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# STRENGTHENING THE CAPACITY FOR REGULATION OF MEDICAL PRODUCTS IN THE AFRICAN REGION

## Report of the Secretariat

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## BACKGROUND

1. Medical products[1] save lives, reduce suffering and improve health, but only if they are of good quality, safe, efficacious, available, properly prescribed and well used by patients. The production, marketing and use of substandards/spurious/falsely-labelled/falsified/counterfeit (SSFFC) medical products can result in therapeutic failure, resistance to medicines and ultimately death. Therefore, quality and safety of medical products require government intervention in the pharmaceutical sector through regulation including promulgation of laws, monitoring of law enforcement and delegation of authority to ensure that the manufacture, marketing and use of medical products are effectively regulated. Strong regulatory measures should be in place and be effectively implemented, especially in countries of the African Region that are increasingly exposed to the threats of SSFFC medical products.

2. Regulation of medical products involves several functions and related activities whose scope and "modus operandi" may vary from country to country. Generally, these regulatory functions include the following: (a) licensing of professionals, premises and practices; (b) evaluation and registration of products; (c) inspection of pharmaceutical establishments; (d) quality control; (e) providing independent information and controlling promotion and advertising; and (f) monitoring adverse reactions[2]. The main goal of regulation is to ensure the quality, safety and efficacy of medical products, as well as the relevance and accuracy of product information through effective implementation of these functions.

3. Regulation of medical products requires that countries: (a) develop a comprehensive legal basis (legislation and regulations) and provide technical guidance (guidelines, norms, standards, specifications and procedures); (b) establish appropriate and adequate organizational entities such as a National Medicines Regulatory Authority (NMRA) that coordinates and oversees the regulatory system; (c) provide adequate numbers of qualified and skilled professionals competent to design and/or implement sound technical and scientific tools and legal provisions; (d) provide adequate and sustainable funding mechanisms; and (e) carry out monitoring and evaluation. In addition, effective regulation of medical products requires political commitment, public adherence and interactions with various stakeholders (e.g. NMRAs, manufacturers, traders, consumers, health professionals, researchers, the police, customs, the judiciary, civil society, parliamentarians and government).

4. The World Health Organization has given high priority to strengthening the regulation of medical products in countries. The World Health Assembly, by its resolution WHA52.19 on the revised drug strategy,[3] urges Member States to develop and enforce medicines legislation and build regulatory capacity. In line with this resolution, the WHO Regional Committee for Africa adopted a technical document (Document AFR/RC56/11) on *Medicines Regulatory Authorities: Current Status and the way forward*. The Sixtieth session of the Regional Committee, in its final report (Document AFR/RC60/21), recommended the creation of an African Medicines Regulatory Agency. In addition to WHO's recommendation, in 2012, the Eighteenth Ordinary Session of the African Union Summit endorsed the Roadmap on AIDS, TB and Malaria and recommended the establishment of a single African Regulatory Agency.[4]

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1 Medical products include medicines, vaccines, pharmaceutical ingredients, medical devices and diagnostics.

2 WHO/EDM/2003.2, Effective medicines regulation: ensuring safety, efficacy and quality, WHO Policy Perspectives on Medicines, Geneva, World Health Organization, 2003.

3 WHO, Resolution WHA52.19, Revised Drug Strategy, Geneva, World Health Organization, 1999.

4 The African Union Assembly Decision No: Assembly/AU/Dec.413 (XVIII); Roadmap on Shared Responsibility and Global Solidarity for AIDS, TB and Malaria Response in Africa, July 2012.

5. Between 2002 and 2010, WHO provided support to 26 countries in the African Region to assess their regulatory systems and to develop and implement institutional development plans.[5] WHO in collaboration with partners has facilitated information exchange, collaborative work and training activities through forums like the African Medicines Regulators' Conferences and African Vaccine Regulatory Forum (AVAREF).

6. Since 2009, the African Union, through the New Partnership for Africa's Development (NEPAD) and in collaboration with WHO, regional economic communities, countries and other partners,[6] have been implementing the African Medicines Regulatory Harmonization (AMRH) initiative. In relation to this, the East African Community has started implementing its project that was launched in March 2012. Other regional economic committees are at various levels of finalizing their project proposals for submission to potential partners. To date, most of the regional economic communities[7] have developed guidelines and strategic plans to harmonize medicines regulation for countries in their respective subregions.

