



AFRICAN STRATEGIES FOR HEALTH



Photo by Pinky Patel

ADDRESSING THE RISE OF NON-COMMUNICABLE DISEASES IN AFRICA THROUGH IMPROVED REGULATION OF MEDICAL PRODUCTS

Health is inextricably linked to a nation's economic growth and development. Non-communicable diseases (NCDs), also known as chronic diseases, are now the leading cause of death in many regions and left unchecked will increasingly lead to lost economic productivity and higher health care costs. In 2012, the World Health Assembly adopted a target of 25% reduction from 2010 levels in premature mortality (under the age of 70 years) from NCDs by 2025. The prevention and management of NCDs in Africa requires stronger health systems and partnerships across multiple sectors, for diagnosis and treatment as well as to reduce risk factor prevalence. This brief outlines the growing burden of non-communicable diseases in Africa, the importance of strengthening regulatory mechanisms for improved access to medicines and medical devices to address them, and the role of trade in improving these processes.

Key Points

- NCDs are a growing cause of death and disability in Africa, reducing individual and collective productivity and increasing health care costs.
- Prevention and management of NCDs requires stronger health systems and partnerships across multiple sectors.
- While most NCDs can be diagnosed, prevented, delayed, and ameliorated, access to appropriate medicines and medical devices has been limited.
- Efforts to support regulatory systems strengthening and capacity building to develop technical skills would not only enhance confidence in the available products, but also in the region as a destination for investment.

The growing burden of non-communicable diseases in low- and middle-income countries

The four primary types of NCDs are cardiovascular diseases, cancers, chronic respiratory diseases, and diabetes. In 2012, 16 million individuals died prematurely from NCDs, with the majority (82%) of premature NCD deaths occurring in low- and middle-income countries (LMICs).¹ LMICs – 54 of which are in Africa – are undergoing what has been described as an “epidemiologic transition” – with fewer people dying at an early age from infectious causes, while more are living long enough to experience diseases driven by the effects of primary risk factors for NCDs including tobacco use, harmful use of alcohol, unhealthy diets, and sedentary lifestyles.² Unplanned and rapid urbanization in Africa, the second-fastest urbanizing region in the world, has contributed to the unhealthy lifestyles that are associated with these risk factors.³ In 2012, almost a quarter of males over age 15 in Africa used tobacco, with 23.3% of the continent’s population having raised blood pressure, and rates of overweight or obesity at 34.5% (female) and 20.6% (male) in 2014.⁴

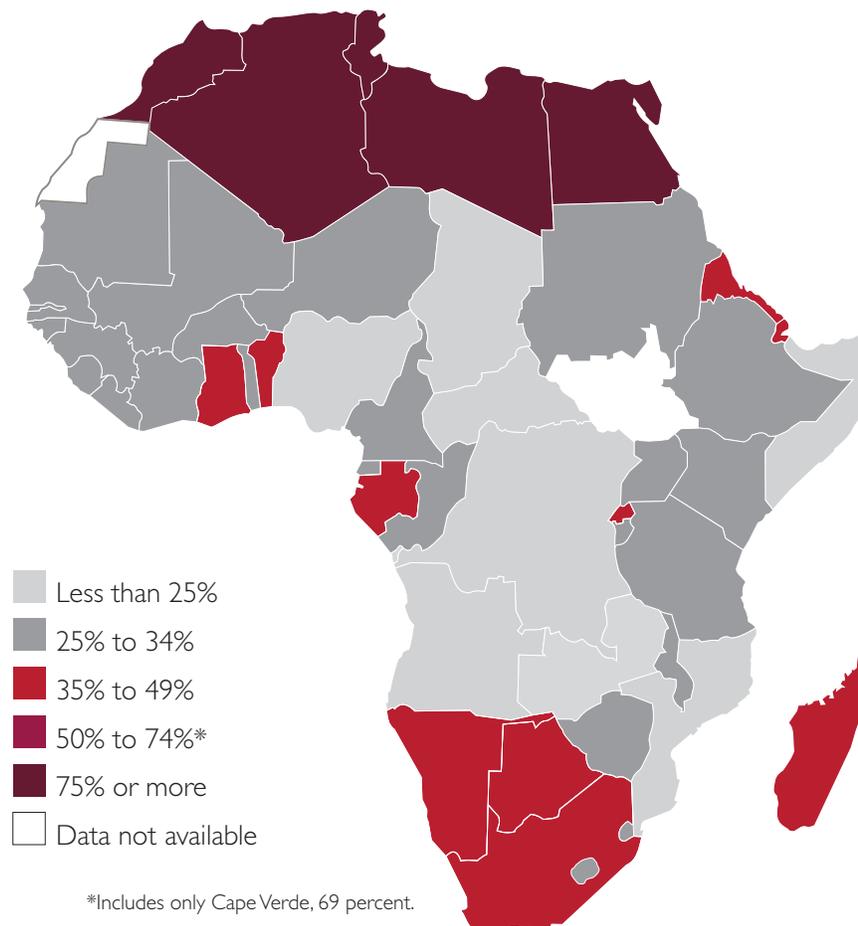
The burden of NCDs is growing most rapidly in Africa

