World Health Organization

EU/ACP/WHO

RENEWED PARTNERSHIP

Strengthening pharmaceutical systems and improving access to quality medicines in 15 African ACP countries

2012–2016

A patient at a pharmacy at Zewditu Memorial Hospital in Addis Ababa, Ethiopia.

ABBREVIATIONS

ACAME	Association des Centrales d'Achats Africaines des Médicaments Essentiels/Association of African Pharmaceutical Procurement Agencies
ACP	African, Caribbean and Pacific Group of States
AMA	African Medicines Agency
CEMAC	Economic and Monetary Community of Central Africa
DES	Direction des Etablissements de Soins
DNPL	Direction Nationale de la Pharmacie et des Laboratoires, Guinea/National pharmaceutical and laboratory department
DRC	Democratic Republic of Congo
DTC	Drug and therapeutics committee
EAC	East African Community
ECOWAS	Economic Community of West African States
EHIA	Ethiopian Health Insurance Agency
EU	European Union
IGAD	Intergovernmental Authority on Development
MSH-SIAPS	Management Sciences for Health Systems for Improved Access to Pharmaceuticals and Services Programme
Nepad	New Partnership for Africa's Development
NRA	National regulatory authority
OCEAC	Organisation de Coordination et de Coopération pour la lutte contre les grandes endémies en Afrique Centrale/Organisation for Coordination in the Fight Against Endemic Diseases in Central Africa
PFSA	Pharmaceutical Funds and Supply Agency
PPB	Pharmacy and Poisons Board
UEMOA	Union Economique et Monétaire Ouest Africaine/West African Economic and Monetary Union
WHO	World Health Organization

ABOUT THE RENEWED PARTNERSHIP

The European Union/African, Caribbean and Pacific Group of States/World Health Organization (EU/ACP/WHO) Renewed Partnership contributes to the achievement of the health-related Millennium Development Goals (4, 5, 6 and 8) and of universal health coverage in ACP countries in Africa. Under the leadership of Ministries of Health, the 15 ACP countries benefit from WHO strategic, technical and monitoring support to increase access to quality essential medicines by strengthening their pharmaceutical systems. The Renewed Partnership kicked off in 2012 and is the sequel to a previous programme on pharmaceutical policies implemented from 2004 to 2010. The specific objectives of the Renewed Partnership are to improve availability, affordability and use of safe, effective and quality-assured essential medicines for priority communicable and non-communicable diseases. It thereby contributes to promoting cost-effective health care and better patient health outcomes. The Partnership's five areas of focus where results can be measured are:

Improved availability and supply of selected essential medicines in national, regional and community health facilities through national supply systems

Reduced medicines prices and improved mechanisms for financing and for coverage of essential medicines in social protection schemes

Improved quality of medicines and reduced occurrence of substandard and counterfeit medicines

Improved medicines selection, prescribing, dispensing and use

Improved access to reliable country pharmaceutical sector information; evidence-based national medicines policies and plans developed and monitored; enhanced transparency and good governance of the pharmaceutical sector

FOREWORD

The right to the highest attainable standard of health is one of the fundamental rights of human beings. This right cannot be realized without strong health systems, functioning in a coordinated and comprehensive way to ensure that basic health services are available to all who need them, including the most vulnerable and marginalized groups of the population. Medicines represent a vital component of these services. Yet a secure supply of quality essential medicines is very difficult to guarantee without strong policy frameworks and regulatory and procurement systems.

The European Union pursues a rights-based approach to health and provides support to countries to develop national health policies and to strengthen health systems. Our contribution to the EU/ACP/WHO Renewed Partnership in 15 African countries reflects this engagement, with a programme that brings partners together to work on improving access to medicines in line with national priorities defined in pharmaceutical policies and to provide a source of guidance on policymaking. It is one of the mechanisms by which the EU supports countries achieve universal health coverage, delivering people the health care services they need and contributing to inclusive economic growth and development.

Aida Liha-Matejicek
Head of Unit Education, Health, Research, Culture,
Directorate-General for International Cooperation and Development
European Commission

The African, Caribbean and Pacific Group of States, the European Union and WHO are close partners in building stronger health systems in ACP States. In the 11th EDF Intra-ACP strategy, the ACP Group of States and European Union agreed that it is vital that national health systems are strengthened to ensure equitable access to health care. It is therefore crucial for ACP States to have the support of partners, who understand and share their national goals. The EU/ACP/WHO Renewed Partnership represents this kind of collaboration. It works not only at the national level, but at the regional level, to support the implementation of national and regional priorities. It helps leaders coordinate activities and benefit from guidance on policy options. It gives Members access to the technical support they need to develop strong and resilient pharmaceutical systems.

At their second meeting, held in February 2015 in Brussels, Belgium, the ACP Ministers of Health underscored the importance of national medicines policy frameworks, national regulatory frameworks, strong quantification methods for procuring medicines and monitoring of utilization of medicines, to ensure access to safe, affordable and quality essential medicines. To this end, the EU/ACP/WHO Renewed Partnership supports ACP Member States to carry out the new global agenda on universal health coverage as contained in the 2030 Development Agenda, particularly with respect to Sustainable Development Goal 3, to ensure no one is left behind.

