



# GOING FURTHER TOGETHER

The case for European Union partnership with  
Africa on regulatory harmonization

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*Paper commissioned by Deutsche Stiftung Weltbevölkerung (DSW)*

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### ACKNOWLEDGEMENTS

This paper was prepared by Jenny Blair with inputs from Lisa Goerlitz, Agustin Martin, Cecile Vernant and Claire Wingfield. Many thanks to Elana Banin, Katie Gray Pauline Irungu, Yolanda Moyo and Simba Onyancha for providing valuable research, fact checking and insights into the development of this paper.

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### ABOUT DSW

Deutsche Stiftung Weltbevölkerung (DSW) is a global development organisation that focuses on the needs and potential of the largest youth generation in history. We are committed to creating demand for and access to health information, services, supplies, and economic empowerment for youth. We achieve this by engaging in advocacy, capacity development, and reproductive health initiatives, so that young people are empowered to lead healthy and self-determined lives. With our headquarters in Hannover, Germany, DSW operates two liaison offices in Berlin and Brussels, as well as maintaining a strong presence in Ethiopia, Kenya, Tanzania, and Uganda. DSW also advocates for investment in research and innovation to fight poverty-related and neglected tropical diseases – diseases that continue to disproportionately affect women and girls.

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### ABOUT PATH

PATH is the leader in global health innovation. An international nonprofit organization, we save lives and improve health, especially among women and children. We accelerate innovation across five platforms—vaccines, drugs, diagnostics, devices, and system and service innovations—that harness our entrepreneurial insight, scientific and public health expertise, and passion for health equity. By mobilizing partners around the world, we take innovation to scale, working alongside countries primarily in Africa and Asia to tackle their greatest health needs. Together, we deliver measurable results that disrupt the cycle of poor health.

[www.path.org](http://www.path.org)

*PATH and Deutsche Stiftung Weltbevölkerung (DSW). Driving Health Impact through Regulatory Harmonization: How the EU Can Support Regulatory Harmonization in Africa to Accelerate Access to Essential Health Products. Seattle: PATH; October 2017.*

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## ABBREVIATIONS

<b>ACP-EU</b>	African, Caribbean and Pacific States and EU
<b>AMA</b>	African Medicines Agency
<b>AMR</b>	Antimicrobial Resistance
<b>AMRH</b>	African Medicines Regulatory Harmonization
<b>ANDI</b>	African Network for Drugs and Diagnostics Innovation
<b>AU</b>	African Union
<b>AVAREF</b>	African Vaccine Regulatory Forum
<b>COHRED</b>	Council on Health Research and Development
<b>CSA</b>	Coordination and Support Action
<b>DCI</b>	Development Cooperation Instrument
<b>DG DEVCO</b>	DG International Cooperation and Development
<b>DGs</b>	Directorate-Generals
<b>DG SANTE</b>	DG Health and Food Safety
<b>DPML</b>	Directorate of Pharmacy, Medicines, and Laboratories
<b>EAC</b>	East African Community
<b>EC</b>	European Commission
<b>ECCAS</b>	Economic Community of Central African States
<b>ECOWAS</b>	Economic Community of West African States
<b>EDCTP</b>	European and Developing Countries Clinical Trials Partnership
<b>EDF</b>	European Development Fund
<b>EFPIA</b>	European Federation of Pharmaceutical Industries and Associations
<b>EFTA</b>	European Free Trade Association
<b>EIP</b>	European Innovation Partnership
<b>EMA</b>	European Medicines Agency
<b>ERAfrica</b>	European Research Area with Africa
<b>EU</b>	European Union
<b>FDA</b>	United States Food and Drug Administration
<b>FP</b>	Framework Program
<b>GCP</b>	Good Clinical Practice
<b>GLP</b>	Good Laboratory Practice
<b>GMP</b>	Good Manufacturing Practice
<b>HLPD</b>	High-Level Policy Dialogue on Science, Technology and Innovation
<b>IGAD</b>	Intergovernmental Authority on Development
<b>IMI</b>	Innovative Medicines Initiative
<b>JAES</b>	Joint Africa-EU Strategy
<b>JPI</b>	Joint Programming Initiative
<b>KFDA</b>	Kenya Food and Drugs Authority
<b>LMI</b>	Lead-Market Initiatives
<b>LMICs</b>	Low-and Middle-Income Countries
<b>MCC</b>	Medicines Control Council
<b>NEPAD</b>	New Partnership for African Development
<b>NRA</b> s	National Regulatory Authorities
<b>NTD</b> s	Neglected Tropical Diseases
<b>PANAF</b>	Pan-African Program
<b>PMPA</b>	Pharmaceutical Manufacturing Plan for Africa
<b>PPB</b>	Pharmacy Poisons and Board
<b>PRND</b> s	Poverty-Related and Neglected Diseases
<b>QMS</b>	Quality Management System
<b>RECS</b>	Regional Economic Communities
<b>R&amp;D</b>	Research and Development
<b>R&amp;I</b>	Research and Innovation
<b>SADC</b>	Southern African Development Community
<b>SAHPRA</b>	South African Health Products Regulatory Agency
<b>SDGs</b>	Sustainable Development Goals
<b>STI</b>	Science, Technology and Innovation
<b>TB</b>	Tuberculosis
<b>TDR</b>	World Health Organization's special program for Research and Training in Tropical Diseases
<b>UNECA</b>	United Nations Economic Commission for Africa
<b>WHO</b>	World Health Organization





## EXECUTIVE SUMMARY

**The regulation of health products is an essential aspect of a functioning health system.**

National regulatory authorities (NRAs) play a critical role in ensuring the safety and efficacy of research, and support timely access to quality-assured, safe, and effective health products.

Unfortunately, many low- and middle-income countries (LMICs) **lack sustained funding and the technical expertise necessary to robustly and comprehensively regulate the research and registration of new health technologies.** As a result, many NRAs are unable to fulfil their mandate, causing delays throughout the product development process.

In order to improve regulatory capacity and infrastructure in Africa, a number of countries are working to harmonize with their neighbors—through pooling resources (both technical and financial), sharing information, and increasing collaboration across countries to ensure the efficient evaluation of health technologies. **Regulatory harmonization across Africa has been endorsed at the highest political levels,** and efforts to harmonize regulatory policies across regional economic communities (RECs) are already having positive impacts. For example, drug approval times have already been reduced by half in the East African Community (EAC).

Despite this progress, many barriers are still hindering the realization of African leaders' vision of a single, harmonized African Medicines Agency (AMA) akin to the European Medicines Agency (EMA). Barriers to continued progress towards this goal include a **lack of sustained funding, limited and varied technical capacity** across countries in Africa, overreliance on a small number of donors, and limited bandwidth to expand regulation to different kinds of technologies and across phases of regulation.

As the leading trade partner and donor of aid to Africa, a global leader in science, technology, and innovation (STI), and the political body with one of the most regionally harmonized medical regulatory systems in the world, the **European Union (EU) is the ideal partner to support regulatory harmonization in Africa.** Through programs like the European Developing Clinical Trials Partnership (EDCTP) and the African,

## PRIORITY SETTING

Caribbean and Pacific States and EU (ACP-EU) partnership, the EU has shown support for harmonization activities in Africa. Though increased commitment is needed from the EU to move current efforts from pilot projects to institutionalized programs. In the coming years, EU policymakers will be tasked with renewing two major frameworks that guide relations between the EU and African countries. The EU will also be renewing and deciding priorities for a number of significant funding mechanisms—all with the potential to strengthen regulatory systems and drive greater partnership between the EU and African Union (AU) in support of regulatory harmonization. As policymakers in the EU begin discussions on renewing partnership frameworks and funding mechanisms, consideration should be given to the following **set of recommendations**:

