Issue Brief

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African Union Model Law for Medical Products Regulation: Increasing access to and delivery of new health technologies for patients in need

Summary

The regulation of health technologies is a critical component of any well-functioning health system, as it enables access to health technologies of assured quality, safety and efficacy. Recent shifts in the product development landscape have seen initiatives to develop products specifically for diseases predominantly prevalent in developing countries. While the prospect of sorely needed new health technologies is encouraging, their successful introduction into national health systems may require new skills or capacities, as well as robust policy and regulatory frameworks, and safety monitoring systems. In many low- and middle-income countries in Africa, such capacities remain underdeveloped. Regulatory requirements differ between countries and can pose difficulties for producers of health technologies seeking to introduce their products into domestic markets. Strengthened and harmonized regulatory systems in Africa will help improve the predictability and efficiency of market approvals, so that new health technologies can become available sooner — ultimately improving access and delivery of health technologies for patients in need. This Issue Brief focuses on key features of the recently adopted African Union Model Law for Medical Products Regulation. The Model Law, which was developed with support from the Access and Delivery Partnership, provides a template for Member States of the African Union to adapt best practices for medicines regulation into their national laws and supports the African Union's vision and efforts to promote and accelerate access to new health technologies for patients in need.

THE ACCESS AND DELIVERY PARTNERSHIP
New Health Technologies for TB, Malaria and NTDs

From the People of Japan

NEPAD TRANSFORMING AFRICA

About the Access and Delivery Partnership

The adverse impact of tuberculosis (TB), malaria and neglected tropic diseases (NTDs) on development outcomes has resulted in new approaches and partnerships to tackle the global deficiencies in research and development, and access to health technologies. Consistent with UNDP's mission to eradicate poverty and reduce inequalities and exclusion, one such initiative is the strategic partnership between the Government of Japan and UNDP, which promotes research and development, and expedites access to and delivery of health technologies for TB, malaria and NTDs. This partnership comprises two complementary components, which reflect the Government of Japan's global health goals and UNDP's *HIV, Health and Development Strategy 2016–2021: Connecting the dots;*

> **The Global Health Innovative Technology (GHIT)** Fund focuses on the promotion of innovation and research through the development of drugs, diagnostics and vaccines for TB, malaria and NTDs. The GHIT Fund stimulates research and development of new health technologies through funding research and product development partnerships between Japanese and non-Japanese organizations.
>
> **The Access and Delivery Partnership (ADP)** aims at assisting low- and middle-income countries (LMICs) enhance their capacity to access, deliver and introduce new health technologies for TB, malaria and NTDs.

Led and coordinated by UNDP, the ADP is a unique collaboration between UNDP, TDR (The Special Programme for Research and Training in Tropical Diseases, which is co-sponsored by UNICEF, UNDP, the World Bank and WHO) and PATH. Working together, the project partners leverage the expertise within each organization to provide the full range of technical skills necessary to strengthen capacity in LMICs. The ADP emphasizes consultation, collaboration and implementation with partner country governments and stakeholders, working to develop LMICs' capacities to access and introduce new technologies.

New health technologies are broadly defined as medicines, diagnostic tools and vaccines that are relevant for the prevention, treatment or cure of TB, malaria and NTDs, but are not yet available for market introduction or have not been introduced in LMICs. The introduction of new health technologies can place burdens on existing health systems, including new requirements for drug regulation, supply and distribution and health personnel training. Accordingly, the ADP will focus on providing LMIC stakeholders with the necessary skills to develop the systems and processes required to effectively access new health technologies, and introduce them to populations in need.

The ADP and the GHIT Fund are both funded by the Government of Japan.

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The Access and Delivery Partnership, *'African Union Model Law for Medical Products Regulation: Increasing access to and delivery of new health technologies for patients in need',* UNDP, New York, 2017.

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1 Introduction

Tuberculosis (TB), malaria and neglected tropical diseases (NTDs) are diseases of poverty and inequality, with the greatest impact on the poorest and most vulnerable. TB is one of the world's deadliest communicable diseases: in 2015, 10.4 million people fell ill from the disease,[1] of whom 2.7 million were in Africa.[2] At the same time, an estimated 750,000 people in Africa died from TB. There were 212 million cases of malaria around the world in 2015, 90 percent of which were in Africa. Malaria caused 394,000 deaths in Africa, 74 percent of which were children under five years of age.[3] The 18 NTDs, as identified by the World Health Organization (WHO), affect people in 149 countries worldwide,[4] accounting for one of the highest burdens among all infectious and parasitic diseases. In 2015 alone, over 1.5 billion people were estimated to need treatment for at least one of the five major NTDs (lymphatic filariasis, onchocerciasis, soil-transmitted helminthiases, schistoso-miasis and trachoma).[5] In Africa, 391 million and 200 million people are at risk of the two most prevalent NTDs: lymphatic filariasis and schistosomiasis, respectively.

