Justification for the African Union Model Law on Medical Products Regulation and Harmonisation

Introduction

Medicines regulation is an important aspect of the public health delivery system that ensures that good quality, safe and efficacious medical products and technologies reach end users, accompanied with necessary information for their rational use by health professionals and patients. National Medicines Regulatory Authorities (NMRAs) are mandated to regulate medicines. Effective structuring of regulatory functions involves mutually reinforcing activities and interface of different stakeholders such as manufacturers, traders, consumers, health professionals, researchers and government officials who have varying social, economic, policy and political objectives. Effective medicines regulation that ensures public health protection and promotion is therefore a complex undertaking that requires the application of sound medical, scientific and technical knowledge and skills in an appropriate legal framework.

1. Rationale for AU Model Law on Medical Products Regulation and Harmonisation

Access to affordable, safe, quality and efficacious medicines on the African continent has been a major challenge for decades. This is partly attributable to weak or non-existent medical products regulatory systems in many African countries. Most of the efforts to improve medicines regulation in Africa are hampered by the lack of clear policies, and legal and regulatory frameworks for regulating medicines at national as well as regional levels. There are, of course, human and institutional capacity and resource constraints as well.

1.1. Studies on Legislative and Legal Frameworks

Various studies conducted to assess the legislative and legal frameworks for medicines regulation have demonstrated that the majority of African countries have weak or non-existent medicines regulatory legislation to protect the public against the hazards associated with use of poor quality and unsafe medical products and technologies. A study conducted by WHO and NEPAD Agency in the East African Community Partner States (2010) revealed that in all Partner States there exists legislation on the regulation of pharmaceuticals, with the governance structures and the scope of regulated products varying significantly from country to country. Another study conducted by Management Sciences for Health (MSH), Strengthening Pharmaceutical Systems (SPS) program in Sub-Saharan Africa (SSA) countries (2011) has shown that of the 46 SSA countries, only 41 (78 percent) have a national medicines policy (NMP) related to pharmacovigilance and medicine safety; and only 30 percent provide a legal mandate to monitor medicine-related adverse events. Only 28 percent of countries have legal provisions that require marketing authorisation holders (MAHs) to report all serious adverse drug reactions (ADRs) to the national medicines regulatory authority and an even smaller proportion (17 percent) require MAHs to conduct post-marketing surveillance activities. The lack of relevant policy and regulations in SSA imposes fundamental limitations on enforcing medicines safety monitoring. The US-Institute of

Medicines Report on Ensuring Safe Foods and Medical Products through Stronger Regulatory Systems Abroad (2012), emphasises that *'a strong legal foundation is a prerequisite for food and medical product regulation'*. It further reveals that *'some of the poorest countries have no laws governing product safety; others have a surfeit of confusing and contradictory ones'.* Hence, 'enforcing product safety laws is a monumental task, one that is often neglected or executed unevenly'.

1.2. NEPAD Agency Situation Analysis of Medicines Regulation and Harmonisation in Regional Economic Communities (RECs) and countries in Africa

The situation analysis carried out by the NEPAD Agency in the regional economic communities (RECs) and NMRAs revealed that; although most of the member states have policies and legislation that gives the government (through the NMRAs) the mandate to regulate medicines within their territories, their comprehensiveness varies from country to country. Most of the countries that have policies in place have not developed their implementation plans, creating gaps in implementation. This has, in turn, affected national medicines regulation as well as the country's participation in regional medicines regulation harmonisation efforts. The inconsistency between regulatory procedures within RECs and within the African region more broadly imposes further burdens on both innovator and generic pharmaceutical manufacturers, who face the added expense of adapting marketing approval applications to the particularities of different countries. Not only is there a loss of efficiency for the manufacturers and registrants of medicines, but there is also considerable and inefficient duplication of effort by over-burdened NMRAs, resulting in delays that ultimately impact on patient health. Similarly, there are no mechanisms for coordination of facilities inspections, recognitions of inspections by other NMRAs, nor pharmacovigilance and product safety/quality assurance.