7. Although they do not cover the full range of the required functions, which need to be strengthened, some initiatives have contributed to capacity building for medical products regulation in countries. Four pharmaceutical manufacturers located in Kenya, South Africa, Uganda and Zimbabwe, one vaccine manufacturer in Senegal and six quality control laboratories[8] in four countries (Algeria, Kenya, South Africa and Tanzania) have been prequalified by WHO.[9] Through this Prequalification programme, several professionals in these countries have received training in Good Manufacturing Practices (GMP) for pharmaceutical manufacturers. Also through WHO support, Burkina Faso, Mali and Niger reviewed their guidelines for marketing authorization and registered the new conjugate meningococcal A vaccine. Moreover, additional countries in the meningitis belt have successfully licensed the vaccine using the WHO expedited review procedure.[10]

8. Overall, evidence[11] shows that the capacity of countries to regulate medical products is weak. This document highlights the major issues and challenges related to countries' capacity to establish a strong and fully functional regulatory system for medical products and proposes relevant actions to address them.

## ISSUES AND CHALLENGES

9. *Low prioritization of the regulation of medical products in national health systems*. In many countries, national health authorities are slow to initiate and lead the process for developing a comprehensive national system for regulation of medical products. For countries that have started, the process is not inclusive enough as some stakeholders in the pharmaceutical sector

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5 WHO/EMP/QSM/2010.4, Assessment of medicines regulatory systems in sub-Saharan African countries: an overview of findings from 26 assessment reports, Geneva, World Health Organization, 2010.

6 African Union Commission, Pan-African Parliament, World Bank, Bill and Melinda Gates Foundation, the UK Department for International Development, Clinton Health Access Initiative, and the Joint United Nations Programme on HIV/AIDS (UNAIDS).

7 Southern African Development Community, East African Community, Economic and Monetary Union of West Africa, Economic and Monetary Community of Central Africa and Economic Community of West African States.

8 Adcock Ingram Limited — Research and Development, South Africa; *Laboratoire national de Contrôle des Produits Pharmaceutiques*, Algeria; Laboratory of the Mission for Essential Drugs and Supplies, Kenya; National Quality Control laboratory, Kenya; Research Institute for Industrial Pharmacy (RIIP) incorporating, South Africa and Tanzania Food and Drugs Authority (TFDA) Quality Control Laboratory, Tanzania.

9 http://apps.who.int/prequal/, accessed on 7 June 2013.

10 WHO/IVB/07.08, procedure for expedited review of imported prequalified vaccines for use in national immunization programmes, Geneva, World Health Organization, 2007.

11 WHO/EMP/QSM/2010.4, Assessment of medicines regulatory systems in sub-Saharan African countries: an overview of findings from 26 assessment reports, Geneva, World Health Organization, 2010.

(civil society, consumer associations) are not involved. Under such conditions, the adherence of stakeholders to regulation of medical products could be compromised. In addition, the medium and long-term priority goals of the pharmaceutical sector are not integrated.

10. *Fragmentation and complexity of the legal and regulatory framework*. The successive laws and decrees often enacted by national authorities are not consistent and coherent. Very often this is done without comprehensive assessment of existing provisions, resulting in increasing complexity of the legal and regulatory frameworks, contradictory measures, fragmentation and unclear definition of the roles and responsibilities of the various stakeholders[12]. The lack of continuous dialogue and coordination between the regulators and stakeholders results in limited adherence to regulation of medical products. In addition, in many countries, national legal and regulatory frameworks for regulation of medical products have not been regularly updated to reflect national realities and to address new related issues as they arise.

11. *Weak implementation of regulatory functions*. A recent assessment shows that, in 2011, 39 countries reported partial implementation of regulatory functions;[13] only four countries (Sao Tome and Principe, Senegal, South Africa and Uganda) regulate vaccines in the Region; an average of 3611 medical products are registered in each country, ranging from 0 to 13 000. Consequently, unregistered products circulate in many countries. The capacity for inspection is weak; this has an impact on the development of local manufacturing industries that comply with GMP standards. Therefore, these manufacturers are ineligible to compete in bids for procurement of medical products for priority diseases from major international donors.[14]

12. *Inadequate adaptation of guidelines and procedures*. Often, guidelines and procedures used in countries are not in line with WHO recommendations.[15] Although WHO regulatory tools and guidelines[16] exist, countries do not adequately adapt them to their needs and use them for decision-making. This may increase the risk of importation of SSFFC medical products.

13. *Inappropriate organizational structure to implement medical products regulatory functions***.** In some countries, the entities responsible for coordinating and overseeing the implementation of medical products regulation are Units under departments of the ministry of health. These Units are entities empowered by the national authorities as regulators (e.g. NMRAs). Although these entities are expected to be autonomous, full-fledged departments with statutory authority (boards or commissions) to ensure independence, transparency and accountability in decision-making, in most cases this do not happen. Consequently, such organizational structures limit the ability of the national regulatory authorities to effectively fulfil their mandate and hamper the establishment of quality management systems to ensure transparent and accountable decision-making.[17]

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[12] WHO/EMP/QSM/2010.4, Assessment of medicines regulatory systems in sub-Saharan African countries: an overview of findings from 26 assessment reports, Geneva, World Health Organization, 2010.