Despite their significant impact, relatively few new health technologies are available for TB, malaria or NTDs. Many of the current treatments and diagnostic tests for these diseases are outdated or lack efficacy. With a view to redressing the disproportionate investment in health research for diseases such as TB, malaria and NTDs, public–private partnerships (PPPs) and product development partnerships (PDPs) have emerged to finance and stimulate research and development (R&D). Their efforts are beginning to yield a number of new products, including, for example, two new chemical compounds for the treatment of TB, and the first malaria vaccine.[6] Most of these investments include as part of their core objectives an aspiration that the development of such new technologies will become available and accessible as soon as possible. Effective regulatory systems are key to ensuring that this objective is realized, given that the swift entry to market of new products and their delivery to patients are central concerns.

The 2030 Agenda for Sustainable Development acknowledges the impact of TB, malaria and NTDs on human development. Hence, Sustainable Development Goal (SDG) 3 on health and well-being sets the ambitious target of ending the epidemics of acquired immunodeficiency syndrome (AIDS), TB, malaria and NTDs by 2030.[7] Since health challenges are inter-connected, effectively tackling these diseases will contribute towards achieving not only other SDG 3 targets, but also SDGs related to poverty and inequality. Towards this end, SDG 3 thus underscores the importance of promoting R&D for new medicines and vaccines, as well as the need to ensure "access to safe, effective, quality, and affordable essential medicines and vaccines for all". In the same vein, the G-7 *Ise-Shima Vision for Global Health* similarly calls for policies to encourage both the development of and access to medical products for diseases not adequately addressed by the market.[8]

To benefit patients in low- and middle-income countries (LMICs), the partnership between the Government of Japan and the United Nations Development Programme (UNDP) aims to build concrete linkages between R&D and access and delivery, through the complementary initiatives of the Global Health Innovative Technology (GHIT) Fund and the Access and Delivery Partnership (ADP).

The GHIT Fund fosters collaborative innovation and R&D for new medicines, vaccines and diagnostics for TB, malaria and NTDs; while the ADP supports efforts to strengthen the capacities of LMICs to improve access to and delivery of these new health technologies to patients in need. These initiatives acknowledge that sole focus on R&D will not automatically lead to the introduction and use of new health technologies in LMICs.

Antimalarials and other essential medicines need to be safe, effective and readily available to communities across the region.
Photo: UNDP/Natasha Scripture

In this context, this Issue Brief focuses on the efforts in the African region, with reference to the initiative of the African Union (AU), through its implementing arm, the NEPAD Planning and Coordinating Agency (NPCA), to optimize access to and delivery of new health technologies that are of assured quality, safety and efficacy. The AU is a union of 55 countries in the African continent, aimed at accelerating regional integration, while the NPCA facilitates and coordinates the development of continental and regional priority programmes and projects.[9] Recognizing the importance of efficient and aligned regulatory systems to ensure access to new health technologies, the AU and the NPCA, in partnership with key stakeholders, developed the AU *Model Law for Medical Products Regulation* (the AU Model Law).

Adopted by the AU Heads of State and Government in January 2016, the Model Law provides a comprehensive legislative template for African countries that can be adopted and adapted by national governments and regional economic communities (RECs) to harmonize regulatory systems and increase South–South cooperation across the region.

2 Strengthening and harmonizing regulatory systems in Africa

Typically, the national legal and regulatory framework provides governments with the mandate to regulate medical products through the national regulatory authorities (NRAs). NRAs are responsible for ensuring the safety, quality and efficacy of health technologies. The mandate of NRAs also often includes the regulation of the clinical trials, manufacturing and marketing of health technologies, although the scope and breadth of this mandate may vary from country to country.[10]

In many of the AU Member States, capacity within regulatory systems remains limited, due to inadequate human and financial resources, overburdened staff and incomplete and incoherent policy frameworks.[11] As a result, many of the NRAs have limited capacity to approve medicines in a timely manner and to ensure acceptable quality, safety and efficacy standards.