The African region is expected to experience the greatest increase in NCD deaths over the coming decade. By 2014, NCDs accounted for more than three-quarters of all deaths in most North African countries, and while communicable diseases and other conditions still predominate in sub-Saharan Africa, NCDs are projected to become the leading cause of death within 15 years.⁵

Management of NCDs is urgent

In light of these projections, the management of NCDs in Africa should be considered an urgent threat that must be addressed with increased attention and resources.⁶ Health services are facing a growing demand for essential medicines to treat ischemic heart disease, diabetes, cancer, and other chronic diseases. Figure 1 shows the proportion of deaths due to NCDs in Africa in 2012. Cardiovascular disease and cancer ranked consistently in the top three conditions.⁷

Figure 1. Percent of deaths due to non-communicable diseases by country, 2012



Reproduced from: Naik R, Kaneda T. Noncommunicable Diseases In Africa. Population Reference Bureau, April 2015

The impact of NCDs is broader than death and disability

The impact of NCDs cannot be viewed only in terms of death and disability alone. Many NCDs require lengthy, at times life-long treatment, amplifying their effects on individuals and families. NCDs lead not only to premature death and disability, but also to poverty, both because they impair individual productivity, and because – when treatment is accessible – the majority of treatment costs in LMICs are paid out-of-pocket. Long-term treatment consumes savings and may require a family member to leave the workforce to become a caregiver; either or both may tip a family into poverty.⁸

NCDs impose tremendous economic harm

NCDs can impose tremendous economic harm on both individuals and entire populations.⁹ The NCD epidemic disproportionately affects people of lower socioeconomic status. Poverty exposes people to behavioral risk factors for NCDs and, in turn, the resulting NCDs contribute to the downward spiral that leads families towards poverty.¹⁰ In LMICs, deaths due to NCDs earlier in the lifecycle occur at a higher rate than in high income countries, with almost 30% of NCD deaths occurring in those under age 60, have potential serious consequences for economic productivity.¹¹