Léonard-Emile Ognimba
Assistant Secretary General, Political Affairs & Human Development
ACP Secretariat

Now that we have entered the era of Sustainable Development Goals, whose health targets centre on universal health coverage, all countries must strive to deliver safe, effective and affordable healthcare to their people. Reaching that goal will require a significant investment in people, institutions, infrastructure and governance. This is particularly true when it comes to access to quality medicines, which has significant financial implications and is dependent on a multitude of evidence-based approaches, best practices and technical skills. Much of the work required to deliver access to quality medicines is not visible on a day-to-day basis to healthcare consumers – but without it, patients' safety would be at risk, treatment would not be available and precious health resources would be lost.

Expenditure on medicines makes up a significant proportion of public and private spending on health. It is critical that countries have the strong foundations in place to ensure this investment is made wisely. Countries must have the fundamentals in place to ensure a steady supply of quality medicines to all, so that patients can get the medicines they need, when they need them. They must have strong systems to ensure the public is protected from substandard or counterfeit products.

The EU/ACP/WHO Renewed Partnership has been an important vehicle for countries to achieve strong pharmaceutical sectors. Through the Partnership, WHO supports the leadership of the Ministry of Health to ensure all interventions in the pharmaceutical sector are coordinated and informed by the highest-quality technical advice on policy options for selection, price and reimbursement, rational use, regulation and procurement and supply management.

For many countries, the work to achieve universal health coverage has just started. WHO therefore looks forward to continued collaboration with ACP countries and the EU to make it possible for the populations of all 15 countries to affordably access the quality essential medicines they need.

Marie-Paule Kieny
Assistant Director-General – Health Systems and Innovation
World Health Organization

Boxes of medicines are offloaded at the national procurement centre in Bamako, Mali, before distribution to health facilities.

RESULT AREA 1
Improving availability and supply of medicines

Ensuring a sustainable supply of medicines at all levels of the health system requires strong and well-performing national procurement and supply management systems and effective coordination of all actors involved.

Many partners are providing support in procurement and supply management in Renewed Partnership countries.[1] To ensure complementarity, WHO supports governments to improve the supply management process and ensure coordination through its National Medicines Advisers, a network of pharmaceutical professionals based in countries. They provide strategic advice on procurement and supply management, facilitate training of local staff and ensure the alignment of partners' actions to national priorities.

Strengthening procurement and distribution of medicines

All functioning health systems rely on strong evidence and current, solid data to inform policies and actions for the procurement of medicines. Thanks to the Renewed Partnership, many African countries now have a much improved evidence base to increase the availability of medicines in health facilities.

Six countries – Burundi, Congo, the Democratic Republic of Congo (DRC), Mali, Tanzania, Togo – carried out price and availability surveys to gain a better understanding of the level of availability and affordability of medicines in health facilities.

The Burundi survey on availability and pricing clearly revealed a number of problems, particularly in medicines availability, which was as low as 42% of coverage needs in all sectors (public, not for profit and private). These findings will help Burundi to identify bottlenecks and enact appropriate corrective actions.

1 The UN Population Fund, the World Bank, Management Sciences for Health Systems for Improved Access to Pharmaceuticals and Services Programme (MSH-SIAPS), JSI, The Global Fund, and UNICEF.

In Congo, WHO National Medicines Adviser, Ray Mankele, supported work on the price and availability survey and says that the evidence collected has provided a strong basis for new policies.

"The survey showed the authorities the low level of availability of medicines in health facilities in both the public and private sectors," he explains. *"It also highlighted weaknesses in the national procurement centre related to the availability in health facilities of originator products purchased outside of the system for the public sector. Based on the outcome of this survey, the government has decided to reform the national procurement centre and has now established a new structure."*

In Kenya, the survey carried out under the Renewed Partnership has helped national health sector stakeholders to adapt policies and recommendations to the process of devolution.[2]

> *"The Renewed Partnership has enabled much-needed continuity to support implementation of the pharmaceutical policy, and also to influence other related health policy and reform processes, such as financing and procurement."*
>
> Regina Mbindyo
> WHO National Medicines Adviser, Kenya

The policy has now been approved by Kenya's Cabinet.

Under the Partnership, the Ministries of Health of Burundi, Congo, Guinea, Senegal, Tanzania and Togo, developed training materials and held workshops for a pool of trainers on medicines management. This is essential to ensuring regular supplies of medicines stocks in health facilities and guarantee continuity of care.

In Guinea, in the context of the Ebola crisis, WHO contributed to the training of staff in charge of the management of medicines and protective equipment in close collaboration with MSH/SIAPS and the Ministry of Health.

In the Democratic Republic of Congo, a large country facing challenges in providing medicines to remote areas, a new working model was developed with support from the Renewed Partnership for securing the supply of medicines in zonal health services in Kisangani. This new model will be assessed in 2016 and, if effective, will be expanded to other provinces.

Regional collaboration

The Renewed Partnership has provided an opportunity for collaboration across borders, to strengthen the development of quality assurance systems in national procurement centres in compliance with WHO's Model Quality Assurance System for Procurement Agencies. In close collaboration with the Association of African Pharmaceutical Procurement Agencies (ACAME) and the Institute of Tropical Medicine in Antwerp, WHO has provided technical and financial support to a project to strengthen quality assurance systems of 10 national procurement centres. This project is designed to help ensure all measures are in place to guarantee the quality of the products supplied to the population, while simultaneously reducing the occurrence of substandard and counterfeit products in the public system.