Another key challenge in ensuring effective regulation of medical products is weak or outdated legal frameworks, or the existence of gaps in the relevant legal frameworks in many African countries. Analysis by NPCA revealed that while some countries have legislation in line with the WHO-recommended standards, some lack comprehensiveness, while others do not have any medicines regulatory laws in place. Aside from hampering effective regulation at the national level, the gaps and inconsistencies in legislation are a major obstacle to harmonization and mutual recognition at the regional level.[12] Differences in application requirements across countries also mean that researchers and manufacturers may have to navigate multiple regulatory systems to register the same health technology across countries.

Despite these challenges, significant progress has been made in the AU Member States to further strengthen regulatory processes, capacities and institutions. The African Medicines Regulatory Harmonization Programme (AMRH) supports African RECs to improve regulatory standards and expedite registration of essential medicines through the process of harmonization.[13] The overall, longer-term aim of the AMRH is to establish the African Medicines Agency, which will be tasked to oversee the registration of a selected list of medicines and coordinate regional harmonization systems on the continent.

The development of the AU Model Law should be understood in the context of these overarching efforts towards regulatory harmonization in Africa. In this regard, the AU Model Law is a tool to provide policy and technical guidance for AU Member States as they review existing national laws, so as to be in line with international standards to ensure more effective regulation of medical products. While it is not a prescriptive document, the use and implementation of the AU Model Law by AU Member States to amend or enact a nationally appropriate version will facilitate the overall harmonization process in the region.

> *"Africa has taken a major step in accelerating access to the needed safe, efficacious and quality medicines for the treatment of priority diseases by adopting the African Union Model Law on Medical Products Regulation. The Summit of Heads of State and Government of the African Union that convened in Addis Ababa, Ethiopia from 30–31 January 2016 adopted the Model Law in recognition of the need to promote and protect the public health of Africa's citizens."*
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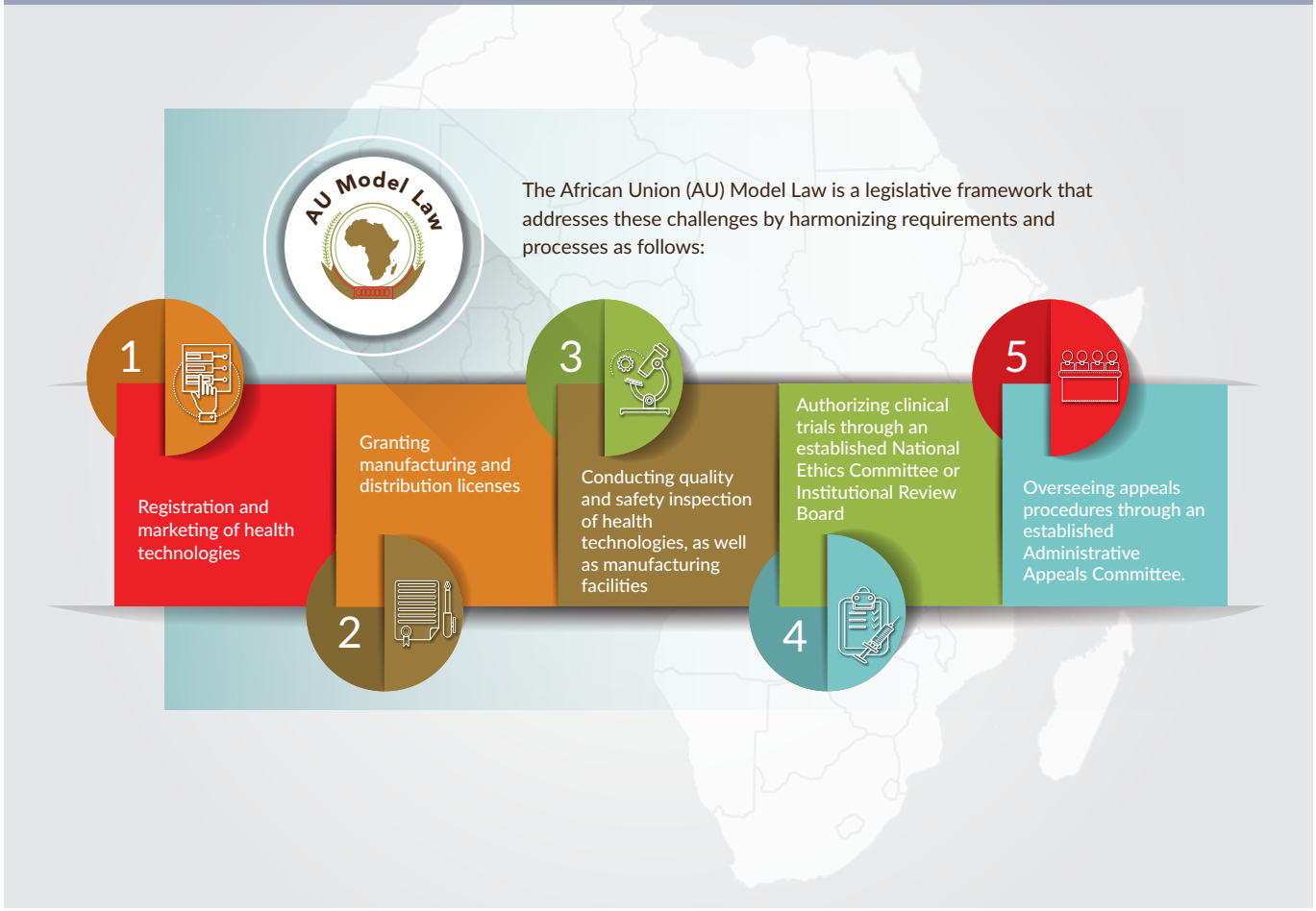
> **NEPAD Planning and Coordinating Agency,**
> *'African Union Heads of State make a major policy decision to improve medicines regulation and access to lifesaving medical products.'*
> e-alert, 1 February, 2016.