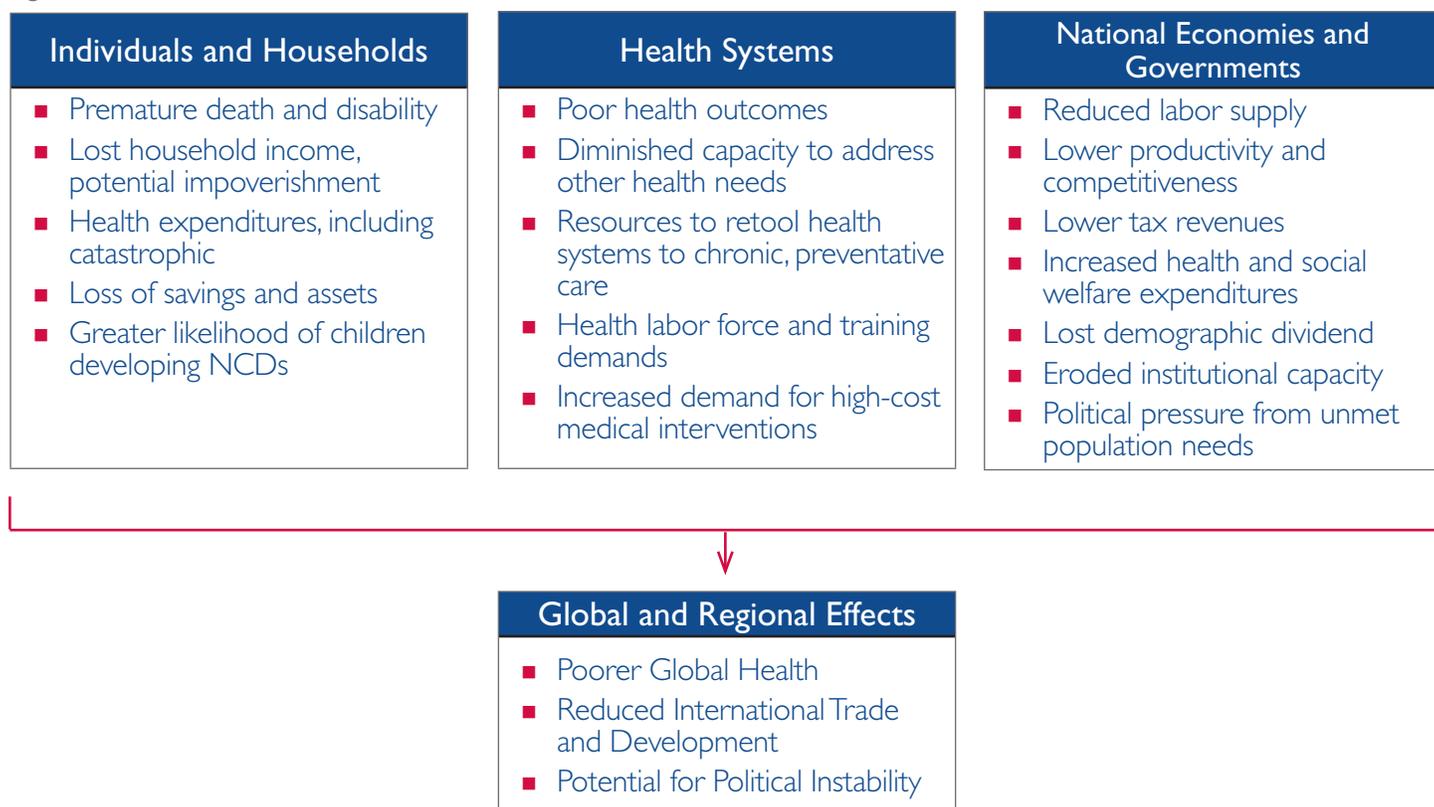
At a macro level, disability and premature death reduce aggregate productivity and increase health-care costs, thereby weakening national economic development.¹² A 2008 study estimated that each 10% rise in the working-age NCD mortality rate is associated with a 0.5% decrease in annual economic growth.¹³ Cumulative lost output associated with the four primary NCD categories from 2011 through 2025 is projected to be more than US\$ 7 trillion in LMICs.¹⁴ The growing NCD burden is weakening already strained health systems and has the potential to stall and reverse health and development progress made to date, contributing to effects that can be felt at regional and global levels (Figure 2).

Access to medicines and medical devices for NCDs is limited

While most NCDs can be diagnosed, prevented, delayed, and ameliorated with adequate access to appropriate medicines, medical devices, in vitro diagnostics (IVDs), and vaccines, access is low, particularly in LMICs.

