensed by the PPB. In order to achieve this overall compliance, the regulator needs to set out a GMP roadmap, establishing milestones and timelines for all local manufacturers to achieve. This should be a collaborative effort with stakeholders, including industry, so that the process promotes 'buy in' and a sense of common purpose among all concerned. Current GMP (cGMP) is viewed by the industry as a moving target and non-specific, in the same way that the versions of GMP enforced by WHO, the European Union (EU), the USA, and Japan differ in certain requirements. It is, therefore, important for the PPB to take a position on the set of GMP standards which will be the objective of the roadmap. One possibility would be for the PPB to spell out specific requirements along a progression path according to dosage form or product category, similar to India's Schedule M[13].

Another important aspect of the move to compliance with GMP standards is that new producers meet GMP from the start. These could serve as guidelines for the suitability of premises of such new producers. There is clearly no sense in helping or requiring existing producers to attain GMP standards over a time period whilst at the same time leaving aside the question of standards for start-ups.

It should be recognized that there is a dearth of understanding of GMP standards, both among PPB / NQCL personnel as well as among the production/QA personnel in the pharmaceutical companies who are ultimately expected to implement the requirements of any GMP roadmap. Therefore, GMP training at both the regulating bodies and the companies is essential for progress. Bearing in mind this situation, Strategy Components have been formulated on accessing know-how and on developing human resources within the industry and the regulating bodies.

Finally, appropriate political will is a necessity to effect movement along the GMP roadmap. The regulator will need high level government support to enforce the requirements of the roadmap in the time frames established and support will be required from the policymaking authorities at MoMS and MoI in the form of directives and notices.

Strategy Component 2: Strengthening mechanisms for quality assurance of medicines in the distribution chain

The Development Strategy for the pharmaceutical sector in Kenya should encompass technological upgrading, as exemplified by the drive to raise standards in the industry and the formulation of a GMP roadmap. However, care should be taken that the competitive position of local industry in the domestic market is not compromised or weakened in the process. Through the GMP roadmap, domestic pharma producers will be required to comply with quality standards for facilities, equipment, and the medicines manufactured. In the short term, industry will be supported through time-limited incentives to remain competitive whilst upgrading their manufacturing standards. However, once these incentives expire, it will be necessary to ensure a level playing field for local producers versus other sources of medicines.

13 Schedule M: Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products, a set of regulations promulgated by the Indian Government laying down the GMP standards that all Indian pharmaceutical firms were required to comply to within a stipulated time.

A national quality assurance framework that encompasses Good Distribution Practices (GDP), Post-Marketing Surveillance (PMS), and testing of medicines on the market is critical. This will help remove from the distribution chain the non-conforming products, including unregistered medicines, substandard medicines, and counterfeits. It is important to understand the linkage between the requirement for local pharma companies to conform to recognized quality standards and stricter PMS, and it is important to get the policy mix right.

Today, there are no reliable estimates of the extent of substandard or counterfeit medicines being distributed in the Kenyan marketplace. Except for some investigative work performed on antiretrovirals (ARVs)[14] and antimalarials[15], there have been no systematic studies to monitor the general level of substandard and counterfeit medicines in circulation. This absence of data makes it difficult to know the full extent of the problem but anecdotal data and evidence from other countries suggests that, without rigorous market oversight, public health risks remain and the ability of local manufacturers to sustain their activities and contribute to improved public health and economic development will be compromised.

There have been previous attempts to introduce a National Quality Assurance Programme (NQAP) and a PMS Strategy was drafted in June 2010 within the PPB. Making the NQAP and PMS Strategy effective will require the rationalization of roles within different Directorates of PPB and NQCL for PMS activities as well as coordination and linkage between their functions. As a matter of policy, PMS needs to receive better visibility and be given higher priority by the regulator whilst PMS activities should become regular and routine.

Tougher Post-Marketing Surveillance by the regulator is a challenge and will require awareness raising about the NQAP and PMS at different levels of the distribution chain. It also calls for specialized training of PPB/NQCL staff on sampling, handling of samples and testing, and follow-on regulatory actions. Developing the appropriate systems will also take time. Yet, from a public health perspective, such developments cannot happen too soon. From the perspective of strategic development of the industry, it is just as necessary that such systems are in place well before the incentives supporting the industry have expired.