3 The AU Model Law

Recognizing the critical importance of sound regulatory systems to the achievement of the twin goals of promoting innovation and access, the ADP has collaborated with the AU and the NPCA to develop the Model Law. This collaboration began at the inception of the Model Law, with the ADP and UNDP providing inputs into this process, including through the support of technical experts who have been instrumental in the development of the Model Law. The collaboration between the ADP and the AU Commission and NPCA continues today, with the ADP supporting the process of implementing the Model Law at the national level.

Figure 1. A summary of the regulatory functions of the AU Model Law on medical products regulation (courtesy of NPCA)



The AU Model Law, officially endorsed by African Heads of State and Government at the AU Summit in January 2016 in Addis Ababa, Ethiopia, is thus designed to assist African countries to address the gaps and inconsistencies in regulatory legislation and enable harmonization.[14]

It is premised on each country having an autonomous NRA, but, to address key challenges and promote harmonization and efficiency in the region, key functions and standards which should form part of any regulatory regime have been identified and incorporated, as follows:

Marketing health technologies: All medical products must be registered and have valid authorization to be marketed and promoted. Applications for this authorization will be reviewed by the NRA.

Licensing: Only with a licence from the NRA may a person or company manufacture or distribute health technologies.

Quality and safety of health technologies: The NRA will be responsible for monitoring and analysing adverse effects of registered health technologies and clinical trials, as well as the recall and withdrawal of substandard products. The NRA will conduct quality and safety inspections of health technologies and manufacturing facilities, and a National Quality Control Laboratory will be established for research, training and the analysis of medical products.

Clinical trials: To conduct a clinical trial with human participants, the trial must be cleared by a National Ethics Committee or Institutional Review Board and authorized by the NRA.

Appeals procedures: The authority overseeing the NRA (e.g. the Ministry of Health) will establish an Administrative Appeals Committee to hear cases lodged against the NRA.

> *"It is very much about getting the right products – the right diagnostics, vaccines, or medicines – to the right people in a timely manner and at the right cost, and working with countries to prepare the ground."*
>
> **Mandeep Dhaliwal,**
> Director, HIV, Health and Development Group, UNDP

A unique feature of the Model Law process is the extent of stakeholder consultation and participation in the development of the legislation, which took place during 2014–2015. The Model Law process (as shown in figure 2) is not an isolated development but is complemented by partnerships, regional integration initiatives, incorporation of global best practices in medicines regulation, and a pharmaceutical manufacturing plan for the continent. These elements will go towards ensuring the Model Law's relevance and sustainability.

> *"The purpose of this [model] law is not for us to prescribe what Member States should do. That is why we will go throughout the Continent to...ensure that this [model] law is widely consultative and owned by Africans."*
>
> **Prof. Aggrey Ambali,**
> Head of the NEPAD Science, Technology and Innovation Hub (NSTIH)

Figure2. A summary of the seven things you need to know about the AU Model Law on medical products regulation (courtesy of NPCA

4
Next steps: Implementation of the AU Model Law

Following the adoption of the AU Model Law, NPCA, with the support of its partners, began conducting situational analyses, needs assessments and advocacy to determine pilot and priority countries and regions.