It is estimated that globally, as many as two billion people – and as much as half the population in the poorer parts of Africa – lack adequate access to essential medicines.¹⁵ Similar problems exist with respect to effective access to medical devices, such as IVDs. IVD tests can detect diseases, conditions, or infections; they are used to inform key

Figure 2. Effects of NCDs in low- and middle-income countries



Reproduced from: Council on Foreign Relations. Independent Task Force Report No. 72: The Emerging Global Health Crisis (New York; CFR, 2014)

Quality of products and services is an essential component to medicines management which cuts across the four dimensions of availability, affordability, accessibility, and acceptability.

decisions regarding appropriate care and management of patients—for screening, diagnosis, treatment monitoring and patient management, and assessment of disease progression. Diagnostic tests should be accurate, simple and affordable for the population for which they are intended, and must provide timely results to facilitate effective treatment decisions.

High-quality IVDs are readily available in most developed countries, but the situation is very different in developing countries, where the costs of imported IVD technology are frequently too high for the public sector. Where IVDs are available, they are often provided by international donors and focused on disease-specific initiatives for communicable diseases.¹⁶

A multi-dimensional approach is needed to increase access

Addressing the challenge of inadequate access to medicines and health devices for managing NCDs requires an understanding that 'access' is multi-dimensional. Four dimensions of access have particular relevance:

Availability, defined by the relationship between the type and quantity of product or service needed, and the type and quantity of product or service provided

Affordability, defined by the relationship between prices of the products or services and the user's ability to pay for them

Accessibility, defined by the relationship between the location of the product or service and the location of the eventual user of the product or service

Acceptability (or satisfaction), defined by the relationship between the user's attitudes and expectations about the products and services and the actual characteristics of products or services.¹⁷

A fifth dimension, the 'quality of products and services', is an essential component that cuts across the four dimensions above, and refers to their safety, efficacy, quality – and cost-effectiveness (Figure 3).¹⁸ Attention to these properties of medicines and medical devices is essential for ensuring all components of access are satisfactorily addressed.

Figure 3. The multidimensional access framework



Reproduced from: Management Sciences for Health. Toward Sustainable Access to Medicines. Chapter in: MDS-3: Managing Access to Medicines and Health Technologies. (Arlington, VA: MSH, 2012).

Overview of Pharmaceutical Manufacturing in Africa¹⁹

- More than 70% of Sub-Saharan Africa's estimated \$1 billion in annual pharmaceutical production is concentrated in South Africa.
- Nigeria, Ghana, and Kenya together represent about 20% of Sub-Saharan medicine production
- Of these three countries, only Kenya produces significant volumes for regional export—between 35 and 45% of Kenyan manufacturers' revenues come from exports to other EAC and Common Market for Eastern and Southern Africa (COMESA) countries.
- 38 Sub-Saharan African countries have some pharmaceutical production, with 34 having capacity for formulation and 25 limited to packaging or labeling.
- South Africa is the only African country with a limited degree of active pharmaceutical ingredients (API) production.

Access is undermined by inadequate regulation

The various barriers in access to essential medicines and health devices reflect key shortcomings of the health systems that struggle to provide them.²⁰ As a result of non-existent, weak, or outdated legal and regulatory frameworks, policy

makers face major difficulties across all of the dimensions of access, particularly in regulating the safety, efficacy, and quality of medicines and technologies. Although many factors are at play, a well-functioning regulatory system is the cornerstone without which efforts to address the other dimensions of access cannot be effective.



Photo by Pinky Patel

Case Study: African Medicines Regulatory Harmonization in Burundi¹⁹

Following the successful establishment of the EAC Medicines Regulatory Harmonization (MRH) program in 2012, Burundi participated in the development and subsequent adoption of harmonized technical guidelines by the EAC Council in 2014.

Two pilot projects: the WHO Medicines Pre-Qualification Program (WHO-PQP) and the EAC Joint Assessments and Inspections enabled Burundi to participate in the approval of five and seven products in 2011 and 2013, respectively. In 2015, the EAC-MRH program conducted a Joint Dossier Assessment of eight medicinal products in Entebbe, Uganda.