Apart from regional treaties existing in the RECs that enable joint medicines regulation, countries' legal frameworks on regulation of medicines are territorial and cannot be used to directly control other countries' requirements. The legislation on medicines regulation of one country is not recognised by another country, neither do the existing national laws impose any obligation to harmonise the regulation of medicines. Unless harmonisation in the RECs is effected administratively, countries are not permitted, let alone obliged, to use any decision or procedures for medicines regulation applied by another country even though the diseases for which the medicines are registered within the region are similar and even though identical medicines are submitted to various NMRAs. This has a negative effect on the harmonisation effort, as countries are legislatively precluded from adopting policies on joint medicine regulatory activities recommended at the regional level.

There are also varying levels of determination and commitment by countries to domesticate regional treaties. The need for national implementing policies, legislation and regulations that enable countries to fulfil treaty obligations on regional medicines regulation harmonisation is therefore essential. It is also essential to adopt other measures in additional to regional

harmonisation that will increase the timeliness, efficiency, and effective of regulatory activities, for example, increased involvement with the WHO Prequalification Programme.

1.3. Various AU Decisions and Declarations aimed to improve access to medicines

The 55th Decision of the AU in 2005 and subsequent endorsement of the Pharmaceutical Manufacturing Plan for Africa (PMPA) in 2007 by African Union Ministers of Health provides a framework for improving medicines access to the African population. In addition, the 19th AU Assembly Decision on Roadmap for Shared Responsibility and Global Solidarity for the AIDS, TB and Malaria Response in Africa, among others, emphasises on the need to accelerate and strengthen regional medicines regulatory harmonisation initiatives and lay the foundation for a single African medicines regulatory agency.

2. Purpose

The purpose of the Draft Model Law on Medical Products Regulation and Harmonisation in Africa is to provide a comprehensive law that can guide member states and RECs in their endeavour to harmonise medicines regulation and provide an enabling regulatory environment for the private sector to ensure access to good quality, safe and efficacious medical products and technologies for the African population. NEPAD has undertaken to develop and promote this Model Law that will provide the national legislative framework for regional and sub-regional harmonisation, and for increased efficiencies in national, sub-regional, and regional procedures.

3. Model Law Process

The process to be followed based on the AU Guidelines for Model Law:

3.1. Validation of the Draft Model law by the Technical Working Group (TWG) on Medicines Policies and Regulatory Reforms established under the African Medicines Regulatory Harmonisation Advisory Committee. The TWG which met in April and September of 2013, is composed of Legal and NMRA experts from the 5 African regions and AMRH Partners. The TWG has also obtained technical assistance from UNDP, UNAIDS, WHO and other partners in drafting the Model Law and some of its implementing regulations.

3.2. The Draft Model Law was presented to the Pan African Parliamentary (PAP) Committee on health, labour and Social Affairs in August 2013.

3.3. Regional consultative meetings with Governments, Legal Experts, NMRAs and Parliamentarians from all AU member states during July 2014 – March 2015.

3.4. Presentation of the Final Draft Model Law to the meeting of Ministers of Health for technical review and endorsement in April 2015.

3.5. Presentation of the Final Draft Model Law to the meeting of Ministers of Justice/Attorneys for legal review and further endorsement in April 2015.

3.6. Submission of the Final Draft Model Law on medicines regulation harmonisation for consideration by the executive Council on the recommendations of the PRC prior to adoption by the AU Assembly in January 2016.

3.7. Domestication of the Model law by Member States.

Given that the Model Law is not a binding instrument, a combination of approaches will be employed, including meetings with national speakers and chairpersons of parliamentary health committees organised through PAP.

4. Expected Output

4.1. Domestication of the Model law by at least 20 Member States by 2018

4.2. The adoption of regionally harmonised policies and legislative frameworks by at least 5 regions by 2018.

4.3. The establishment of at least 2 regional medicines regulatory agencies by 2018.

5. Conclusion

The AU Model Law on Medical Products Regulation and Harmonisation in Africa aims to address legislative gaps that hamper effective medicines regulation and regional harmonisation; it will ensure a systematic approach for the development of a harmonised legislation on medicines regulation in African countries, thereby also supporting the African Union's desire to promote local production of pharmaceuticals with a view to the protection of public health and contribution to economic growth.