Implementation at national level has involved a com-bination of situation and needs analysis, advocacy and technical assistance. A number of countries have already used the Model Law to update their national legislation. Côte d'Ivoire, Lesotho, Seychelles, Swaziland, the United Republic of Tanzania (Zanzibar) and Zimbabwe have used the AU Model Law to review their existing laws.

The target is to have at least 25 AU Member States using a version of the AU Model Law that befits their country context by 2020.[15]

Regional roadmaps for the implementation of the Model Law have also been developed; where possible and appropriate, RECs have also begun harmonization of regulatory requirements for their member countries.

The AMRH is currently being implemented in the Economic Community of West African States (ECOWAS),[16] with a view to taking a regional position to promote national adoptions. Implementation of harmonized standards and tools for registration of medicines in the East Africa Community (EAC)[17] came into effect in January 2015,[18] aiming to facilitate the marketing authorization of products in five of the Partner States. The EAC has also initiated a process of drafting a regional pharmaceutical policy and bill for the establishment of an EAC Medicines and Food Safety Commission. In the Southern African Development Community (SADC) region, harmonization efforts build on the ZAZIBONA initiative, a collaborative medicines registration process initially involving Zambia, Zimbabwe, Botswana and Namibia, and recently joined by South Africa and Swaziland.[19] The model used is one based on work-sharing in the assessment of medicines and the inspection of manufacturing sites and testing facilities. In these instances, the AU Model Law can be a useful guiding template to facilitate the process of strengthening and harmonizing of regulatory systems.

5
Strengthened and harmonized regulatory systems: Implications for access

Strengthened and harmonized regulatory systems in Africa will improve the predictability and efficiency of marketing approvals, so that innovative new health technologies can be delivered and used sooner – ultimately improving health outcomes of patients in need. It has been demonstrated that regional initiatives for harmonization can avoid duplication of regulatory reviews, accelerate scientific risk–benefit- adjusted reviews, facilitate mutual recognition and accelerate access. For example, in a pilot demonstration project for the joint regional evaluation of product registration applications conducted in March 2014, the EAC Partner States jointly assessed applications and registered two antimalarial drugs and three generic pharmaceuticals in less than one year. The procedure was completed **30 to 40 percent faster than usual,** resulting in significant cost and time savings.[20]

The AU Model Law seeks to provide a framework to guide AU Member States in strengthening the regulatory environment for the delivery of quality, safe and efficacious health technologies, and will be an important tool in promoting an integrated and coordinated approach for medicines regulation and facilitating the efficient and speedy introduction of new health technologies. The next phase in the process entails ongoing work on the domestication of the Model Law across Africa, and laying the foundations for the establishment of the African Medicines Agency.

The experience of the collaboration between the ADP and regional entities such as the AU Commission and NPCA, to promote policy coherence in access and delivery, has begun to bear fruit. It promises a coordinated approach to innovation and access, through the strengthening and professionalization of medicines regulation on the continent. This will be a huge step forward in tackling Africa's disease burden, and to helping countries in the region to achieve the health goals of the SDGs.

Mass drug administration of praziquantal to school children at risk of schistosomiasis, which is a major neglected tropical disease in Africa. *Photo: UNDP/Natasha Scripture*

ADP Partners

Government of Japan

The collaboration between the United Nations Development Programme (UNDP) and the Government of Japan is a strategic partnership to promote research and development, and to increase access to and delivery of health technologies used to address neglected tropical diseases (NTDs), tuberculosis (TB) and malaria.

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United Nations Development Programme

UNDP partners with people at all levels of society to help build nations that can withstand crisis, and drive and sustain the kind of growth that improves the quality of life for everyone. On the ground in more than 170 countries and territories, UNDP offers global perspective and local insight to help empower lives and build resilient nations.

The Special Programme for Research and Training in Tropical Diseases

TDR is a global programme of scientific collaboration that helps facilitate, support and influence efforts to combat diseases of poverty. It is hosted at the World Health Organization (WHO), and is sponsored by the United Nations Children's Fund (UNICEF), UNDP, the World Bank and WHO.

PATH

PATH is an international nongovernmental organization that drives transformative innovation to save lives and improve health, especially among women and children. PATH works to accelerate innovation across five platforms – vaccines, drugs, diagnostics, devices, and system and service innovations – that harness entrepreneurial insight, scientific and public health expertise, and passion for health equity. By mobilizing partners around the world, PATH takes innovation to scale, working alongside countries primarily in Africa and Asia to tackle their greatest health needs. Working together with countries, PATH delivers measurable results that disrupt the cycle of poor health

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