Strategy Component 3: Improving regulatory capacity

The Pharmaceutical Sector Development Strategy will place greater demands on PPB and NQCL as the key regulating bodies. First and foremost, the independence of PPB and NQCL as executors of pharmaceutical policy and regulating bodies needs to be assured. For this, regulation needs to be delinked from pharmaceutical policymaking and sector administration. This principle is enshrined in the Constitution as a means of promoting good governance. As such, PPB and NQCL require urgent restructuring into autonomous bodies, as proposed in the Kenya National Pharmaceutical Policy Sessional Paper[16] in the

14 *Survey of the quality of antiretroviral medicines circulating in selected African countries, WHO, Sept. 2007*

15 *Survey of the quality of selected antimalarial medicines in six countries of sub-Saharan Africa, WHO, Jan. 2011*

16 *Kenya National Pharmaceutical Policy Sessional paper was approved by the Cabinet in January 2012.*

section on 'Revamping Pharmaceutical Sector Governance and Policy Direction'[17]. This paper advocates "reforming the pharmaceutical sector to ensure equitable access to Essential Medicines and essential health technologies for all Kenyans" and points to the need to "restructure institutions that are envisaged to play a key role in the implementation of this Policy and its attendant strategies, in particular: a) Restructure the PPB to establish a Food and Drug Authority (FDA) as an autonomous regulatory agency within the ministry responsible for health, and delinked from the Directorate of Medical Services". It also goes on to propose the restructuring of the NQCL "as an autonomous body corporate within the ministry responsible for health, delinked from the drug regulatory authority". These proposals should be speedily implemented. At present, PPB and NQCL staff are deployed from MoMS and any employee of either body can be transferred at any time by the Ministry.

For effective functioning, accountability, and independence, PPB and NQCL will have to invest in the training and upgrading of staff. Indeed, recognition of the need for capacity-building within these institutions was a salient feature of the inputs on the SDS from these institutions themselves and it has now been highlighted as a Component of the SDS (see Strategy Component 6). The skills required for effective regulation are specialized and are not part of pre-service pharmacy training in the country. Consequently, this investment in specialized skills needs to be protected by achieving greater employment stability for PPB and NQCL personnel. As autonomous bodies, these institutions would be governed by their own Management Boards and they would be in a position to develop a strong functional relationship between them and be able to recruit their own staff.

Feedback from PPB and NQCL on the SDS also makes abundantly clear that the current functional/working relationship between these two bodies needs to be improved. Each activity in which PPB and NQCL must necessarily collaborate should be examined and representatives of management of both bodies at the appropriate working level should be brought together to establish explicit, written memoranda of collaboration, Standard Operating Procedures (SOPs), guidelines, and agreed performance benchmarks for the areas of collaboration. These SOPs / guidelines / benchmarks could then be reviewed and approved by senior management at both institutions.

An essential element of the improved joint functioning of PPB and NQCL is better communications between these institutions. In fact, overall, there is an important problem of information capture and sharing between all stakeholders. PPB and NQCL obviously need to share test results, both during pre-product registration and for investigations as part of PMS. Information on product registrations and complaints should be shared between Directorates at PPB and NQCL and information on product recalls and withdrawals should be widely disseminated. In addition, import/export data collected by PPB is of interest to industry but is currently not accessible, or even retrievable. In view of this, both institutions could consider setting up a system which would allow sharing of key data by involved stakeholders but with selective access on a need-to-know basis.

Finally, strong policy guidance and support is required to enable PPB and NQCL to harmonize their capacities, as necessary, with regional and international regulatory frameworks. This is critical for Kenya's role in the emerging regional integration agenda.

17 *Ibid, page 23, item 65, number 4.*

Strategy Component 4: Accessing investment funds

It is anticipated that pharmaceutical manufacturers will need significant capital to make the necessary investment in plant and equipment in order to comply with the GMP roadmap which will require them to upgrade to specific GMP levels by certain deadlines. Most of the companies are small, family-owned or closely held businesses with a few, often related, shareholders, and they fall within the definition of Small and Medium-sized Enterprises (SMEs). Access to finance to fund the necessary improvements is difficult and, in view of this, an important Component of the SDS relates to the promotion of investment in the sector.

Currently, most firms rely on short-term debt financing from commercial banks, with the attendant high interest rates in Kenya. There appears to be little knowledge among entrepreneurs of other possible forms of finance. A reluctance to disclose detailed information about company performance, coupled with concerns about giving up controlling interest, and interference in management by investors have also discouraged companies from examining financing options other than their usual banking relationships. In these circumstances, the companies will certainly benefit from assistance to explore and understand other potential sources of capital. On the other side of the equation, there seems to be a lack of awareness in the financial community about investment opportunities in the pharmaceutical sector.