Phase two of the EAC-MRH program has expanded to include strengthening pharmacovigilance; clinical trials oversight; harmonization of regulation of vaccines; and regulation and quality assurance of medical devices, including diagnostics.

Regulatory capacity is weak for medicines ...

Across Africa, the majority of National Regulatory Authorities (NRAs) face persistent resource constraints, often rendering them incapable of adequately performing core functions. Poorly funded, under-staffed, inadequately skilled, and overextended, they are often unable to provide needed guidance to developers and manufacturers, or to conduct proper oversight of products being studied, introduced, manufactured, and used in their countries.

While the capacity to perform specific regulatory tasks varies across countries, the World Health Organization (WHO) has estimated that as many as 80% of African NRAs lack sufficient capacity to ensure the quality, safety, and efficacy of medicines sold in their markets due to persistent shortages of human, technical, logistical, and financial resources.²¹ As a result, not only are many NRAs unable to critically evaluate efficacy and safety, they also cannot assess or approve products in a timely manner, or impose or ascertain acceptable quality standards.

... but even weaker for medical devices

Regulatory capacity for medical devices is generally even less well-developed than it is for medicines and vaccines. Approaches to the regulation of medical devices are qualitatively different from those applied to medicines, for a variety of reasons, including a typically much shorter product lifecycle. There are also major differences in the nature of the clinical trials that may be undertaken to support the safety and performance of medical devices, as well as differences in intellectual property protection issues, among others. For these reasons, medical device regulatory regimes should not be based on a model developed for medicines.

It is perhaps not surprising that only 15 (32%) of African NRAs register medical devices or control their importation.²² A 2012 study that assessed regulation of diagnostics and devices within the East African Community (EAC) found that control of medical devices and IVDs in EAC partner states was largely confined to national communicable disease programs such as tuberculosis, HIV, and malaria.²³ Regulation was weak across the region, and although the majority of states had legal mandates to regulate medical devices, there was limited capability to do so. Many NRAs focused on pharmaceutical products did not have the capacity to also regulate diagnostics and medical devices, and post marketing surveillance was uncommon.²⁴ The study reveals that training in key areas is essential for strengthening regulatory capacity for IVDs and other medical devices, and streamlining regulation in the EAC is seen as a positive aspiration – with diagnostic tests considered a priority area for harmonization.

The importance of effective regulation is not well recognized

Many of the challenges facing NRAs in the region are compounded by a lack of political will and inadequate recognition of the importance of effective regulation, collectively leading to an unwillingness among other portfolios within government (for example, ministries of finance or other funding agencies) to support NRA funding or investment in strengthening regulatory capacity. This hampers the ability of NRAs to manage their workloads and recruit, train, and retain skilled staff. Therapeutics regulation requires specific expertise to evaluate the complex application dossiers, perform facility inspections, and monitor quality and safety post market. In some countries there are also challenges in balancing the needs of central and regional governments, which may have overlapping responsibilities, for example in manufacturing or other facility inspections.



Photo by Pinky Patel

Box 2. Regulating Medical Devices in Tanzania

Case Study: Medical Device Regulation in Tanzania

The Tanzania Food & Drugs Authority (TFDA) has been regulating medical devices since 2008. Section 51 of the Tanzania Food, Drugs & Cosmetics Act, Cap 219 requires TFDA to register medical devices before they may be allowed to enter the Tanzanian market. Medical devices are divided into four main classes and regulation is risk-based.

The processes for registration began in 2008, with notification of medical devices. In 2010 the first phase of registration of medical devices started. As of June 2013, a total of 96 medical devices had been registered between 2010 and 2013.

The TFDA also

- registers manufacturing facilities and warehouses and inspects these and wholesale and retail shops; and
- issues permits for import or export of medical devices and in the 10 years to 2013, a total of 4,967 and 34 import and export permits respectively were issued.

Post marketing surveillance (PMS) of medical devices began 2012 and involves testing of samples of medical devices being used in the market. In carrying out PMS, TFDA works in collaboration with other institutions such as Medical Stores Departments, the Private Health Laboratory Board and the National Health Laboratory – Quality Assurance and Training Center.