[13] WHO/EMP/MPC/2011, Pharmaceutical country profile, Regional summary report, Geneva, World Health Organization, 2011 (unpublished).

[14] WHO/EU/ICTSD, Local Production for Access to Medical Products: Developing a Framework to Improve Public Health, Geneva, World Health Organization, 2011.

[15] WHO/EMP/QSM/2010.4, Assessment of medicines regulatory systems in sub-Saharan African countries: an overview of findings from 26 assessment reports, Geneva, World Health Organization, 2010.

[16] WHO medicines regulatory package: a collection of tools for medicines regulatory authorities in regulatory support series 14, Geneva, World Health Organization, 2011. http://www.who.int/medicines/areas/quality_safety/regulation_legislation/regulatory_package/en/, accessed on 28 March 2013.

[17] UEMOA, *Etude de faisabilité sur le changement de statut des autorités de réglementation pharmaceutique des Etats membres de l'UEMOA, CHRCP, 2011.*

14. *Conflict of interest.* The inadequate management of conflicts of interest between stakeholders involved in medical products regulation is widespread. Where they exist, the codes of conduct of professionals performing regulatory functions are not effectively implemented. In some countries, the same professionals in charge of law enforcement are also involved in non-regulatory tasks such as the manufacture, importation, distribution and promotion of medical products. This undermines objectivity in the analysis of dossiers related to implementation of regulatory functions, report findings and stipulated sanctions of the national regulatory authority.

15. *Weak intersectoral collaboration*. The different stakeholders (NMRAs, trade officials, police, customs, the judiciary and professional organizations) involved in the implementation of regulatory decisions and enforcement do not collaborate sufficiently. The stakeholders do not share a common vision and the definition of roles and responsibilities is not clearly established within an appropriate mechanism of coordination. Consequently, customs officials often authorize entry of unregistered medical products in countries without inspection by the national regulatory authorities. Similarly, the judiciary and police do not involve the national regulatory authorities in combating fraud and illicit circulation and distribution of medical products in countries. This situation has contributed to increased circulation and use of medical products that are sub-standard, spurious, falsely-labeled, falsified or counterfeit (SSFFC).

16. *Shortage of qualified human resources*. The number of professionals qualified and skilled to perform regulatory functions in countries is not sufficient. This is aggravated by the widespread and high turnover and brain drain of skilled staff. Incentives to retain staff and implement appropriate human resources development plans are lacking. Initiatives for pre-service and in-service training of regulatory personnel are inadequate. Institutionalized training and postgraduate courses in regulation are limited. In addition, medical products regulation is not yet widely recognized as a specialty and an attractive career choice.

17. *Inadequate and unsustainable funding*. Funding for regulation of medical products in the African Region is generally inadequate and unsustainable. Governments are not yet making adequate budget provision to fund well-defined mechanisms for sustaining regulatory functions for medical products. Experience in some countries shows that the regulatory functions are financed from a combination of the fees generated by the entities responsible for regulation of medical products, government subsidies and donor funds. For example, apart from government subsidy and industry fees, the contribution of bilateral and multilateral donors to funding is 20% in Burkina Faso, 60% in Guinea[18] and 10% in Uganda.[19] Very often, NMRAs are not authorized to use fees collected for services rendered to cover the recurrent and capital costs related to the implementation of regulatory functions. They are therefore largely dependent on external donor funding that is not sustainable.

18. *Weak international, intergovernmental collaboration and harmonization of medical products regulation*. South-South and intercountry collaboration and coordination are weak. For example, in 2011, only 12 countries[20] in the Region had mechanisms to recognize marketing authorizations issued by other countries' regulators. This weak capacity in the Region to interact with relevant stakeholders in medical products regulation at subregional, regional and global levels exposes the population to substandard medical products. Against this background, the Eighteenth Ordinary Session of the AU Summit stressed the need to strengthen collaboration,

[18] AU/NEPAD, Situational analysis study on medicines registration harmonization in Africa, final report for the Economic Community of West African States (ECOWAS), 2011.

[19] AU/NEPAD, Situational analysis study on medicines registration harmonization in Africa, final report for the East African Community (EAC), 2010.

[20] Botswana, Chad, Gambia, Ghana, Guinea, Guinea-Bissau, Liberia, Mauritius, Mozambique, Sierra Leone, Uganda, Zimbabwe.

coordination and harmonization of medicines regulation in the Region, and recommended the creation of a single African Regulatory Agency.

## ACTIONS PROPOSED

19. The following actions are proposed to address the issues and challenges related to the capacity to regulate medical products in the Region.