### **Establish a joint EU/AU expert group on global health to strengthen African research and innovation capacity**

An expert group under the management of the European Commission (EC) should be established to focus on global health. The goal of the group should be to develop a joint strategy for collaboration on global health research and innovation (R&I) between the EU and AU, including the identification of priority areas for collaboration to strengthen global health R&I capacity across Africa. The expert group should be composed of representatives from the EU, the AU and member states, and technical experts from academia, civil society and the private sector. *For example, this model has been used successfully in the creation of expert groups through the Joint Africa-EU Strategy (JAES) High Level Policy Dialogue on Science, Technology and Innovation (HLPD) which has set up groups on food security, nutrition, and sustainable agriculture, and climate change and sustainable energy.*

## COORDINATION

### **Improve synergies between Directorate-Generals (DGs) through the development of a joint science, technology, and innovation for development (STI4D) strategy**

The EC should further promote complementarity between EDCTP calls, Horizon 2020, development funds, and member state activities. To accomplish this, the EC should develop a joint strategy on Science, Technology, and Innovation for development (STI4D), ensuring regulatory convergence and harmonization are cross cutting priorities, particularly between DG Research and Innovation (DG RTD) and DG for International Cooperation and Development (DG DEVCO). *For instance the collaboration through the Knowledge, Statistics and Data Hub Unit may serve as a basis for further joint efforts. Deepening of this type of collaboration specifically on STI4D, will help promote knowledge sharing to improve synergies between DGs for global health R&D and harmonization.*

## FUNDING

### **Utilize funding instruments to support regulatory strengthening and harmonization**

- The EC should make funds available through mechanisms such as the Pan-African Program (PANAF) under the Development Cooperation Instrument (DCI), and the European Development Fund (EDF) and its regional envelopes, to provide additional support for regulatory harmonization in Africa, including for the African Medicines Regulatory Harmonization (AMRH) Initiative. *For example, funds from H2020 could be paired with funding from the PANAF in support of the AMRH initiative.*
- To maximize critical EU investment, the EC should explore ways to leverage funding to diversify the funding base for global health R&I and regulatory harmonization. This can be accomplished using co-funded activities or by creating new incentives, like matching funds, for investments from the private sector and AU member states. *For example, co-funded programs like European Research Area with Africa (ERAfrica), could be expanded to include funding for regulatory harmonization.*

## TECHNICAL ASSISTANCE/ CAPACITY- STRENGTHENING

### **Increase resources for technical assistance activities in support of regulatory harmonization in Africa**

The EMA should increase resources for technical assistance activities that strengthen the capacity of African regulators, help align regulatory standards across the region, and avoid regulatory duplication. *This should include increased technical support through existing mechanisms like Article 58 and regular meetings with African regulators to share best practices and lessons learned in support of regulatory harmonization.*









# 1. INTRODUCTION

## 1.1. INTRODUCTION AND SCOPE

The EU is a leading funder of overseas development aid to Africa. As economies in LMICs grow, aid priorities and partnerships between donors and recipients must reflect these changes. Many countries in Africa are undergoing profound economic, demographic, and epidemiological transitions that are presenting new challenges and opportunities for development. Countries such as South Africa are developing health innovations that can affect the rest of the world. The EU has been a leader in recognizing the importance of partnerships built on co-ownership and, as capacities across Africa grow, the EU has the **opportunity to invest in strengthening health infrastructure and capacity with key partners across the region.**

Recognizing the changing development landscape and the challenges and opportunities of living in a globalized world, leaders from across the globe came together in 2015 to agree upon a set of shared goals—the Sustainable Development Goals (SDGs)—to be reached by 2030. Goal 3 includes a commitment to ensure good health and well-being, including aims to support access to safe and effective medicines and vaccines, to support **research and development for new tools for poverty-related and neglected diseases (PRNDs)**<sup>a</sup>, and to strengthen capacity in developing countries to manage global health risks. Goal 9 puts a focus on building resilient infrastructure and fostering innovation, and goal 17 focuses on building global partnerships for sustainable development. The EU played a leading role in the development of the SDGs. Through commitments like the new Consensus on Development, it has set out an ambitious framework for leading on the implementation of these goals. And through reports like *The Role of Science, Technology and Innovation Policies to Foster the Implementation of the Sustainable Development Goals (SDGs)*, the EC has recognized and prioritized the **importance of STI to achieve these goals**, including the importance of strengthening innovation capacity in LMICs<sup>1</sup>.

<sup>a</sup> PRNDs include major diseases such as HIV/AIDS, tuberculosis (TB) and malaria, as well as a range of neglected tropical diseases (NTDs).





The aim of this report is to describe how **the EU can play a central role accomplishing SDGs 3, 9, and 17** by strengthening health care and innovation systems in Africa through regulatory harmonization. The regulation of health technologies and research is a critical component of every country's public health system, and well-functioning regulatory systems ensure that quality-assured, effective, and safe health tools (vaccines, drugs, devices, and diagnostics) are approved and scaled in a timely manner. Well-functioning regulatory systems help ensure the safety and efficacy of every step of the development pipeline, including regulating research, reviewing clinical trial protocols, registering new products, and conducting oversight of the manufacturing and marketing of medical products. Conversely, poorly functioning regulatory systems can result in delays throughout the development process and can jeopardize the safety of research and clinical trials, as well as result in poor-quality, unsafe, or falsified products. Poorly functioning systems can also disincentivize innovators who do not want to go through the hassle of registering products in a broken system. Many NRAs, particularly in LMICs, are over-burdened and under-resourced and are not functioning at optimal capacity. Regulatory harmonization facilitates the pooling of resources and expertise between NRAs to accelerate the development and rollout of lifesaving health technologies through a coordinated safe review of research, clinical trials, product registration, and post-marketing surveillance.

**The EU has perhaps one of the strongest models of regulatory harmonization** and can serve as an example for nations across Africa that are beginning this process. EU member states established a central regulatory body, the EMA, in 1995. The AU, with the establishment of the AMRH initiative in 2012 and the passage of the African Union Model Law on Medical Products Regulation (Model Law) in 2016 has begun a similar process of harmonization. As countries across Africa continue to strengthen regional regulatory capacities and demonstrate a commitment to regulatory harmonization, there are new opportunities for the EU to support these processes. The EU is currently reviewing multiple guiding frameworks and policy mechanisms, which include the Joint Africa-EU Strategy (JAES); the Research and Innovation (R&I) Framework Program

(FP); the ACP-EU partnership; and the EDCTP. Decisions around these policies present opportunities for the EU to bolster its support for harmonization activities. This paper seeks to explore ways that the EU, as a model of harmonization and as a major donor in Africa, can seize opportunities to support regulatory harmonization activities in Africa.

Specific objectives include assessing the status of current harmonization activities in Africa, mapping joint Africa-EU efforts that relate to or have the potential to support harmonization in Africa, and identifying opportunities for strengthening Africa-EU cooperation for regulatory harmonization.

## 1.2. METHODOLOGY

The mapping and analysis have applied the following basic methods for collecting and analyzing data and forming policy recommendations:

- Conducting literature reviews of policies, laws, strategies, and plans that exist in relation to medicines harmonization in both the EU and Africa.
- Consulting with key stakeholders from government, industry, and civil society to understand stakeholders' views on the challenges and opportunities related to harmonization efforts, both within the EU and African institutions.
- Building off the findings of previous mappings of the health R&D landscapes undertaken by PATH in Kenya, Southern Africa, and the EAC.

## 1.3. HARMONIZATION AS A MEANS TO ALLEVIATE REGULATORY CHALLENGES

**Significant disparities in health outcomes around the world** are emblematic of unequal access to lifesaving drugs, diagnostics, and vaccines. Although scientific advances have led to the creation of new health tools that have saved millions of lives in high-income countries, and these new tools have the potential to save millions of lives in LMICs, many of the people who need them most lack access to these essential technologies. **The regulation of health technologies is a critical component of every country's public health system** and ensures that high-quality vaccines, devices, diagnostics, and drugs reach the people who need them most efficiently and safely; this is particularly true in epidemic outbreaks, as evidenced during the Ebola or Zika crises. Central to a functioning health system is ensuring the proper regulation for the development and distribution of new health products. For example, regulatory authorities must regulate research for quality assurance, review protocols and ethics for clinical trials to ensure quality and safety standards are met, and be responsible for the approval of new products, as well as for ongoing post-market surveillance to ensure safe and effective manufacturing and distribution of new products.