Various guidelines for the control of medical devices have been developed outlining requirements for applicants seeking to market medical devices and include:

- Guidelines for Registration of medical devices of 2009;
- Guidelines for Registration of medical devices premises of 2011; and
- Guidelines for Good Distribution Practices for medical devices of 2011.

From: TFDA (2013). Ten years of regulating food, medicines, cosmetics and medical devices: Milestones attained.

Strengthened efforts toward trade integration and liberalization, together with investments in capacity building to support improvements in regulatory processes and manufacturing standards, can lead to improved access to medicines and technologies to detect and address NCDs among Africans.

Despite these human capital and financial resource constraints, only a few African countries rely on or refer to registration decisions or evaluations of other regulators (such as stringent NRAs or the WHO Prequalification Programme), or competent authorities. The limited capacity of NRAs often results in significant delays in registering products, hampering timely access for patients, undermining the development of the health sector, and creating disincentives for direct foreign investment and for the introduction and diffusion of novel products.²⁵ Regional work-sharing, adopting decisions of other NRAs, and focusing capacity development in those areas where local expertise is essential, are examples of approaches that could reduce lengthy approval processes.

The roles of trade and capacity building in improving regulation

A key requirement for market growth and robust trade in medicines and medical devices is the development and application of regulatory standards and processes that promote trust among consumers and businesses in goods manufactured and/or supplied within and by the African continent. Efforts to reduce regulatory barriers, improve standards of regulation, achieve consistency and clarity in regulatory requirements, and ensure the quality of products available in the marketplace are essential to stimulating market participation and ensuring confidence in the available products.

Rigorous, uncorrupted, evidence-based, and transparent regulatory processes are critical to safeguard the health of the public and to maintain public and investor confidence in the integrity of the health system. Investment is needed to support the development, modification, or reform of underlying legal and regulatory policy frameworks, to ensure clarity in the role and responsibilities of the NRAs, establish

clear legislative mandates to enforce requirements and standards, and promote confidence in the medicines, medical devices, and diagnostic technologies available in the market.

Building and retaining technical capacity is also critical, both pre- and post-market. Evidence of significant penetration of sub-standard and counterfeit products across the African continent illustrates the need for capacity building in local manufacturing.²⁶ Africa currently imports more than 95% of the API it needs and roughly 75% of finished formulations.²⁷ Although 38 African countries have some form of pharmaceutical manufacturing capacity, there are only two with limited API production, considered important for the security of supply.²⁸

Strengthening Africa's ability to produce high-quality essential medicines is expected to contribute towards improved health and economic outcomes through greater reliability of access and supply. However, the success of local production will partly depend on the expansion of intra-regional and intra-continental trade to create viable market sizes, harmonization of the administrative and technical requirements for medicines registration, and removal of barriers to the free movement of products manufactured in Africa.

Strengthened efforts toward trade integration and liberalization, together with investments in capacity building to support improvements in regulatory processes and manufacturing standards, can lead to improved access to medicine and technologies to detect and address NCDs in African countries. An example of one area in which trade and capacity building could serve to improve regulatory standards explicitly would be in achieving compliance with US Sanitary and Phytosanitary (SPS) standards – recognizing that this could raise the cost of African exports, even in the absence of significant tariff barriers.



Photo by Daniel Adedigba

■ Examples of current global and regional initiatives ■

Pharmaceutical Manufacturing Plan for Africa

The African Union (AU) approved the Pharmaceutical Manufacturing Plan for Africa (PMPA) in 2007. The PMPA specifically recognizes that robust regulatory systems are essential to ensuring the quality, safety, and efficacy of locally manufactured products, and that African countries must pool their resources if they are to strengthen their medicines regulatory systems.