2 In 2010, the new Kenyan constitution mandated the devolution of power to 47 counties. This process has had wideranging implications for the health sector in Kenya as stakeholders struggle to understand the impact of the new political structure on their programs and services. See: http://www.healthpolicyproject.com/index.cfm?id=publications&get=pubID&pubId=719

Patients at the dispensary room in a health centre in Tanzania.

RESULT AREA 2
Working towards universal health coverage via affordable medicines

In most Renewed Partnership countries, medicines costs represent the biggest portion of household expenditure on health. Some countries have now started to move towards universal health coverage by putting in place national health insurance schemes in order to reduce the financial burden of treatments on their populations. In this context, it is critical that prices of medicines are affordable to both patients and health systems. WHO is providing guidance and technical support to countries to develop sound benefits packages and design pricing and reimbursement policies that will allow them to control prices and ensure affordable health care.

With Renewed Partnership support, the Ethiopian Health Insurance Agency (EHIA) has developed a list of medicines that should be reimbursed based on their national essential medicines list. The Renewed Partnership has also given EHIA staff the opportunity to meet with their counterparts from other countries to share experiences in implementing pricing and reimbursement policies. The Deputy Director of EHIA, Abduljelil Reshad, is grateful for the technical support the young agency has received from WHO.

> *"Our plan is very ambitious: to cover around 80% of districts and also 80% of households. Out-of-pocket expenditure will be dramatically reduced."*
>
> Abduljelil Reshad
> Deputy Director, Ethiopian Health Insurance Agency

On a regional level, the WHO African Regional Office has supported countries to better monitor cost by establishing an electronic system to record procurement prices of medicines.

Ensuring fair prices

Ensuring fair and affordable prices is partly dependent on the availability of price information, an activity the Renewed Partnership has supported across the 15 countries. In Burundi and Mali, the outcome of the pricing surveys carried out in the public and private sectors has provided the basis for the development and review of national medicines pricing policies.

"Fifty products were surveyed across 60 facilities," says the WHO National Medicines Adviser in Burundi, Donatien Bigirimana. *"We found prices were high and availability was weak. The Renewed Partnership then provided technical support for the Ministry of Health to draft a national medicines pricing policy."*

"A pricing policy is an important mechanism to taking a focused approach to addressing complicated medicines challenges," adds Mr Bigirimana. *"For it to be useful and sustainable, it must be based on evidence."*

In both Burundi and Mali, the policy focused on fixing the profit margin in the private sector in order to limit the prices of medicines for patients and thus improve affordability.

Similar work was done in Congo, in relation to prices of medicines in the public sector. The survey, carried out in 2013, showed large variability in the prices of medicines in public facilities – up to 10 times more expensive in some places – in the absence of price controls in the supply chain.

"This will serve as a basis for further discussions on defining margins to be applied in the public system in the context of the establishment of an insurance system," says Dr Ray Mankélé, WHO Medicine Adviser in Congo.

> *"We found prices were high and availability was weak. The Renewed Partnership then provided technical support for the Ministry of Health to draft a national medicines pricing policy. This is an important mechanism to taking a focused approach to addressing complicated medicines challenges."*
>
> Donatien Bigirimana
> WHO National Medicines Adviser, Burundi

Senior analyst at the Ethiopian Food, Medicine and Healthcare Administration Authority, Atlaw Abate, using a screening method to detect substandard and counterfeit products.

RESULT AREA 3
Building regulatory strength at the national level

The Renewed Partnership has been a driving force for strengthening national medicines regulatory authorities (NRAs). NRAs are a fundamental component of a strong pharmaceutical system. Their work may not be visible to patients but, when functioning effectively, NRAs protect patients and promote public health on a daily basis. They deliver public confidence in the quality and safety of health products, which translates into confidence in national health services and in the government's commitment to protect its people.

All Renewed Partnership countries have carried out activities to strengthen the capacity of their NRAs.

Assessing the functionality of national regulatory authorities

The first step in this effort was for WHO to assess NRAs in six countries – DRC, Ghana, Kenya, Mozambique, Senegal and Zambia. This helped countries identify strengths and weaknesses in the implementation of regulatory functions, such as registration of medicines, inspections, quality control, authorization of pharmaceutical establishments and pharmacovigilance. The findings of these assessments serve as a basis to develop an implementation plan for the NRAs and to define priorities to improve regulatory functions.

"Zambia is dedicated to improving the quality of care to patients. We cannot deliver quality care without access to quality, safe and efficacious medicines. This requires continued strategic investment across the pharmaceutical sector, not least in regulatory capacity," says Mrs Bernice Mwale from the Zambia Medicines Regulatory Authority.

In DRC, based on the outcome of the assessment, the NRA organized a meeting to inform donors about the recommendations of the assessment and to identify funding gaps for further actions. As a result, the World Bank has assigned funding to DRC to strengthen its NRA. Close collaboration between WHO and the World Bank is now in place to better support the reinforcement of national regulatory capacity.

In Kenya, the government asked WHO to assess the NRA, the Pharmacy and Poisons Board (PPB), to inform the ongoing regulatory reforms in Kenya. The findings and recommendations of the assessment report have informed the development of policy and legal instruments for the establishment of the proposed Kenya Food and Drug Authority, to replace the PPB.

Strengthening the capacity of NRAs and improving tools and guidelines

NRAs need specific tools to perform their job more effectively and to better communicate the results of their work to all national stakeholders.