**The regulation of health products requires significant technical expertise and sustainable funding.** With great variation in capacities and resources across Africa, the proper and timely regulation of new health products has become a major challenge in increasing access to quality-assured health products across the continent. For example, few LMICs regulate medical devices, even though they are critical tools to prevent, diagnose, and treat disease. A lack of regulation leads to major barriers in access to these devices in LMICs<sup>2</sup>. An additional challenge facing sub-Saharan Africa is the fact that regulatory policies and processes are different from country to country, meaning manufacturers must navigate multiple regulatory bodies with uneven capacities, resources, and timelines. Weak capacity and misaligned regulatory systems can create a significant delay in the registration of health technologies. A recent study found that in sub-Saharan Africa, the lag in regulatory approval was typically four to seven years after first regulatory submission in high-income countries<sup>3</sup>. This can mean life or death for patients waiting to have access to lifesaving drugs. For example, one HIV drug was approved by the United States Food and Drug

Administration (FDA) within six months, yet after seven years, the same drug still had not been approved in some countries in Africa<sup>4</sup>. **Weak and misaligned policy for the regulation of health technologies** also contributes to the proliferation of falsified and counterfeit products that may create public health risks and damage trust in the health system<sup>5</sup>.

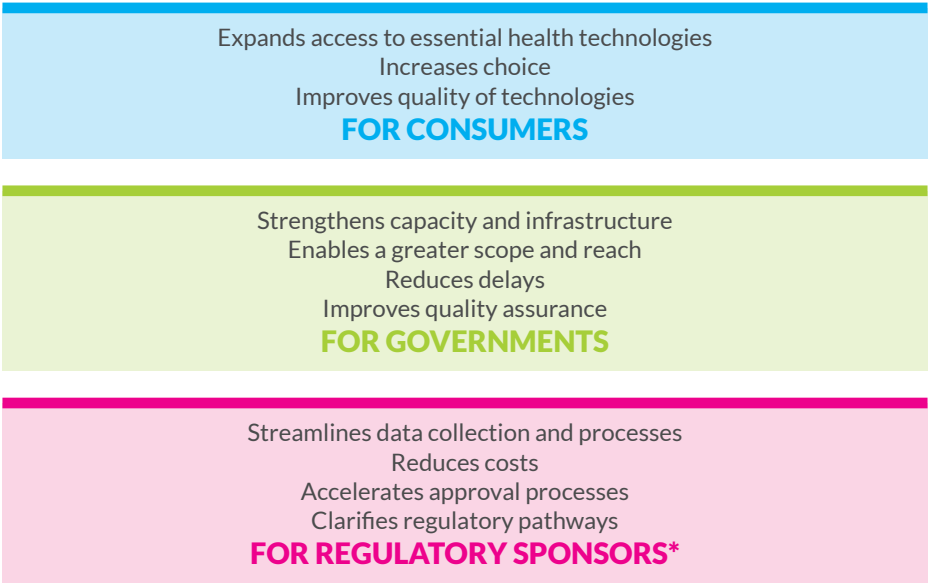
To address these barriers and accelerate access to safe and effective products, many countries in Africa are working together to harmonize regulation. **Harmonization efforts help to address the lack of adequate financing and technical expertise** faced by many countries in Africa by pooling resources (both technical and financial), sharing information, and increasing collaboration across countries to ensure the efficient evaluation of technologies. Harmonization activities can take many forms and encompass a broad spectrum of joint and shared undertakings, ranging from information sharing between NRAs, to joint inspections and protocol reviews, to convergence of standards and processes, to mutual recognition of product safety and efficacy. Harmonization efforts aim to decrease the time to register essential medicines, to treat priority diseases and reduce duplication of efforts through collaboration between partner states' NRAs. Even the most promising health technologies will not have impact if they cannot reach those in need due to regulatory barriers. **Regulatory harmonization is critical in accelerating the development and delivery of lifesaving health technologies**, including new tools to address PRNDs and new tools to prepare for future epidemics.

**FIGURE 1** The what and why of regulatory harmonization

**Regulatory harmonization can involve one or a combination of the following:**



**Regulatory harmonization:**



\* Sponsors are entities that initiate and take responsibility for clinical investigations, and request the authorisation of new health tools from regulatory authorities; sponsors include Pharmaceutical companies, academic institutions, private organizations, etc





## 2. MAPPING OF REGULATORY HARMONIZATION EFFORTS IN AFRICA

### 2.1. AFRICAN UNION HARMONIZATION EFFORTS

To spur economic growth, many African countries have made commitments over the past decade to bolster the STI sector. In 2007, for example, African leaders pledged to allocate 1 percent of gross domestic product to research and development (R&D). In the same year, the AU also endorsed the Pharmaceutical Manufacturing Plan for Africa (PMPA), which aims to strengthen the capacity of pharmaceutical manufacturers to produce high-quality, affordable medicines<sup>6</sup>.

#### The African Network for Drugs and Diagnostics Innovation

The African Network for Drugs and Diagnostics Innovation (ANDI) focuses on the promotion of African-led innovation and the development of new health tools. ANDI is supported through the WHO's special program for Research and Training in Tropical Diseases and is based at the United Nations Economic Commission for Africa (UNECA) in Addis Ababa, Ethiopia. Though ANDI does not have a specific focus on regulatory harmonization, the network is a strategic platform that may be leveraged to complement other harmonization activities going on across the region. As a significant funder of ANDI, the EU should provide assistance to ensure that products developed through ANDI meet standards for good manufacturing practice (GMP) and research adheres to good clinical practice (GCP) and good laboratory practice (GLP) standards. One way to do this is through increased support for regulatory harmonization across sub-Saharan Africa.

To ensure that these commitments translate to increased access to health technologies, many countries and RECs are working to strengthen and align regulatory systems through the AMRH initiative. Regulatory harmonization has received strong political support across the African continent at the highest levels of government, and harmonization efforts are starting to show some success at regional and national levels.



Harmonization efforts in Africa are being guided by the Model Law. The Model Law provides a framework for helping countries realize the vision of the AMRH initiative and provides guidance for countries on how to implement harmonization, with the ultimate goal of creating safe and effective regulatory systems.

### Model Law on Medical Products Regulation

In January 2016, the AU Heads of State adopted the Model Law on Medical Products Regulation. This legislation is meant to guide national governments and RECs to harmonize regulatory systems and increase collaboration across countries. Ultimately, the Model Law is meant to accelerate access to lifesaving interventions and ensure that promising health technologies are developed, tested, and scaled up to improve health impact.

The Model Law was developed in line with WHO recommendations and international safety and quality standards. Through the process of domestication, a country can adapt the Model Law to ensure alignment with its constitutional principles and legal system—and amend or repeal inconsistent national laws. Once adopted and implemented by RECs and countries, the goal of the Model Law is to resolve discrepancies in current regulatory legislation and improve the efficiency and effectiveness of regulatory systems.

In accordance with the Model Law, each country must have an autonomous NRA with the power to regulate the manufacture, import, export, distribution, and use of health technologies. The NRA is also responsible for authorizing clinical trials, granting licenses to manufacturers, and setting standards for the appropriate use of new health technologies. The Model Law also sets expectations and standards for marketing health technologies, licensing, quality and safety of health technologies, clinical trials, and appeals procedures.

Now that the Model Law has been endorsed by AU heads of state, it is up to the RECs, regional organizations, and member states to update and enact regional legal frameworks and national laws. The Model Law should serve as a reference guide for member states as they update or enact national laws on medical product registration.

### The African Medicines Regulatory Harmonization initiative

was created in 2009 through a joint effort of the New Partnership for African Development (NEPAD), the Pan-African Parliament, and the AU Commission—in collaboration with the WHO, the World Bank, the Bill & Melinda Gates Foundation, and the United Kingdom's Department for International Development—to increase access to health technologies through regulatory harmonization. The AMRH initiative supports RECs and other regional organizations to align regulatory standards, develop joint review processes, and strengthen regulatory capacity. The long-term objective of the AMRH is to establish an AMA to oversee and coordinate the registration of priority health technologies across the continent. The NEPAD Agency, the technical body of the AU, is responsible for coordinating the implementation of the AMRH initiative.