African Medicines Regulatory Harmonization (AMRH) Initiative

The African Medicines Regulatory Harmonization (AMRH) initiative, implemented as part of the PMPA, is a key component in helping African countries respond to AU's mandate to fulfill national obligations to provide all citizens with safe, good quality, and effective essential medicines.²⁹ AMRH works in three areas: policy alignment, regional integration and harmonization, and human and institutional capacity development. The AMRH Strategic Plan sets the agenda for medicines regulatory harmonization in Africa, provides direction to advance the development of the pharmaceutical sector; and offers guidance in monitoring and evaluation. Its overall aim is to establish – in partnership with the AU and WHO – the African Medicines Agency, which will oversee the registration of a selected list of medicines and coordinate regional harmonization across Africa.³⁰

Currently manufacturers or suppliers wishing to access and develop markets in Africa face a landscape of disparate regulations, frequent delays, and limited transparency. The AMRH agenda is intended to promote capacity building, reduce duplication, improve consistency in decision-making and support uniformity in regulatory requirements – thus creating an enabling regulatory environment for pharmaceutical sector development in Africa. While it does not yet include diagnostics and other medical devices, it sets the stage for future cooperation and harmonization across the span of therapeutics regulation.³¹

Regional Centres of Regulatory Excellence (RCOREs)

In 2014 AMRH announced that 10 academic institutions or partnerships of institutions and NRAs had been selected to become Regional Centres of Regulatory Excellence (RCOREs), to help strengthen regulatory capacity development in Africa.³²

The RCOREs initiative was developed through a series of extensive and inclusive consultations with key stakeholders and experts. The designated institutions are expected to play a crucial role in regulatory capacity development in Africa through the provision of academic and technical training in regulatory science; skills enhancement through hands-on training, twinning and exchange programs among NRAs; and practical training through placement in pharmaceutical industry and/or NRAs. RCOREs will institutionalize structured regulatory curricula and provide practical and hands on training experience and structured competence assessment and certification. At the present time, none of the designated RCOREs are focused on medical devices or diagnostics.

The Model Law for Medical Products Regulation and Harmonization

The New Partnership for Africa's Development (NEPAD), in collaboration with the AU and the Pan-African Parliament (PAP), has developed the Model Law for Medical Products Regulation and Harmonization within the framework of the AMRH Program, which is a part of the operationalization of the PMPA 2012 Business Plan.³³ The Model Law addresses legislative gaps that exist in most AU member states that hamper effective medicines regulation and undermine the potential for regional harmonization.

Developed through a consultative process with key stakeholders including Regional Economic Communities (RECs), NRAs, the pharmaceutical industry, and other African and international partners, the Model Law will provide a systematic approach for developing legislation on medicines regulation in African countries that will also support the AU's objective of promoting local production of medicines. It will also provide a comprehensive guide to member states in the development or review of national legislation and offer a framework to support Member States in the harmonization of medical products regulation within RECs.

Pan African Harmonization Working Party

While the AMRH agenda does not yet include diagnostics and other medical devices, the activities of the Pan African Harmonization Working Party on Medical Devices and Diagnostics (PAHWP) may be seen as complementary.

The PAHWP has as its key goals to establish, strengthen and harmonize regulatory capacity for medical devices and diagnostics, and to encourage countries to learn from the experience of others and adopt best practices from more mature regulatory frameworks, thereby improving access to safe, efficacious, and affordable quality medical devices and diagnostics in the EAC region. Ultimately, the use of harmonized, coordinated controls is expected to facilitate cross-border leveraging of regulatory resources, reduce regulatory burden on industry and expand public health benefits. Currently the PAHWP has 15 members. In 2013, PAHWP was accepted as a member of the AMRH Advisory Committee; consequently the scope of the AMRH Advisory Committee was expanded to include medical devices and IVDs.