In addition to commercial banks, there are at least three other possibilities for pharma companies to raise funds, namely Development Finance Institutions (DFIs); venture capital / private equity; and public listing. As a first step, the financing options available within the country are being explored by UNIDO. This research will be expanded to include possible sources of capital within Africa and beyond. The findings from this work will be shared with the FKPM and will outline the specific characteristics of each type of financing. Further means for facilitating access to investment capital will also be explored (e.g. forums to link up representatives of industry and potential investors). The need to make the pharmaceutical industry attractive to potential investors will be kept as an imperative whilst structuring other aspects of the Strategy.

The regulatory and business environments are key factors when it comes to raising finance for pharmaceutical ventures. In addition to assessing individual companies, financial institutions evaluate the attractiveness and/or risk associated with the sector as a whole. Consequently, factors including the sector's capacity to compete with cheap imports from India and China, the regulator's success in enforcing uniform quality standards across all supply sources, regulatory efficiency in areas such as product registration, and Government measures to support local manufacturers are all important considerations when evaluating an investment opportunity in the pharmaceutical sector.

In addition, financiers look for key elements within a pharmaceutical company which will qualify the business for funding. These include:

- a solid management team
- a track record (ideally three or more years) of performance and profitability
- a strong business case, backed by market knowledge and projections, all detailed in a convincing business plan
- corporate governance practices, such as open audited accounts, regular reporting and disclosures, independent Board members, and hiring based on merit rather than family ties

The Kenya Investment Authority (KenInvest) could also play an important role in promoting investment into the sector. The pharma sector could be highlighted in its road shows and publications as an attractive destination for Foreign Direct Investment. KenInvest could also undertake to produce special promotional materials focused on the pharma sector for distribution abroad.

Strategy Component 5: Devising time-limited incentives for industry

There are examples of countries, such as India, which have provided special, time-limited incentives to their pharmaceutical companies during the time frame allowed in the GMP roadmap for reaching international standards. In a similar move, such time-limited incentives could be devised and implemented for the Kenyan pharma industry. Structuring the incentives package will require an understanding of the current economics of manufacturing in Kenya as well as the implications for the future operating environment (i.e. at which stage GMP will be required). UNIDO is working to define such an understanding and this will be greatly facilitated if the local industry cooperates in providing data relevant to this objective. A cost-benefit analysis of possible incentives would add to the evidence base that will support the Government of Kenya in its decision making. The Ministry of Industrialization would also have to ensure that recommended incentives do not violate the Common Market Protocol signed by member states of the East African Community.

One incentive already available is the provision, under the Public Procurement and Disposal Regulations of 2006 derived from the Kenya Public Procurement and Disposal Act of 2005, of a 15% price preference for local manufacturers in public procurement of medicines by KEMSA. The Public Procurement and Disposal (Preference and Reservations) Regulations were gazetted in 2011 and KEMSA is committed to implement the price preference for local medicine producers.

Strategy Component 6: Developing necessary human resources

The Kenyan pharmaceutical industry cannot be upgraded without a parallel upgrading of human resources in the sector. This initiative could be implemented on two fronts:

- increasing the absolute output of pharmacists (particularly industrial pharmacists) and pharmaceutical technologists required to support an expanded and growing pharma sector; and

- continuing skills and know-how development to build capacity in the regulating bodies (PPB and NQCL) on the one hand and in the pharma companies on the other hand. This activity would also include providing basic GMP training to pharmacists, technicians, and other professionals (e.g. process engineers, analytical chemists, biochemists, microbiologists) in the industry.

To increase the overall output of pharmacists, training courses and programmes would have to be expanded beyond the basic stage or should be introduced in local educational insti-

tutions, and partnerships should be built with institutions already training pharmaceutical technologists. In situ training would have to be provided in the regulating bodies and pharmaceutical companies through targeted workshops and training courses. Fragmented training initiatives are already conducted domestically, sub-regionally and by the international community. As part of a holistic strategy for the sector, it will be necessary to develop a sub-strategy for human resource development that seeks to leverage the support on offer and to structure it in such a way as to enable the skilled human resources in the country to grow and develop for the sector.

The development of a skilled work force will take time. However, in the short term there is a need for companies to access know-how and to design programmes to meet the requirements of the GMP roadmap. Some of this expertise will most probably need to be imported in the near term. To that end, the government could consider support measures, including increasing the allocation of visas for expat expertise available to individual pharma companies. UNIDO and other partners will also explore how know-how could be accessed through foreign direct investment, joint ventures, and technology transfer arrangements (e.g. North-South and South-South).