## 2.2. HARMONIZATION AT THE REGIONAL LEVEL

### 2.2.1. Implementation of the African Medicines Regulatory Harmonization initiative across the Regional Economic Communities

#### Regional Economic Communities

RECs were established across Africa in 1991 to provide a framework for economic integration. The eight RECs act as the implementing arms of the AU and, along with a focus on the economy, work to promote regional peace and stability. RECs have been key to economic growth and development across Africa and have been central to the work of NEPAD<sup>7</sup>.

Many EU member states have engaged with RECs on STI projects, including the Southern Africa Innovation Support Programme, Partnership Agreement for Sustainable Development of Lake Victoria Basin, and the Consortium for Research, Innovation and Training in Central Africa. Though these initiatives have concerns that are broader than health or medicines regulatory harmonization, they provide examples of partnerships between the EU and RECs to promote collaboration on research, innovation, and capacity-building.

Though harmonization has been endorsed by heads of state across Africa, progress varies greatly by region and country. For example, the AMRH initiative began in the EAC in 2012<sup>b</sup>. As the first REC to begin implementation of the AMRH, the EAC has already shown progress. Technical working groups in the EAC have developed harmonized guidelines, requirements and standards for GMP, medicines evaluation and registration, and quality management systems. In addition to developing common technical documents, the EAC Secretariat and member state NRAs began joint dossier assessments in 2015. To date, 27 products have been jointly assessed and four products registered<sup>7</sup>, and drug approval time has been reduced by 50 percent<sup>8</sup>. As part of the EAC's medicines regulatory harmonization initiative, technical experts in the EAC have also conducted joint inspections in facilities in Kenya and Uganda in accordance with GMP. These accomplishments demonstrate the potential impact that harmonization can have to ultimately accelerate the delivery of essential medical tools and improve quality. Additionally, the EAC is working to expand its scope to include harmonization of clinical trials, pharmacovigilance, and other health technologies, including devices, diagnostics, and vaccines<sup>9</sup> (though additional resources will be needed). Although this work is promising, gaps in funding and technical capacity have made progress slow, particularly in the area of medical devices, where harmonization has lagged. A recently released call from the EDCTP asking for proposals to support ethics and regulatory capacity-strengthening may present one opportunity for additional resources in support of the AMRH initiative<sup>10</sup>.

Another successful effort has been the Zazibona initiative<sup>c</sup>, a harmonization platform consisting of six countries in the Southern Africa Region. Zazibona began in 2013 as a framework for collaboration for medicines registration. Initially founded by four countries<sup>d</sup> with an agreement to pool resources and share inspections and assessments for World Health Organization (WHO)-listed priority generic medicines<sup>11</sup>, Zazibona has shown significant progress. Since its founding, 156 health products have been reviewed, and at least 50 have been registered for use. The progress already achieved by Zazibona in the Southern Africa Region can serve as the foundation of the expansion of the AMRH initiative in the Southern African Development Community (SADC). There is room to build on Zazibona's achievements, and the initiative may expand its scope to include pharmacovigilance and post-marketing quality assurance.

Building on the progress of harmonization efforts in the EAC and SADC, efforts have also begun in the **Economic Community of West African States<sup>e</sup> (ECOWAS)**, the **Economic Community of Central African States<sup>f</sup> (ECCAS)**, and the **Intergovernmental Authority on Development<sup>g</sup> (IGAD)**. Though progress has been made, this work is still in the early phases. For example, in ECOWAS, countries have harmonized technical documents across the region and created a common technical document, providing a standard format for quality, safety, and efficacy information for new medical product submissions.

<sup>b</sup> The **EAC** is made up of Burundi, Kenya, Rwanda, Tanzania, Uganda, and South Sudan. South Sudan joined in 2016 but has not fully engaged in the AMRH initiative.

<sup>c</sup> **Zazibona** is made up of Zambia, Zimbabwe, Botswana, Namibia, South Africa, and Swaziland (observer status).

<sup>d</sup> Founding countries included Zambia, Zimbabwe, Botswana, and Namibia. South Africa and Swaziland joined after founding.

<sup>e</sup> **ECOWAS** is made up of Benin, Burkina Faso, Cape Verde, Ivory Coast, Gambia, Ghana, Guinea, Guinea-Bissau, Liberia, Mali, Niger, Nigeria, Senegal, Sierra Leone, and Togo.

<sup>f</sup> **ECCAS** is made up of Angola, Burundi, Cameroon, Central African Republic, Congo-Brazzaville, Gabon, Equatorial Guinea, Democratic Republic of Congo, Sao Tome and Principe, and Chad.

<sup>g</sup> **IGAD** is made up of Djibouti, Ethiopia, Eritrea, Kenya, Somalia, the Sudan, South Sudan and Uganda.





The document sets a standard for what information is collected and provides a baseline of standards that will help lay the foundation for future harmonization activities. This is an important step, but progress in these regions is still far behind that of the EAC, in large part because implementation of the AMRH is being launched in stages across the RECs and is only just beginning in these regions. Implementation of the AMRH initiative is still pending in ECCAS and IGAD, though both have demonstrated political support and readiness. In the Central African Region, a framework has been established to guide harmonization in ECCAS, and IGAD adopted a proposal for implementing harmonization in August 2017 (although leaders across IGAD have noted that there is no funding available to support the initiative)<sup>12</sup>.

### 2.2.2. African Vaccine Regulatory Forum

The WHO established the African Vaccine Regulatory Forum (AVAREF) in 2006. From its inception, **AVAREF has strengthened the capacity of NRAs** to make decisions about clinical trial authorization and product evaluation for vaccines. In late 2016, AVAREF announced that it was expanding its mandate to include medicines and diagnostics, as well as expanding its membership to include all AU member countries<sup>13</sup>. This is a promising opportunity for AVAREF to build on its early successes. Additionally, a new governance structure is working to align AVAREF with the AMRH<sup>14</sup>, which may also be an occasion to expand more rapidly, though close alignment with the AMRH will be critical to ensure harmonization efforts are complementary and not duplicative.

During its first ten years, AVAREF worked with NRAs to assess clinical trial applications. **AVAREF's work has already had real-world impact**; for example, joint reviews through AVAREF helped pave the way for timely approval of the MenAfriVac® vaccine<sup>h</sup>, which has protected more than 270 million Africans from meningitis A<sup>15</sup>. AVAREF has also worked with NRAs to monitor clinical trials and evaluate clinical data in registration dossiers of vaccines. Since its establishment, AVAREF has set innovative regulatory pathways for clinical trials and harmonized guidelines for submission of clinical trial applications<sup>16</sup>. AVAREF's progress was highlighted during the Ebola epidemic in 2014, where joint regulation of vaccine clinical reviews played a critical role in supporting the fast-track approval of clinical trials of Ebola vaccine candidates.

<sup>h</sup> MenAfriVac is a registered trademark of Serum Institute of India Private Ltd.

## 2.3. HARMONIZATION AT THE NATIONAL LEVEL

Ultimately, the successful implementation of the Model Law and harmonization across RECs is the responsibility of participating member states. To have any impact, regional legislation must be adopted and enforced by each country.

### 2.3.1. Kenya case study

In Kenya, **complex national regulatory structures, as well as fears over loss of sovereignty** or loss of potential revenue from application and registration fees, have led to delays in domestication of regional medicine regulatory harmonization. Additionally, domestication requires legislative action that may require parliamentary approval. For example, the government of Kenya has a complex policy framework for medicines regulation. The Pharmacy and Poisons Board (PPB) is Kenya's medicines regulatory authority and is responsible for the regulation of pharmaceutical products, registration of medicines, and clinical trial approval. Medical device regulation, however, is divided between PPB, the Kenya Bureau of Standards, and the Kenya Radiation Board. The National Commission for Science, Technology, and Innovation provides regulatory oversight.