In Guinea, the Renewed Partnership supported the installation of software for drug registration and monitoring of imports. The software (SIAMED) allows the authority to easily access information on medicines under registration and registered, as well as on medicines imported, including important information on expiry dates, quantity imported and cost.

In Senegal, the Renewed Partnership provided support to the NRA to develop a database of all products registered in the country. This database allows all people procuring or importing medicines to access the information and adhere to national regulations.

"This database has also helped to clarify whether medicines are registered," says Dr Mamadou Ngom, the WHO National Medicine Adviser in Senegal. *"It has enabled us to shorten time for registration, better manage dates for registration renewals as well as to update the list of current suppliers and to collect prices of medicines."*

The Renewed Partnership has also been instrumental in the development of national regulatory guidelines.

In Guinea, the NRA worked in close collaboration with WHO to review guidelines on the destruction of expired and spoiled medicines. This document was particularly important at the time of the Ebola crisis, when a huge number of medicine donations arrived in the country. It allowed for the more timely destruction of those not appropriate for use in Guinea. The risks are that if such medicines remain in dispensaries and warehouses, they may be illicitly circulated or accidentally prescribed to patients with potentially harmful consequences.

> *"One important part of our work is to ensure patients are not receiving dangerous products and to be sure expired or spoiled products are destroyed properly,"*
>
> Dr Kabiné Souaré
> Director of Direction Nationale de la Pharmacie et des Laboratoires (DNPL), the NRA in Guinea.

"We now have clear instructions in place to be applied by all stakeholders in the health system to destroy non appropriate medicines safely," adds Dr Nagnouma Sano, head of the DNPL section on pharmaceutical establishments in Guinea.

Pharmaceutical manufacturers must apply to have their medicines registered in markets, and it is important that NRAs are capable of stringently assessing such applications. The Renewed Partnership has contributed in this area by building capacity of NRA staff to assess product dossiers for registration.

Three workshops were organized in Ouagadougou and Brazzaville in collaboration with the West African Economic and Monetary Union (UEMOA) and the Organisation for Coordination in the Fight Against Endemic Diseases in Central Africa (OCEAC) respectively, and in Dakar. The objective was to build the capacity of NRA assessors to evaluate the quality of medicines before registration, thereby making quality-assured generic medicines available to the populations. The workshops were also designed to identify promising staff who could be further trained to develop a pool of trainers in Africa. Similar training sessions have been held in other countries, including Mali and DRC and is planned in Senegal. This will allow the training of more assessors in the future.

"Strengthening medicine registration systems is a key step in improving access to quality, safe and efficacious medicines for the populations. Providing quality healthcare to patients is a priority for Senegal."

Professor Amadou Moctar Dieye
Director, Direction de la Pharmacie et du Médicament, Senegal

Stronger medicines registration is also an important priority for Mali. "To achieve a stronger health system, we need high-quality medicines for all," says Dr Bakary Diarra, General Secretary at the Ministry of Health and Public Hygiene, Mali.

The Renewed Partnership has also helped to build the capacity of staff working in national quality control laboratories. A first training session organized by the Collaborating Centre at North-West University in South Africa helped staff from seven Renewed Partnership countries to better understand good practices for pharmaceutical quality control laboratories. This will help countries to further develop their quality control capacities. The training was followed by further workshops for laboratory staff on specific analysis techniques such as in the National Laboratory of Health in Mali. The Quality Assurance manager of the quality control laboratory in Mozambique was also given the opportunity to spend few weeks in a WHO prequalified laboratory in Uruguay to better understand the different steps required to obtain WHO prequalification.

LANACOME in Cameroon benefitted from the Renewed Partnership to improve its practices in order to help them to attain WHO prequalification requirements. The WHO African Regional Office supported this effort by facilitating links with Algeria's WHO Prequalified national quality control laboratory. Three experts from the Algerian laboratory were seconded to work with LANACOME staff to validate techniques and to help to put in place good laboratory practices.

Monitoring and preventing adverse drug reactions

Regulatory oversight of medicines does not end with a medicine's registration and entry on markets. Authorities must continue to monitor medicines even after they are approved for use for unanticipated adverse reactions. This aspect of regulatory practice is called pharmacovigilance.

While pharmacovigilance has not traditionally been practised in many ACP countries, that trend is now changing thanks to the Renewed Partnership.

In collaboration with the regional group, OCEAC, the Renewed Partnership supported the training of pharmacists from NRAs in pharmacovigilance. Opportunities were also given to other NRA staff to participate in the regular training organized in the WHO Collaborating Centres in Morocco, Ghana and Uppsala.

The WHO National Pharmaceutical Adviser for Mozambique, Ana Fernandes, says the training of pharmacists has led to tangible results.

"The pharmacists do not have deep knowledge of the subject when they start their journey in this area," she explains. *"A vision of what is being done internationally and what can be achieved with the improvement of this system is key for the better performance of the sector."*

A notable result of the pharmacovigilance training comes from Zambézia, a province of Mozambique. A pharmacist from the province attended a pharmacovigilance workshop in a WHO Collaborating Centre in Ghana. Consequently, the number of spontaneous

notifications of adverse drug reactions in Mozambique increased from 118 in 2012, to 936 in 2014. Most of them came from Zambézia.

Like Mozambique, Burundi, Congo, DRC, Guinea, Mali, Senegal and Zambia have also been building their national pharmacovigilance systems, and have taken part in the regional training.