20. **Prioritize the development of medical products regulation**. Governments should establish or reinforce a high level platform for dialogue and coordination among stakeholders[21] involved in the pharmaceutical sector to provide advice on the development and implementation of comprehensive national medicines regulation systems. This platform should promote strong public support for regulation and urge governments to give attention to emerging and priority issues of the pharmaceutical sector such as SSFFC medical products. Regulation of medical products should be prominent in the national pharmaceutical policy with clear assignment of the responsibilities of each of the stakeholders. Countries should improve public adherence to regulation through continuous dialogue.

21. **Strengthen the coherence and performance of the medicines regulatory system.** Governments have primary responsibility for establishing a comprehensive and functional regulatory system in countries. Systematic approaches to regular assessment of the regulatory systems should be adopted to achieve the goals of the pharmaceutical sector. In addition, countries should update the legal and regulatory framework for medical products where necessary, with adequate provisions to ensure coordination and appropriate definition of mandates between stakeholders in medical products regulation.

22. **Adapt and use guidelines in line with WHO recommendations**. Countries should develop, adapt where appropriate and implement good regulatory practices based on comprehensive standard operating procedures. WHO's existing mechanisms such as the Prequalification Programme, assessment of medicines regulatory systems, joint reviews of registration dossiers and joint GMP inspections should be used to strengthen regulatory capacity.

23. **Increase implementation of regulatory functions**. Countries should establish comprehensive regulatory systems including establishing and/or strengthening national pharmacovigilance systems. Countries that are partially performing the regulatory functions should develop and implement strategic plans to expand the scope. Those that have not yet started to perform the regulatory functions should prioritize the development of a new strategic plan based on the assessment of their regulatory systems. Countries in which pharmaceutical manufacturers are located should develop capacity in GMP inspection through building the capacity of professionals for regulation of medical products.

24. **Enhance the status of National Medicines Regulatory Authorities (NMRAs)**. Countries should establish autonomous NMRAs that have efficient quality management system. In countries where the organizational structures of NMRAs are currently organized as units under departments of the ministry of health, institutional reform aiming at progressively establishing autonomous regulatory authorities with governing bodies should be initiated.

25. **Institute sustainable mechanisms to effectively manage conflicts of interest**.

[21] NMRAs, manufacturers, traders, consumers and other representatives of civil society, health professionals, researchers, police, customs, the judiciary, governments and parliamentarians.

Governments have to take appropriate measures to ensure that staff performing medical products regulatory functions are not involved in non-regulatory tasks. Entities mandated to implement medical products regulatory functions should develop and implement a system that prevents conflict of interest of their staff and others such as external experts involved in regulatory functions. There should be a comprehensive code of ethics in countries.

26. **Strengthen intersectoral collaboration between relevant stakeholders.** Countries should strengthen intersectoral collaboration between relevant stakeholders involved in the enforcement of regulatory decisions (e.g. NMRAs, trade officials, police, customs, the judiciary and professional organizations). Countries should provide appropriate training for these stakeholders and institute ad-hoc national committees on regulation of medical products. They should also update and encourage sharing of information on issues related to regulation such as regulatory decisions, information from market surveillance and monitoring.

27. **Ensure availability of qualified human resources for regulation of medical products**. Countries should develop and implement sustainable strategies to enhance human resources capacity for regulation through pre-service and continuing education. Countries, through NMRAs and academic institutions, should collaborate in the establishment of regional centres of excellence in regulatory functions to serve as training hubs. Moreover, national authorities may supplement their technical capacity through using external experts to perform the various regulatory functions.

28. **Ensure adequate and sustainable financing of the medicines regulatory system.** Governments should institute budget lines and adequate funding mechanisms for medical products regulation, to cover recurrent and operational costs. The funding mechanism could be a mix of government resources and fees from services rendered by structures mandated to implement medical products regulatory functions. The governing bodies of the NMRAs could explore other sources of funding such as grants and donations that do not create conflict of interest.

29. **Improve collaboration, coordination and harmonization of medical products regulation.** While reinforcing the capacity of the NMRAs, countries should accelerate the operationalization of a single African Medicines Agency (AMA), in line with the decision of African Heads of State and Government**.** This future regional entity will serve all AU Member States, and support rather than supplant existing national medicines regulatory authorities. It will provide, for Member States, technical support and independent information about the quality, safety and efficacy of medical products. Regional economic communities should pursue their action towards harmonization of medical products regulation through implementation of the AMRH, AVAREF and other initiatives. That should lead to the development of common technical documents, information sharing as well as mutual recognition of regulatory decisions and the creation of a centralized medicines regulatory system.

30. The Regional Committee is invited to review this document and provide policy guidance towards strengthening medicines regulatory authorities and creating the basis for establishing the African Medicines Agency to enhance the capacity of all African countries in the manufacture, marketing and use of medical products.