The number of government entities involved in regulation contributes to a long and complex regulatory pathway that research institutions, manufacturers, and other regulatory sponsors must navigate to register a health product or receive clinical trial clearance. **Preclinical trials, for example, require research permits from six different regulatory agencies.** A draft piece of legislation, however, aims to harmonize national policies related to food and drug regulation and to create an independent national authority, known as the Kenya Food and Drugs Authority (KFDA), with a broader mandate than the PPB. A task force composed of government bodies and technical experts is currently developing the KFDA bill.

In addition to efforts to streamline the medicines regulatory framework, the PPB leads the EAC AMRH initiative's technical working group on quality management systems (QMS). The group developed a compendium to enable partner states to adopt standard quality system requirements.





### 2.3.2. Burundi case study

Kenya's regulatory system is relatively advanced compared to that in other members of the EAC, whose capacities vary widely. In Burundi, for example, the Directorate of Pharmacy, Medicines, and Laboratories (DPML) functions as the country's medicines regulatory authority. The DPML only regulates medicines—not vaccines, medical devices, or diagnostics—and does not have the capacity to provide oversight for clinical trials. This gap in regulation is largely due to chronic shortages of human, technical, and financial resources; a lack of infrastructure; and an inadequate legal regulatory framework. Harmonization can help solve some of these barriers, and Burundi has fast-tracked the enactment of a legal framework to recognize regulatory decisions made by NRAs of other EAC member states—but stakeholder interviews revealed that this does not yet happen in practice.

### 2.3.3. South Africa case study

The government of South Africa is working to streamline its **complex regulatory system** and achieve regional alignment through the establishment of the South African Health Products Regulatory Agency (SAHPRA). Under the previous regulatory regime, researchers were required to apply to a number of institutions for clinical trial approval, and the application and approval process often lacked transparency. The Medicines Control Council (MCC), which was responsible for regulating medicines and clinical trials, commonly experienced delays in registration and application backlogs, stemming from insufficient staff and resources, as well as a flood of generic medicines applications.

To solve these problems, **in 2015 Parliament passed an amendment to the Medicines and Related Substances Act** of 1965 to replace the MCC with SAHPRA, an independent, public regulatory agency. Regulatory authority officially shifted to SAHPRA in June 2017<sup>17</sup>. Moving forward, SAHPRA will regulate drugs, vaccines, medical devices and clinical trials. The 2015 amendment also created a framework for the South African government to recognize and align with other regulatory bodies through the AU Model Law—reducing duplication and increasing efficiency. Moreover, the **newly established Institute for Regulatory Science** will first work to develop regulatory capacity of SAHPRA staff, with future plans to scale and support SADC and AMRH capacity-strengthening initiatives<sup>18</sup>. The Zazibona initiative will continue to support SAHPRA in the evaluation of dossiers and the training of evaluators.





## 2.4. COMMON CHALLENGES TO REGULATORY HARMONIZATION

Though progress has been made, much work remains to achieve the vision of a fully harmonized AMA, and many barriers must be overcome to ensure that promising health technologies are developed, tested, and scaled up to improve health.

### Harmonization requires a long-term vision and sustained funding

Harmonization is complicated and requires political buy-in and action at multiple levels of government and across governments and regions. Realizing the vision of the AMA will require long-term political commitment of technical and financial resources.

### Limited and varied capacity

RECs and member states have limited infrastructure and human resources to regulate health technologies, and regulatory authority capacity varies widely from country to country, and from REC to REC. For example, some national regulatory bodies regulate clinical trials, medical devices, and diagnostics, whereas others lack the capacity or mandate to do so. Variations in skill, capacity, language, and resources complicate mutual recognition of regulatory decisions and joint registration.

### Overreliance on a small number of funders

Though governments have shown strong interest, much of the funding for harmonization efforts to date has come from donors such as the World Bank, the UK Department for International Development, and the Bill & Melinda Gates Foundation<sup>19</sup>. These donors have been instrumental in initiating harmonization efforts, but a lack of long-term, more varied funding provides challenges for sustainability. Accomplishing the vision of a harmonized AMA will require funding from multiple donors over a long period of time that can leverage domestic investments.

### Limited bandwidth

Accomplishments of EAC member states, progress by Zazibona in Southern Africa, and AVAREF's success in harmonizing clinical trials for vaccines demonstrate the impact that these initiatives are having, but all of these initiatives are limited in scope. For example, there is currently a gap in the regulation of diagnostics, which are of critical importance to protecting against future epidemics, ensuring timely and appropriate treatment, and preventing antimicrobial resistance (AMR). Additional funding, expertise, staffing, and political will are required to expand current efforts to more closely align with the vision of a harmonized medicines regulation agency.

### Additional barriers include:

- loss of sovereignty,
- potential loss of user fees/revenue,
- political timelines that do not align with innovation timelines,
- lack of enforcement of international standards at a national level,
- limited capacity and bandwidth to conduct joint activities,
- delayed implementation and absence of a clear regulatory pathway, and
- regional conflicts that result in deprioritization of harmonization.

### Pharmaceutical Manufacturing Plan for Africa

The Pharmaceutical Manufacturing Plan for Africa (PMPA), endorsed by the AU in 2007, aims to strengthen capacity of pharmaceutical manufacturers on the continent to produce high-quality, affordable medicines. The PMPA serves as a vehicle for enforcing good manufacturing practice standards and serves as a platform for joint inspections. A robust local pharmaceutical sector will increase access to essential medicines, ensure a sustainable supply, and lead to improved public health outcomes, as well as industrial and economic development.

The PMPA and AMRH initiative are closely aligned—in fact, the AMRH initiative grew out of recognition that an enabling environment for medicines regulation is necessary for the pharmaceutical industry to flourish<sup>20</sup>. NRAs have a significant bearing on pharmaceutical industry activities through oversight, application review, GMP certification, and inspection. Therefore, harmonized, high-functioning regulatory systems are critical for improving access to medicines as well as for promoting regional pharmaceutical capacity<sup>21</sup>.



### 3. MAPPING OF JOINT EU-AFRICA EFFORTS ON HARMONIZATION

As the leading trading partner and a global leader in STI, and as the political body with one of the most harmonized medical regulatory systems in the world, **the EU is the ideal partner to support regulatory harmonization in Africa**. The EU has already made bold investments in research and development for new tools to prevent and treat PRNDs, many of which are having lifesaving impact. For example, EU funding has contributed to the development of nearly half of new malaria drugs registered since 2000, including support for the first first-line malaria drug designed specifically to treat children<sup>22</sup>.

The development of new products is critical, but for the products to have impact they must get into the hands of people in need. Increasing investments in the strengthening of regulatory systems in LMICs is one important way the EU can build upon its already strong support for the development of lifesaving tools for PRNDs. With its own harmonized regulatory system—the **EMA**—the EU is uniquely positioned to support harmonization efforts across Africa.

The EU is currently involved in some activities related to strengthening regulatory capacity, including activities supporting harmonization in sub-Saharan Africa, via the EMA<sup>23</sup>, the EDCTP<sup>24</sup>, and the ACP-EU partnership, but there is greater opportunity for increased engagement and support. In the coming years, EU policymakers will be tasked with renewing two major frameworks that guide relations between the EU and Africa and will also be renewing and deciding priorities for a number of significant funding mechanisms—all with the potential to increase access to lifesaving products and drive greater partnership between the EU and Africa in support of regulatory harmonization.

## Policy Frameworks and Financing Mechanisms Central to EU-Africa Collaboration on Regulatory Harmonization

### OVERARCHING POLICY FRAMEWORKS

#### Joint Africa-EU Strategy (JAES)

- Primary political framework guiding cooperation between the EU and Africa.
- The HLPD is one way the JAES is implemented; current focuses have been on food security, nutrition, sustainable agriculture, and on climate change, and sustainable energy.
- The current JAES roadmap expires in 2017.

#### Cotonou Agreement

- Provides a legal basis for relations and sets priorities for cooperation between the EU and the ACP states)
- Expires in 2020.

#### Consensus on Development

- Provides the framework for a common approach to development policy across EU institutions and EU Member States.
- New Consensus was adopted in 2017.