"The training has raised awareness of the dangers of drug effects and the need to notify to the competent authority to make decisions in due course," says the WHO National Medicines Adviser in Guinea, Cécé Vieux Kolié. *"It has also improved the reporting of such effects at all levels."*

DRC has now established a National Pharmacovigilance Centre.

"The very dynamic National Pharmacovigilance Centre hosted in the University of Kinshasa has developed quickly and staff is working in close collaboration with the Uppsala Monitoring Centre and is publishing regularly articles in scientific journals," says Anastasie Mulumba, the WHO National Medicines Adviser in Democratic Republic of Congo. *"Today, many partners such as The Global Fund, USAID and foreign universities are giving support to pharmacovigilance in DRC."*

Building regulatory strength across the African region

A key focus of the Renewed Partnership has been to ensure regulatory strength across the region to build effective medicines regulatory systems through harmonization and regulatory capacity building. This has included work at a regional level to harmonize practices, improve capacity and share experiences.

Different harmonization initiatives were already taking place in Africa with support from various partners when the Renewed Partnership started, so the Renewed Partnership decided to work with regional economic communities receiving less support at that time. Contacts were established with UEMOA and Economic Community of West African States (ECOWAS) and also with the Economic and Monetary Community of Central Africa (CEMAC), and later in the project with the Intergovernmental Authority on Development (IGAD) in northeastern Africa. Countries that are part of other sub-regions, such as Tanzania and Burundi in the East African Community (EAC), worked together to build effective medicines regulatory systems through harmonization and regulatory capacity building. It is hoped that having common documents and procedures will eventually lead to low registration transaction costs for manufacturers as well as the NRAs, and streamlined processes to ensure medicines reach patients faster.

In the Central African region, countries are responding to the challenge via OCEAC. The Coordinator of OCEAC's Regional Sub-Programme Harmonization of National Pharmaceutical Policies in Central Africa, Dr Bernard Aimé Djitafo Fah, says WHO's efforts through the Renewed Partnership reinforce OCEAC's work to ensure that regulatory authorities across the region have the necessary skills to ensure medicines given to their populations meet national standards.

"The challenge is to develop the technical expertise of regulators in quality assurance and marketing authorisation," says Dr Djitafo. *"They need to adopt the same practices on all topics and then implement them in each country and, one day, may consider pooling resources to become more efficient."*

The Renewed Partnership has provided critical support for the push to establish a medicines regulatory agency for the region an African Medicines Agency (AMA).

> *"This concept has been around for a long time – the issue has been to find strategic partners in terms of technical capacity and financial support to make the idea a reality. That is what the Renewed Partnership has brought to the project."*
>
> Dr Jean-Baptiste Nikiema
> WHO African Region Medicines Adviser

The AMA would build on and develop the capacity of the region's national medicines regulators, and ultimately contribute to improving access to medical products in compliance with international standards of quality, safety and efficacy.

"One of the priority areas of intervention of the Renewed Partnership is to ensure the quality of medical products circulating in the region and to ensure that these medicines are meeting international requirements in terms of standards," says Dr Jean-Baptiste Nikiema. *"The AMA is one of the elements that will contribute to coordinating the effort in terms of capacity building and pooling expertise in the region to review applications for marketing authorization. That's why the Renewed Partnership has been involved."*

The WHO Africa Regional Office supported the development of a technical document on strengthening the capacity for regulation of medical products in the African region. This document was adopted by the AFRO Regional Committee in 2013, including proposed actions. The Regional Office also supported the development of the AMA concept paper, which was endorsed by African ministers of health in 2014. Based on these initial documents, the WHO Regional Office, in close collaboration with the New Partnership for Africa's Development (Nepad) and the African Union Commission, organized a meeting of the AMA Task Team and provided additional support to develop a legal and institutional framework and a business plan for the AMA.

In many countries in Africa, legislations on medical products are not up to date or comprehensive enough to cover all medical products. Not only does this hinder regulation at a country level, it also makes harmonizing regulations and establishing mutual recognition between countries difficult.

With the support of Renewed Partnership funds, the WHO Africa Regional Office has also supported Nepad to develop an African Union Model Law on Medical Product Regulation. This will help countries take a systemic approach to reviewing and developing their legislations on medical products, and will improve governance of regulatory systems as an essential component in aid of universal health coverage and better health outcomes. The model law was adopted in January 2016 by the African Union and marks significant progress in accelerating access to safe, effective and quality medical products in Africa.

Combatting substandard and counterfeit products

Substandard and counterfeit medicines pose an unacceptable risk to public health. Nowhere in the world is immune from them, and they span all categories of health products, from medicines to vaccines and medical devices. The Renewed Partnership has worked with countries to minimize the risks from substandard and counterfeit medical products by collecting data and transferring knowledge and good practices to countries.

"Renewed Partnership activities were a good opportunity to learn more about why surveillance and monitoring of medicines are very important worldwide," says Burundi WHO National Medicines Adviser, Donatien Bigirimana. *"Participants have been sensitized and encouraged to be attentive in their own country and work more effectively with the WHO Global Surveillance System."*

As a result of this support, Ethiopia and Mozambique are now screening for substandard and counterfeit products at ports of entry to identify suspicious products to be sent for more in-depth analysis in their national quality control laboratories. The work has meant that they are now contributing to the global fight against substandard and counterfeit products, by reporting their incidence to WHO's global database.