Specific objectives of the project are to:

- develop and implement harmonized regional regulatory and mutual recognition frameworks and guidelines for the regulation of medical devices and diagnostics based on risk classification
- build human resource and infrastructure capacity for the regulation of medical devices and diagnostics in the EAC Partner States
- implement quality assurance, audit and management systems in each of the EAC Partner States' NRAs for the regulation of medical devices and diagnostics
- implement a common information management system for registration and post market surveillance of medical devices and diagnostics in each of the EAC Partner States' NRAs.³⁴

Asian Harmonization Working Party

The goals of the Asian Harmonization Working Party (AHWP) are to study and recommend ways to harmonize medical device regulations in Asia and other regions, and to work in coordination with the Global Harmonization Task Force, the Asia-Pacific Economic Cooperation Forum, and other related international organizations working toward the establishment of harmonized regulatory requirements, procedures and standards. The AHWP is made up of experts from the medical device regulatory authorities and the medical device industry. Membership is open to those representatives from the Asian and other regions that support the above stated goals. Tanzania is currently the only member from Sub-Saharan Africa.³⁵

The WHO Global Model Regulatory Framework for Medical Devices including IVDs

In May 2007, the first resolution on health technologies adopted by the World Health Assembly (WHA 60.29) set an agenda for unprecedented focus on health technologies, specifically medical devices. A subsequent resolution, in 2014, addressed regulatory system strengthening for medical products (WHA 67.20). In light of Resolution 67.20, a growing interest in medical devices in the global health community, and the lack of regulatory systems for medical devices in many countries, WHO developed a draft Global Model Regulatory Framework for Medical Devices, released in May 2016, to provide guidance and support to WHO Member States yet to develop and implement regulatory controls on medical devices.³⁶

Recognizing that many countries have neither the financial resources nor technical expertise to transition successfully from an unregulated market to a comprehensive medical devices law in a single program, the Model recommends a progressive, or stepwise, approach to regulating the quality, safety, and performance of medical devices. It provides guidance for staged development beginning with developing laws with basic regulatory requirements, through registration of establishments that put medical devices on the market, to listing of medical devices and post-market controls. It also recognizes that regulation of medical devices does not take place in isolation, but should be coordinated with regulation of other medical products (such as medicines, vaccines, etc.) and other government policy objectives.³⁷

The Model's main elements refer to guidance documents developed by the Global Harmonization Task Force (GHTF) and its successor, the International Medical Device Regulators Forum (IMDRF). The Model is particularly relevant for WHO Member States with no or limited regulation for medical devices in place, but anticipates that countries will progress from basic controls towards higher levels using a stepwise approach, as their resources permit. It also describes circumstances in which a regulatory authority might rely on, or recognize, the work products of a trusted regulator (scientific assessments, audit and inspection reports), or WHO prequalification, as well as the importance of international convergence of regulatory practice.³⁸

Conclusion

Key elements for promoting health and economic growth across Africa are expanding markets and increasing trade.³⁹ The growing impact of NCDs on population health status and economic development in Africa underscores the urgency with which these issues should be addressed. Prevention and treatment of NCDs requires effective access to a range of interventions. For medicines and medical devices, building regulatory frameworks – and strong health systems to implement and support them – is critical to stimulating market growth and availability of quality medical products.

Efforts to support regulatory systems strengthening and capacity building to develop technical skills, harmonize regulatory requirements, minimize barriers to the free movement of products within and across regions, reduce

duplication of effort, and ensure quality, will not only enhance confidence in the available products, but also in the region as a destination for investment—in people, products, and infrastructure. To date, the focus of strengthening and harmonization has been overwhelmingly directed toward medicines. This reflects in part the fact that regulatory models for medicines cannot simply be extrapolated to devices and diagnostics. This focus is gradually changing, however, acknowledging not only the importance of medical devices and diagnostics in modern healthcare, but also the tremendous market opportunities these products represent. ■

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ABOUT ASH

African Strategies for Health (ASH) is a five-year project funded by the U.S. Agency for International Development's (USAID) Bureau for Africa and implemented by Management Sciences for Health. ASH works to improve the health status of populations across Africa through identifying and advocating for best practices, enhancing technical capacity, and engaging African regional institutions to address health issues in a sustainable manner. ASH provides information on trends and developments on the continent to USAID and other development partners to enhance decision-making regarding investments in health.

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