### FINANCING MECHANISMS

#### European Development Fund

- Primary source of funding for implementation of the objectives of the ACP-EU partnership; also contributes to the objectives of the JAES.
- Financed directly through Member State contributions and jointly programed with the ACP states.
- Responsible DG: DEVCO.

#### Development Cooperation Instrument

- Provides some funding for implementation of the JAES.
- Responsible DG: DEVCO.

#### European Developing Clinical Trials Partnership

- Public-public partnership with a mission to accelerate the development of new technologies to prevent, diagnose, and treat PRNDs.
- Funded on a matched funding model with funds from the EC and European Participating States.
- Responsible DG: RTD.

#### Innovative Medicines Initiative

- Mission is to foster collaboration between European pharmaceutical companies and to accelerate the development of safe and effective medicines.
- Responsible DG: RTD.



## European Medicines Agency (EMA)

The EMA was established in 1995 with the goal of harmonizing NRAs across EU member states as well as the European Free Trade Association (EFTA) states of Iceland, Liechtenstein, and Norway. The EMA is responsible for the regulation of health products developed for use in the EU. As the centralized body, the EMA works closely with the NRAs that make up the participating members of the EU and EFTA to share expertise and safety information regarding new medical products. The EMA establishes guidelines to direct the development of high-quality products and provides product-specific guidance to innovators. The EMA's centralized procedure allows for the submission of a single application and assessment that allows for marketing of a new product across the EU. EU regulatory policy also allows companies to apply through a decentralized procedure where they can apply for simultaneous review in multiple EU member states or for mutual recognition, where companies can request that previous authorizations be recognized in additional EU member states<sup>25</sup>.

Though the EMA was formally established in 1995, countries across Europe put into place a legal framework for harmonization beginning in 1965, demonstrating that harmonization is not a quick process.

The EMA offers a unique example of the benefits of regulatory harmonization for regulators across African RECs. African regulators working to advance the AMRH initiative in the EAC recently visited the EMA and held two days of meetings to see what lessons they could use to further advance their own harmonization efforts<sup>26</sup>. Following the meetings, the heads of the member states' NRAs, together with the EAC Secretariat, agreed upon five next steps, which included establishing a clear framework for decision-making, developing fee structures to support joint regulatory services, and strengthening collaboration between the EAC and the EMA, specifically with the goal of capacity-building on the use of Article 58.

Article 58 is a mechanism within the EMA that, in cooperation with the WHO, can provide a scientific opinion for the evaluation of drugs and vaccines intended for use exclusively in markets outside of the EU and can expedite prequalification by WHO, which in turn accelerates registration at the national level. This scientific opinion must then be adopted by NRAs. To be eligible for this mechanism, products must be used to treat diseases of major public health interest, including HIV/AIDS, malaria, TB, and other neglected diseases. To date, seven products have gone through this mechanism<sup>27</sup>.

The two high-level frameworks that guide the EU's funding and partnership priorities as they relate to cooperation with Africa are the JAES and the Cotonou Agreement. Both frameworks are coming up for renewal and will present opportunities to bolster greater support for health, R&I for PRNDs and harmonization. An additional framework, the new Consensus on Development, sits alongside the JAES and Cotonou Agreement and provides a common approach to development across the EU institutions and member states. Together, these guiding frameworks help set priorities and provide guidance for implementation across the EU and, because of their focus on Africa and development, help determine how the EU may provide support for regulatory harmonization in Africa.

### 3.1. JOINT AFRICA-EU STRATEGY

The JAES, adopted by the African and EU Heads of State in 2007, is the primary political framework guiding cooperation between both regions. The JAES is implemented via roadmaps that are revisited every three years. The current roadmap (2014–2017) focuses on five priority areas<sup>i</sup>, which include peace, sustainable human development and growth, and emerging global issues. Among the overall objectives of the partnership, the JAES aims at promoting regulatory and policy reform and convergence in Africa. Current reform and convergence efforts focus on trade integration, private-sector development, official statistics, and the information, communications, and technology sector<sup>28</sup>. Promoting harmonization for health regulation in Africa, though not a current focus, fits within the overall scope of the JAES and is a potential opportunity for alignment<sup>29</sup>. The JAES does explicitly acknowledge the **importance of promoting STI**, and STI is recognized as a cross-cutting theme to achieve all five of the JAES priorities<sup>30</sup>.

One important element of the JAES strategy is the HLPD, which was established in 2010 to serve as a regular platform for exchanges around STI. The HLPD is the primary platform for deciding on the most important STI areas for collaboration and has a

<sup>i</sup> JAES priorities are: peace and security; democracy, good governance, and human rights; human development; sustainable and inclusive development and growth and continental integration; global and emerging issues.



critical role in shaping future areas of focus for the JAES. For example, during the second HLPD in 2013, a R&I partnership on food security, nutrition, and sustainable agriculture was launched, with a dedicated roadmap adopted in 2016. A second partnership with a focus on climate change and sustainable energy is expected to be launched in October 2017. These partnerships aim at mobilizing public and private actors and supporting capacity-building and coordination efforts with a long-term goal of promoting enabling environments for R&I.

Much has changed since the development of the current JAES roadmap in 2014 and the last convening of the HLPD in 2016. **Outbreaks of Ebola and Zika and the worsening threat of AMR** have reprioritized the need for a stronger focus on epidemic preparedness and system readiness. At the same time, as shown through the progress of harmonization efforts in the EAC, Zazibona, and AVAREF, countries in Africa have demonstrated their ability and desire to expand local and regional innovation capacity. **Consideration should be given to launching a third research and innovation partnership on global health, including with a focus on policy and regulatory harmonization.**

### 3.2. COTONOU AGREEMENT

The Cotonou Agreement provides a legal basis for relations and sets priorities for cooperation between the EU and the ACP states<sup>31</sup>. Within its priorities for the development strategies, ACP and EU collaboration should support capacity-building in social areas, including policies conducive to technological R&I. Under the Cotonou Agreement umbrella sits the **African, Caribbean, and Pacific EU Science and Technology Program** (ACP S&T Program II), which is focused on strengthening STI as a means of poverty reduction, addressing the STI divide between the ACP states, and building capacity in ACP states. Under the previous S&T Programs (phase 1 was in 2000–2006 and phase 2 in 2007–2013), health represented a small fraction of the funded projects, which focused on the two priority areas of energy access and efficiency, and agriculture and food security<sup>32</sup>. Though health has not been a priority area of focus, a few relevant global health initiatives have come out of the ACP S&T Program II, such as an initiative to promote policy convergence on disease surveillance in the Caribbean<sup>33</sup>.

The Cotonou Agreement expires in 2020, and discussions for its successor are already under way, with official negotiations set to take place over 18 months starting in 2018<sup>34</sup>. One of the scenarios proposed by the EC is to establish a joint agreement with ACP states under a common umbrella and with regional partnerships that will “build on and integrate” existing ones such as the JAES<sup>35</sup>. The revision should focus on updating the framework to address changes that have taken place in recent years, including the adoption of the Sustainable Development Goals (SDGs) and a number of global health-specific challenges. As this process coincides with changes to the **JAES STI program**, and the **next R&I FP (FP9)**, there is a critical opportunity to promote coherence and synergy between different programs to maximize the impacts of EU policies, which share common objectives but lack specific coordination mechanisms<sup>36</sup>, and to address the fragmentation of the EU and EU member states’ initiatives on STI for development in Africa<sup>37</sup>.

### 3.3. NEW EUROPEAN CONSENSUS ON DEVELOPMENT

Alongside the JAES and Cotonou Agreement, the European Consensus on Development provides the framework for a common approach to development policy across EU institutions and member states. The Consensus on Development guides EU development policy and funding priorities, including work funded through the DCI and the EDF. The newly adopted 2017 Consensus on Development outlines how the EU will accomplish the SDGs and recognizes the importance of promoting research and investment in the development of new health technologies, as well as the importance of supporting partner countries to address global health threats and pursue a 'health in all policies' approach. As decisions are made regarding the future of the JAES and the Cotonou Agreement, priorities should be aligned with the Consensus on Development and the SDGs. **Harmonization can be a key tool to realizing the health priorities outlined in the Consensus.**

### 3.4. EUROPEAN COMMISSION

Multiple Directorate-Generals (DGs) are responsible for implementing and carrying out the visions and priorities laid out in the JAES, Cotonou Agreement, and Consensus on Development. This mapping is not exhaustive and focuses on the roles of the different DGs as they relate to or have the potential to relate to regulatory harmonization in Africa.