"Screening for substandard and counterfeit products is essential to protecting public health. Working with partners, we have implemented innovative, efficient and cost-effective ways to carry out screening," says Dr Paula Raimundo, the Director of the National Quality Control Laboratory in Mozambique.

In Togo, work has been undertaken to raise awareness of the presence of substandard and counterfeit products through the development of key messages to be used on television and radio spots to sensitize the population.

"This activity was considered as a very important one, because the prevalence of substandard and counterfeit health products and the illicit market are undermining the national procurement system for pharmaceutical products," says the WHO National Medicines Adviser in Togo, Minzah Pekele.

Tanzania has been among the partners involved in the Renewed Partnership's regional efforts to fight substandard and counterfeit products.

> *"Tanzania is dedicated to fighting substandard and counterfeit medicines. But we can't succeed unless we work across borders and especially through regional economic communities such as the East African Community and Southern African Development Community. Through the Renewed Partnership, we have worked together with our neighbours through regional medicines regulatory harmonization initiatives to prevent our people from being exposed to useless and dangerous products."*
>
> Hiiti Sillo
> Director General, Tanzania Food and Drugs Authority

Putting in place blood and blood products regulation in Africa

The Renewed Partnership has taken significant steps to establish sound blood regulations in ACP countries in collaboration with the African Society for Blood Transfusion. The collaboration delivered Africa's first workshop on blood and blood products regulation. The training workshop, in South Africa in 2013, provided training and expert guidance to delegates of the national blood transfusion services and the national regulatory authority of 11 countries. Burundi, Ghana, Kenya, and Zambia are now moving to introduce regulation to improve the collection, safety and quality of blood products, using the guidelines and tools developed with the support of the Renewed Partnership. The objective of a second workshop organized with 12 countries in Benin in 2015 helped to review the draft Africa Regional strategy for blood safety and guidelines for the establishment of national regulatory systems for blood and blood products This will serve as a basis for countries to develop national regulation.

"During the Ebola outbreak we saw that we had an urgent need to undertake action in terms of regulation and building capacity in terms of blood collection, quality, and regulation, so it is a regional priority," says the WHO's African Region Medicines Adviser, Jean-Baptiste Nikiema.

Through its work with the Renewed Partnership, Kenya's national medicines regulatory authority, the Pharmacy and Poisons Board, has begun regulating blood and blood products. It is now drafting guidelines for the regulation of blood and blood products, in collaboration with the national blood transfusion service. This work has been supported by WHO, including with training of staff and institutional reform of the Kenya National Blood Transfusion Services.

"These reforms will ensure clear delineation of roles for blood safety between the Pharmacy and Poisons Board and the Blood Transfusion Services," says Regina Mbindyo, WHO National Medicines Adviser in Kenya. *"It will facilitate the necessary institutional collaboration to ensure the safety and availability of blood and blood products in Kenya."*

A pharmacist giving information to a patient as she dispenses his medicines at a pharmacy at Zewditu Memorial Hospital in Addis Ababa, Ethiopia.

RESULT AREA 4
Updating and implementing national essential medicines lists

Through the Renewed Partnership, Burundi, Congo, Ethiopia, Ghana, Mali, Mozambique and Zambia have benefited from technical support to revise and better implement their national essential medicines lists. The selection of cost-effective medicines needed to treat the majority of the population is the basis of the essential medicines concept and continues to be a pillar of any work in access to medicines. It serves to inform procurement, reimbursement and training of health workers.

With support from the Renewed Partnership, Mali has revised its national list of essential medicines to include paediatric formulations for the most common child diseases in the country. This has allowed the country's regulatory authority to register medicines for children and the national procurement centre to make them available throughout the country.

"It makes a huge difference," says Dr Minkaïla Maiga, WHO Medicines Adviser in Mali. *"Before we had to break the tablets into smaller pieces for children, not really knowing if we were using the right dose."*

Working in collaboration with WHO National Medicines Advisers, countries have benefited from the latest evidence in the constantly evolving field of knowledge on treatments for major health problems. That evidence, reviewed and updated every two years, informs the WHO Model List of Essential Medicines, which in turn provides guidance to countries to update their national lists.

Effective use of scientific evidence was the subject of a regional workshop organized in Ghana in 2013 with the objective of improving the capacity of Ministries of Health to select medicines according to sound data rather than simply on experience and marketing ploys.

The Renewed Partnership has also contributed to the review of some important sections in the WHO Model List of Essential Medicines and supported a technical working group in 2014 to review the cancer sections in the context of the global rise of noncommunicable diseases. This will help countries to identify the services and medicines they need to treat priority cancers nationally.

Supporting the fight against antimicrobial resistance

Antimicrobial resistance has become a global public health threat, including for the African Region. The Renewed Partnership helped to produce a regional antimicrobial resistance action plan following a regional consultation organized in Brazzaville in May 2015, thereby contributing to the WHO Global AMR plan.

In addition to this consultation, eight Renewed Partnership countries have committed to conducting antimicrobial consumption and use surveys as they develop their national action plans to combat resistance. The consumption surveys will be based on WHO methodology that was developed and used in the WHO European Region. A group of experts met in early 2016 at WHO Headquarters to adapt the methodology for use at global level. With additional resources from the Fleming Fund, a training workshop was organized in May 2016 in Ouagadougou to train Ministry of Health representatives in this methodology to allow them to start consumption surveys.