Strategy Component 7: Developing support services for the local pharma industry

There is currently a shortfall in a variety of services required by local manufacturers, which results in an inability to access these services in a timely and affordable fashion. Improving access to support services is therefore a key step in delivering an environment that enables the local pharmaceutical industry to thrive. The range of services is broad and covers a variety of areas such as equipment calibration and servicing, maintenance and repair, and outside laboratory services. If Kenya's pharmaceutical industry is to grow and successfully follow the GMP roadmap in a timely fashion, various support services will be required to be expanded and in some cases developed from scratch.

III. CONCLUSION

Kenya has the most strongly established pharmaceutical sector in the sub-region, along with a relatively strong regulatory infrastructure. It therefore possesses the basis for a strong pharmaceutical industry, and the ambition of both the MoI and MoMS is to see this strengthened. Through the adoption of a holistic strategy, the sector can be developed in order to become a sustainable and competitive source of quality-assured essential medicines. This will help to improve access for the population to safe, efficacious medicines. In addition to public health benefits, such an approach should enable local manufacturers to increase their domestic market share and to further expand their exports to the sub-region and beyond.

The holistic Strategy described in this document recognizes the complexity of the sector and the significant challenges both it and its stakeholders face in order to achieve the ultimate goal. This Strategy comprises seven Components that will need to be addressed in a coordinated fashion, including establishing the GMP requirements that manufacturers will have to meet and describing a pragmatic, realistic roadmap. The legitimate concerns of manufacturers regarding the impact on their competitiveness of increased costs and investment will be mitigated by time-limited incentives. These will support the industry to upgrade and encourage structural change to ensure sustainability once incentives have expired. The Strategy also describes a number of initiatives that could be considered by the regulatory bodies in the country since enhanced regulatory oversight of GMP standards and surveillance of the marketplace are critical if the industry is to develop and deliver both the public health and economic development benefits of which it is capable.

Other components of the Strategy include assisting companies to mobilize the requisite capital to upgrade their facilities (both active and passive approaches could be included, such as investment subsidies and dissemination of research into financing options, respectively) and developing the human resources that such a high tech industry requires. In the short term, companies will need to access expertise that is in short supply in the country and the Strategy will explore how access to know-how can be facilitated.

From a regional perspective, the Strategy Components outlined here are broadly compatible with the primary strategic objectives described in the EAC's Pharmaceutical Manufacturing Plan of Action[18]. This also includes promotion of competitive and efficient pharmaceutical production regionally; facilitation of increased investment in Local Pharmaceutical Production; strengthening of regulatory capacity; and development of appropriate skills and knowledge on pharmaceutical production.

Finally, this Strategy recognizes that reaching the goal of universal high-quality competitive production cannot happen overnight. It will take time and coordination. In view of this, implementation of such an approach will require appropriate management and coordination structures to be established and the maintenance of high-level government support and political will.

18 *East African Community Regional Pharmaceutical Manufacturing Plan of Action, EAC Secretariat, March 2011*

ANNEX: A NOTE ON IMPLEMENTATION OF THE PHARMACEUTICAL SECTOR DEVELOPMENT STRATEGY

It is envisaged that the KPSDS will be implemented by the Government of Kenya through the Ministry of Industrialization and the Ministry of Medical Services (the Ministries responsible for industrialization and health respectively when the government structure is aligned with the Constitution), with the support of UNIDO and other development partners. Therefore, it is recommended that a Steering Committee be formed to guide the implementation of the KPSDS, led by the Permanent Secretary of the MoI (Chair) and the Permanent Secretary of the MoMS. The Committee would make the overall policy decisions and monitor implementation while the Working Group would be responsible for the actual implementation activities and would make progress reports to the Steering Committee. For efficacy of implementation, the KPSDS could be made part of the performance contracts of the government departments and officials involved. The Strategy will require simultaneous progress on a number of fronts and therefore the governance and coordination of the implementation steps will perhaps be as important as the steps themselves.

The Round Table forum

The Round Table forum held in August 2011 was attended by 42 participants from across the industry and Government, and stakeholders endorsed the draft Kenya Pharmaceutical Sector Development Strategy. The meeting was co-chaired by the Permanent Secretary in the Ministry of Industrialization, Dr (Eng) Karanja Kibicho and the Permanent Secretary in the Ministry of Medical Services, Ms Mary Ngari. Also participating were the UNIDO Country Representative for Kenya and Eritrea; representatives of WHO; the Ministries of Public Health and Sanitation; Trade; and Livestock Development; as well as representatives of the pharma manufacturing industry and regulatory institutions such as the Pharmacy and Poisons Board , the Anti-Counterfeit Agency, and others.