#### 3.4.1. Directorate-General for International Cooperation and Development

DG DEVCO is responsible for the development of aid policy and implementation and manages the EU's primary development funding instruments, including the EDF and the DCI.

##### European Development Fund

The EDF makes up the **largest of the EU's development funding instruments**<sup>j</sup>. Established through the Cotonou Agreement, it serves as the primary source of funding for the implementation of the objectives of the ACP-EU partnership and complements the DCI in development aid to Africa. The EDF is unique in that it is not funded through the EU's general budget, but is financed directly through member state contributions, and is jointly programed with the ACP states. Negotiations around the future of the Cotonou Agreement may include a review of this arrangement with an eye towards incorporating it into the EU's general budget process to allow for greater parliamentary oversight and alignment. In the past, EDF investments have been used to support some harmonization activities. For example, funding from the EDF provided support for the **EU/ACP/WHO Renewed Partnership (2012–2016) for strengthening pharmaceutical systems and improving access to high-quality essential medicines**—a partnership between DG DEVCO, the ACP Secretariat, and the WHO Department of Essential Medicines and Health Products. One focus of this partnership was support for RECs to harmonize medicines regulation<sup>38</sup>. This partnership resulted in the harmonization of policies and regulations for seven subregional groups and set up schemes for pooled procurement mechanisms<sup>39</sup>. For example, through the partnership, ECOWAS began developing shared guidelines for GMP and product registration. The EU/ACP/WHO partnership is now funded under the DCI<sup>k</sup> (cf. below). Though the current EDF (which provides funding from 2014–2020) does not have a specific objective on regulatory harmonization for health, it does provide limited funding to build the R&I capacities of ACP states under a regional envelope called Intra ACP. Likewise, the EU collaboration with some regions—such as the SADC, the EAC, and Eastern Africa, Southern Africa, and the Indian Ocean—foresees actions on industrial development strategy for pharmaceuticals (and other sectors), including improving the regulatory environment and regional economic integration. This collaboration could be extended to global health.

<sup>j</sup> The budget for EDF is 30.5 billion euros for the period from 2014 through 2020.

<sup>k</sup> The DCI has provided 750,000 euros for the period between 2016 through 2018.





In the future, funding through the EDF could provide support for AMRH initiatives, particularly in RECs like ECOWAS that are starting to show some progress but lack funding and resources to move forward. This would require an agreement with the ACP states and with EU member states in the framework of EDF programming negotiations.

#### Development Cooperation Instrument

DG DEVCO also has oversight over the DCI. Though much of the funding for the DCI focuses on the geographies of Latin America and Asia, a portion of the DCI has been carved out to support the newly established PANAF, which is meant to support the implementation of the JAES. The PANAF has previously provided funding to policy and harmonization efforts in the areas of information and communications technologies, so it may be primed to fund harmonization for health regulation<sup>40</sup>. The DCI is positioned to provide funding for future harmonization activities, particularly if in the future, the JAES includes a more explicit focus on regulatory harmonization.

#### 3.4.2. Directorate-General for Research and Innovation

Responsible for defining and implementing EU research and innovation policy, the DG RTD has a strong yet under-acknowledged role to play in achieving the visions of the JAES, the Cotonou Agreement, and the Consensus on Development. The mechanism under DG RTD's mandate with the clearest link to harmonization is the **EDCTP**. Opportunities also exist to strengthen support for harmonization through the IMI and the bi-annual work program of the R&I FPs (currently Horizon 2020, and the future FP9).

#### European and Developing Countries Clinical Trials Partnership

EDCTP is a public-public partnership with a mission to accelerate the development of new technologies to prevent, diagnose, and treat PRNDs. This focus makes EDCTP a natural fit to provide support for harmonization in sub-Saharan Africa. EDCTP is funded on a model of matched funding, where the EU provides a certain amount<sup>41</sup> based on matching contributions (cash or in-kind) by European EDCTP Participating States. African Participating States also contribute to EDCTP's budget. Funding to projects is provided through grants via calls for proposals to address certain topics under EDCTP's scope. Though regulatory harmonization has not been a strong focus of EDCTP funding, EDCTP2's Strategic Business Plan 2014–2024 states that they will work “to establish an enabling environment for research, particularly by helping sub-Saharan Africa countries to strengthen their ethical, regulatory and legal frameworks for research, ensuring they are able to host clinical studies consistent with international standards and respecting local regulations”<sup>41</sup>. In support of this objective,

<sup>41</sup> EDCTP2 will receive up to 683 million euros of EU funding over a 10-year period.



EDCTP has issued a number of calls to provide funding for capacity-strengthening for national ethics committees and NRAs<sup>m</sup>; in August 2017, EDCTP issued a call that specifically encouraged proposals to contain activities including regional collaborative bodies such as the AMRH initiative<sup>42</sup>.

EDCTP is also a partner of the **Council on Health Research and Development (COHRED)**, a nonprofit organization focused on strengthening innovation capacity in LMICs. COHRED offers technical support to strengthen innovation systems and set priorities; tools such as the RHInnO Ethics, a cloud-based management system to help strengthen ethics reviews; and opportunities for constituencies to share best practices and share new ideas<sup>43</sup>.

**EDCTP2 is primed to scale up support for harmonization.** Its unique governance structure<sup>n</sup> may also act as a collaborative model to increase and strengthen participation from African partners for harmonization activities. An additional opportunity may be to pair participating EU member states with participating African countries to act as technical advisors to build regulatory capacity.

### **Innovative Medicines Initiative**

This joint technology initiative is another mechanism with potential to support harmonization efforts. The IMI's focus is to foster collaboration between European pharmaceutical companies and to accelerate the development of safe and effective medicines. Though primarily focused on advancing health for Europeans and boosting innovation in the EU, recent and emerging health threats have led the IMI to invest in the development of global health products. In response to the 2014 Ebola epidemic, IMI launched eight projects to speed the development and scale-up of vaccines and diagnostics to prevent and diagnose Ebola<sup>44</sup>. IMI has also launched the world's biggest public-private AMR research partnership, the Bad Bugs Programme. This program could have additional implications for global health, as the threat of AMR to current treatments for PRNDs such as TB, malaria, and diarrheal disease is growing. Consideration should be given to how IMI can ensure close coordination with EDCTP, particularly in epidemic and AMR preparedness. For example, harmonization to accelerate clinical trial reviews in Africa may be an area for increased collaboration.

IMI's governing board consists of equal members of the EC and the European Federation of Pharmaceutical Industries and Associations (EFPIA), which represents the EU research-based pharmaceutical industry. Increasing IMI's focus on regulatory harmonization would require agreement between the two groups on the importance of prioritization.

<sup>m</sup> In its first phase, EDCTP1 (2004–2013) launched 13 calls and awarded 78 grants to support the establishment of ethics and regulatory frameworks for clinical trials in African countries and supported work towards a common regulatory framework at the regional level. EDCTP1 also provided support to AVAREF and contributed to setting up the Pan African Clinical Trials Registry (PACTR).

<sup>n</sup> EDCTP's governance structure is made up of 28 countries, including 14 in Europe and 14 in sub-Saharan Africa, which are full and equal partners.

### 8th R&I Framework Program (Horizon 2020)

Horizon 2020 and previous FPs have been the primary mechanism used to fund research and development for PRNDs in the EU. Funding is organized within different priorities, including one dedicated to health, demographic change, and well-being (societal challenge 1) that included funding calls for PRND research. Funding through previous FPs and Horizon 2020 has also provided support to STI coordination activities. This includes funding for **Caast-Net Plus and RINEA—platforms** focused on strengthening cooperation around research and development between the AU and EU. Though neither of these platforms has had a major focus on regulatory harmonization for global health, their mandates are broad enough that this could play a larger role in the future. Caast-Net Plus offers a broad platform for increased engagement between the EU and the AU and includes a focus on health, and RINEA helps support the function of the JAES HLPD on STI. These or similar future platforms may offer additional opportunities for regulatory coordination and harmonization.