This work will increase the capacity in the African region to routinely collect data on antimicrobial consumption and support the identification of key interventions to improve the use and preservation of antimicrobials, as recommended by the World Health Assembly.

> *"We have made significant steps in developing the regional action plan on antimicrobial resistance. We have worked together to ensure that across the region, we understand how medical staff prescribe antibiotics. One of the biggest problems is that they are used in the wrong way. Antimicrobial resistance knows no borders – we need to work together in the spirit of 'one health' to stop it."*
>
> Martha Gyansa-Lutterodt
> Director of Pharmaceutical Services, Ministry of Health, Ghana

Ensuring efficient spending and rational use of medicines

A significant proportion of a hospital's budget is spent on medicines. Without proper management, resources can be wasted through inappropriate and irrational use. Hospitals' well-functioning drug and therapeutics committees (DTCs) are key to addressing this challenge. They bring together all the relevant people involved in different aspects of drug management and use in a hospital (managers, clinicians, nurses and pharmacists), and allow them to implement coordinated strategies to address the problem.

In Ethiopia, the Renewed Partnership has supported the national procurement agency, the Pharmaceutical Funds and Supply Agency (PFSA), in an effort to strengthen national DTCs. The work began with an assessment of 111 structures.

"It was not that DTCs didn't exist in Ethiopia, it was that we needed to know how well they were working," says Abraham Gebregiorgis, the WHO Medicines Adviser in Ethiopia.

Based on the evidence, a plan was formed to train DTC members. WHO collaborated with Management Sciences for Health to support PFSA to develop training manuals and facilitate a series of training sessions. This has seen a dramatic improvement in the performance of DTCs, including in one of Addis Ababa's biggest hospitals, Zewditu Memorial.

"We have met five times in six months," says Hana Likas, the Secretary of the hospital's DTC. *"We have developed a medicines list for the hospital, we review prescriptions, we have developed leaflets in Amharic [Ethiopia's official language] so patients understand how to take their medicine better, and we have prepared manuals and standard operating procedures for staff to help reduce shortages and waste."*

> *"Drug and therapeutics committees are gateways for supply chain management and for improving the use of pharmaceuticals. We have trained more than 1000 professionals from public health facilities. The result has been increased product availability and improved quality of services offered at facility level."*
>
> Yared Yiegezu Zegiorgis
> Director of Forecasting and Capacity Building Directorate, PFSA, Ethiopia

"The DTC is a backbone of the hospital," says the CEO of Zewditu, Dr Tarafa Azarfa. *"One of our biggest budget investments is on medicines and medical equipment. This budget must be properly managed. Support from an organization such as WHO is very important for us. We do have a lot of gaps and to fill these gaps we should work together."*

The Renewed Partnership also provided support to ACP countries to review their standard treatment guidelines. In Cameroon, national standard treatment guidelines are now available and could help to rationalize medicines use in facilities. Support was also provided by the Renewed Partnership to develop training material and to develop trainers' capacity to train health workers on rational use of medicines. The objective was to increase responsible use of medicines and improve quality of care for patients.

Hospital staff discuss hospital medicines policy at a drugs and therapeutics committee meeting at Zewditu Memorial Hospital in Addis Ababa, Ethiopia.

RESULT AREA 5
Developing strong policies

Renewed Partnership countries are increasingly focused on improving the quality of care provided to their populations – strong pharmaceutical policies are a key component of this. A national pharmaceutical policy commits all sections of the pharmaceutical sector to a decided set of goals and provides a guide for action. The development of policies requires building consensus through consultation of all stakeholders.

In Cameroon, Ethiopia, Ghana, Guinea, Senegal and Tanzania, the Renewed Partnership has supported the review of national medicines policies and the development of implementation plans.

> *"It was good to have an external evaluator to undertake this exercise, so as to remove any bias or partiality in the report due to familiarity. It was also good practice to have in-country persons being part of the team, to give appropriate guidance as needed."*
>
> Edith Annan
> WHO National Medicines Adviser in Ghana

Updating a policy is often a lengthy exercise as it requires situation analyses and assessments of the implementation of the previous policy to identify new priorities in the pharmaceutical sector and to build consensus among stakeholders. It requires an inclusive process and the final validation of the policy should be given by the government to ensure proper resources would be made available to achieve the defined objectives.

"Cameroon's National Medicines Policy is designed to deliver better health outcomes for all, with a particular focus on access to good quality medicines," says Dr Jean-Baptiste Roungou, WHO Representative in Cameroon. *"It has been developed with inputs from stakeholders from across the pharmaceutical sector to ensure it's comprehensive, sustainable and achievable."*

Another important aspect is to regularly monitor different elements of the national policies and to assess key indicators to measure progress towards defined targets. Mali, through the Renewed Partnership, did an evaluation in 2015 of key indicators and this assessment will serve as a basis to update the current implementation plan of the national pharmaceutical policy.

Working together towards the same goals

A key advantage of the Renewed Partnership has been its ability to coordinate activities across the pharmaceutical sector. This is vital to ensuring sustainable and effective policy implementation, and to avoiding duplication. With the support of the Renewed Partnership, Burundi and Ghana both now have well-functioning coordination platforms between national actors and the partners supporting the pharmaceutical sector.