The following salient points emerged from speeches and subsequent discussions:

- The implementation of the KPSDS would result in the shortening of lead times in the supply chain of essential medicines and result in better regulatory oversight of the sector; this would enable the country to attain self sufficiency in the supply of essential medicines

- The gap between imports and exports should be an incentive for local manufacturers to capture a greater share of the local market

- The KPSDS should form part of that policy as well as resolve problems associated with affordability, counterfeit and substandard medicines

- Both Vision 2030 and the Constitution envisage investing in the people of Kenya by strengthening health service delivery, separating regulatory functions, boosting local production and expanding the regional market

- The pharmaceutical industry is unique and is knowledge intensive. Its success will give impetus to the growth of other industries thereby contributing to the realization of the Kenyan Government's Vision 2030 and to achieving the Millennium Development Goals (MDGs) through helping to improve access to affordable safe and efficacious medicines

- The implementation of the Kenya National Pharmaceutical Policy and the Kenya Pharmaceutical Sector Development Strategy require government support at the highest levels, goodwill from all stakeholders, and concerted and unrelenting efforts by industry and the regulator

In the ensuing discussions, contributions and clarifications were made in relation to various stakeholder concerns and a summary of these is given below:

- **Incentives:** there are existing government incentives which should be exploited to the full; for example, the tax break providing for recovery of 100% of investments within Nairobi and 150% outside the capital.

- **Harmonization:** there is a need for harmonization of the KPSDS with other papers before submitting it to Cabinet. The WG needs to liaise with the Kenya Investment Authority to incorporate the incentives available to industries.

- **Regional cooperation and mutual recognition:** the EAC harmonization of standards should be fast tracked because manufacturers experience long down times caused by multiple inspections and differing recommendations. It was emphasized that there is a need for reciprocal recognition agreements through a mutual recognition scheme between countries.

- **Exports:** the Pharmaceutical Industry is strategic to Kenya and increased investment in R&D could result in the development of new products from, for example, local plants. In the longer term, this could lead to increased exports.

- **Quality:** the importance of attaching quality standards was underlined, including the need for compliance with WHO GMP requirements, the benefits of which would be considerable. The same standards should be maintained irrespective of the size of the business.

- **GMP Inspectorate:** The GMP Inspectorate functions of the PPB should be independent and clearly distinguished from the testing functions of NQCL.

- **Accreditation function of NQCL:** The testing functions of the NQCL have grown enormously since it attained WHO accreditation status. The demands on this service may result in it becoming overstretched in the near future. Whilst there are plans to establish another unit with the specific responsibility of training and accreditation for applicants from the private sector, it was clarified that this unit will not have inspectorate functions like the PPB.

- **GMP roadmap:** Pursuing WHO GMP standards is difficult but achievable for those aspiring to high quality manufacturing. The GMP roadmap will outline a step wise approach with specific milestones required by set points in time…

- **Veterinary:** Livestock is a major subsector representing 10% of GDP and 30% of output from the agri-business sector. High quality input from the pharmaceutical sector is required. It was emphasized that the requirements for quality standards of veterinary products are no different from those of human pharmaceutical products. The export potential of the livestock subsector will be enhanced by similar quality standards. Moreover, this is consistent with the harmonization within the EAC.

- **Curriculum development:** there is a need for input from stakeholders in relation to the future introduction of a Masters degree in Industrial Pharmacy. The role of universities should be defined in the course of implementing the KPSDS. Industry should also participate in the training activities and provide attachment opportunities; it should also reward staff members who participate in advanced training by better remuneration. This will help industry to both attract and retain staff.

- **Strategy Component 6:** It was suggested that the contents are diverse and should be disaggregated so that Human Resource Development stands alone and this has already been done in the current document.

- **Implementation and fast tracking of some issues:** There is a need to incorporate timelines and action plans into the KPSDS. It was emphasized that implementation should be taken seriously by all stakeholders. There are certain aspects of the Strategy which are very low cost and these should be identified and implemented on a priority basis.

On the basis of the input from the Round Table, the Permanent Secretary re-circulated the draft KPSDS to other government Ministries for validation, information and input. It is noteworthy that the responses, particularly from the Ministry of Medical Services, the Ministry of the East African Community, and the Federation of Kenya Pharmaceutical Manufacturers reiterated that the KPSDS faithfully reflects the current state of the industry and calls for a concerted effort to achieve its implementation.

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