Because the FP also provides funding to the JAES STI, EDCTP, and IMI, the future 9th R&I FP (Horizon2020 ends in 2020), so-called ‘FP9’, **will have a critical role to play in ensuring that current barriers and gaps to the development and scale-up of new global health technologies, including regulatory barriers, are addressed.** As negotiations occur around FP9, consideration should be given to how FP9 can strategically use its funding in support of harmonization activities through coordination and support action grants (CSAs).

### Coordination and Support Action Grants within Horizon 2020

Within Horizon 2020, there is a specific grant modality called CSAs, which does not focus on research but instead on accompanying measures such as standardization, dissemination, and policy dialogues. The EU uses different models of partnership and collaboration that could support actions to promote regulatory harmonization and coordination between Africa and Europe. The models include:

- **Joint Programming Initiatives (JPIs).** These are coordination models for countries (public stakeholders only) based on concerted and joint planning, implementation, and evaluation of their research programs on areas of common interest. Thus, JPIs could potentially help to identify and develop specific actions around regulatory harmonization of medicines in Africa. As an illustration, the JPI-Water<sup>45</sup>, composed of 18 EU countries and South Africa, aims at improving the harmonization, alignment, and coordination of their water R&I agendas and frameworks.
- **European Innovation Partnership (EIP).** This initiative was created under the Europe 2020 flagship Innovation Union to break down research silos in key societal challenges, accelerate R&D innovation, and pool public and private expertise and resources. The first EIP focused on healthy aging; it aimed to mobilize EU institutions and member states to screen their regulatory frameworks in this area to jointly identify the rules that had to be improved, updated, or replaced to provide sufficient and continuous incentives to drive innovation<sup>46</sup>. This EIP also includes as a horizontal objective the development of regulatory and standardization frameworks “to facilitate and enable deployment of innovative solutions...as well as to ensure clarity, flexibility, and robustness of the legal system”<sup>47</sup>. While non-EU actors can participate in EIPs, de facto, this has been very limited. A recent official evaluation report recommended that EIPs open to actors from outside of Europe, “whose input would be invaluable with respect to solutions to the grand societal challenges and the international opportunities for European firms”<sup>48</sup>.
- **Lead-market initiatives (LMIs).** Launched from 2008 to 2011 in six strategic areas (including e-health), LMIs are demand-side innovation policy instruments. As an illustration of the potential of this instrument, the projects CALLIOPE<sup>49</sup> and EpSOS<sup>50</sup> supported the development of interoperable e-health networks, which respectively contributed to the harmonization and standardization of the e-health field in the EU and to the development of a legal, technical, and organizational blueprint for medical care processes in the EU.
- **ERA-NET.** ERA-NET supports public-public partnerships or initiatives (e.g., JPI) developing transnational research and/or innovation projects through joint calls. It also co-funded FP-based projects such as ERAfrica, a pilot initiative to develop and implement joint funding programs for research and innovation partnerships from Africa and Europe and promote African partners to contribute to the JAES STI agenda<sup>51</sup>. ERAfrica2 is currently being discussed. Similarly, ERA-NET has also co-funded the partnership LEAP-AGRI, a Horizon 2020 project that contributes to the implementation of the JAES partnership on food security, nutrition and sustainable agriculture.





### 3.4.3. Directorate-General for Health and Food Safety

Though DG SANTE's primary focus is on promoting the health of Europeans, it is also responsible for policy related to the pharmaceutical sector and is critical to oversight of the EMA and, notably, its Article 58.

One of the unique tools of the EMA, **Article 58 is a mechanism by which the EMA, in cooperation with the WHO, can provide a scientific opinion for the evaluation of drugs and vaccines intended for use exclusively in markets outside the EU.** Article 58 is also aligned with WHO prequalification (PQ) mechanisms and can expedite PQ processes. This scientific opinion must then be adopted by NRAs in countries where the technology will be used. To be eligible for this mechanism, products must be used to treat diseases of major public health interest, including HIV/AIDS, malaria, TB, and other PRNDs. The EMA enacted Article 58 in 2004 in response to the need to protect public health and to give scientific assistance to non-member countries while allowing for faster access to important new medical products outside of the EU. The EMA and WHO decide on a case-by-case basis whether a product falls within the mandate of Article 58.

Though Article 58 holds great potential for improving access to lifesaving health products and strengthening regulatory capacity, this potential has yet to be fully leveraged. Since its introduction in 2004, only seven products have used the procedure. A recent review of Article 58 identified the lack of collaboration with NRAs (including limited awareness of the mechanism among NRAs) as a barrier to Article 58 realizing its full potential<sup>52</sup>. An additional challenge is that NRAs are often slow to approve products, even once they have received a positive opinion as a result of Article 58. This problem is compounded by the fact that many NRAs do not trust the quality of the Article 58 opinion. One opportunity to address these challenges and build on recent harmonization efforts in Africa would be to establish stronger collaboration between the EMA and NRAs during the review process that will accompany efforts to implement the AMRH initiative in RECs across Africa. This desire for closer coordination came out strongly in the recent visit between regulators in the EAC and regulators at the EMA (mentioned earlier in this paper). Collaborative reviews could help strengthen capacities across Africa while at the same time accelerating the approval of positive EMA opinions.



## 4. RECOMMENDATIONS

### PRIORITY SETTING

#### **Establish a joint EU/AU expert group on global health to strengthen African research and innovation capacity**

An expert group under the management of the EC should be established to focus on global health. The goal of the group should be to develop a joint strategy for collaboration on global health R&I between the EU and AU, including the identification of priority areas for collaboration to strengthen global health R&I capacity across Africa. The expert group should be composed of representatives from the EU, the AU and member states and technical experts from academia, civil society and the private sector. *For example, this model has been used successfully in the creation of expert groups through the JAES HLPD which has set up groups on food security, nutrition, and sustainable agriculture, and climate change, and sustainable energy.*

### COORDINATION

#### **Improve synergies between DGs through the development of a joint science, technology, and innovation for development (STI4D) strategy**

The EC should further promote complementarity between EDCTP calls, Horizon 2020, development funds, and member state activities. To accomplish this, the EC should develop a joint strategy on STI4D, ensuring regulatory convergence and harmonization are cross cutting priorities, particularly between DG RTD and DG DEVCO. *For instance the collaboration through the Knowledge, Statistics and Data Hub Unit may serve as a basis for further joint efforts. Deepening of this type of collaboration specifically on STI4D, will help responsibilities and promote knowledge sharing to improve synergies between DGs for global health R&D and harmonization.*



#### Utilize funding instruments to support regulatory strengthening and harmonization

- The EC should make funds available through mechanisms such as the PANAF under the DCI and the EDF and its regional envelopes, to provide additional support for regulatory harmonization in Africa, including for the AMRH Initiative. *For example, funds from H2020 could be paired with funding from the PANAF in support of the AMRH initiative.*
- To maximize critical EU investment, the EC should explore ways to leverage funding to diversify the funding base for global health R&I and regulatory harmonization. This can be accomplished using co-funded activities or by creating new incentives, like matching funds, for investments from the private sector and AU member states. *For example, co funded programs like ERAfrica, could be expanded to include funding for regulatory harmonization.*

#### FUNDING

#### Increase resources for technical assistance activities in support of regulatory harmonization in Africa.

The EMA should increase resources for technical assistance activities that strengthen the capacity of African regulators, and help align regulatory standards across the region, and avoid regulatory duplication. *This should include increased technical support through existing mechanisms like Article 58 and regular meetings with African regulators to share best practices and lessons learned in support of regulatory harmonization.*

#### TECHNICAL ASSISTANCE/ CAPACITY- STRENGTHENING



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