In Burundi, key national actors and aid partners meet monthly to discuss all pharmaceutical issues, such as registration of medicines, quality assurance, access (supply chain, prices and availability), pharmacovigilance, coordination of activities, the logistics management information system, rational use of medicines and the legal and regulatory framework. These meetings ensure that they are all working to national priorities and in complementarity, and promote transparency and good governance within the sector.

"One of the key achievements of the coordination platform has been the harmonized planning of activities," says the WHO National Medicines Adviser in Burundi, Donatien Bigirimana.

In Togo, the Renewed Partnership has helped to strengthen the policy dialogue on medicines. The NRA (Direction des Pharmacies et du Médicament – DPM), the national procurement centre (Centrale d'Achat des Médicaments Essentiels et Génériques – CAMEG) and the department in charge of the management of health facilities (Direction des Etablissements de Soins – DES) have held joint discussions on priorities and have developed joint action plans.

Improving transparency and fighting corruption

With support from the Renewed Partnership, Burundi, Cameroon and Zimbabwe have been working on improving governance in their pharmaceutical sectors.

> *"The ultimate objective of good governance for medicines is to ensure that essential medicines reach the intended end users, who are the patients."*
>
> Stanley Midzi
> WHO National Medicines Adviser, Zimbabwe

A team of assessors was trained to conduct a national assessment of governance in Zimbabwe, under the Good Governance for Medicines programme. The team's preliminary report is being considered by stakeholders. Eventually, it will lead to the development of a good governance framework to promote individual and institutional integrity in the pharmaceutical sector.

Participants at a workshop in Addis Ababa, Ethiopia, on the reporting of substandard and counterfeit medical products.

CONCLUSION

The EU/ACP/WHO Renewed Partnership: a strong approach for better access to quality medicines to support countries in the SDG agenda

The EU/ACP/WHO Renewed Partnership is one of the most important projects in Africa involved in building an enabling environment for the sustainable supply of quality affordable essential medicines to populations. Its contribution has been vital in a number of specific technical areas, as described. It has also reinvigorated the focus on improving access to safe, effective, quality and affordable medicines as a fundamental component of a health system and indispensable to the achievement of universal health coverage.

Thanks to the Renewed Partnership and the support of the European Commission and the ACP Secretariat, ACP countries now have the foundations to deliver better pharmaceutical services to their populations. Progress to date is encouraging, but requires continuity of support from funding partners and from WHO, whose deep understanding of countries' individual health systems and needs makes it the ideal technical partner.

A major pillar of WHO's vision for the Sustainable Development Goals agenda is a world in which everyone has access to the medicines and health products they need to live healthy and productive lives. We believe countries and their people are striving for that same goal, and we must persevere and work with all partners to reach it.

> *"In order to achieve universal health coverage with essential services, it is crucial to have universal access to medicines that are of good quality, as part of well-functioning national health systems. I believe that our Member States are now committed to strengthening their pharmaceutical sectors with effective policies and plans. I call upon the EU to consider continuing the partnership with WHO in order to sustain the progress made in beneficiary countries, but also to consider expanding the partnership to additional countries that also need help to work towards universal health coverage."*
>
> Dr Matshidiso Moeti
> WHO Regional Director for Africa

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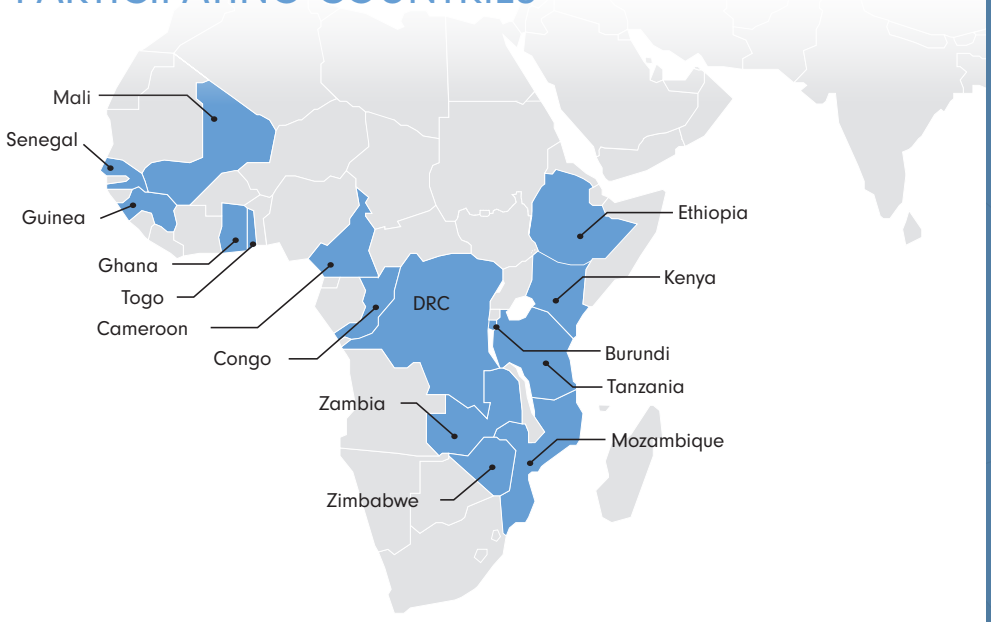
EU/ACP/WHO RENEWED PARTNERSHIP PARTICIPATING COUNTRIES



The EU/ACP/WHO Renewed Partnership to strengthen pharmaceutical systems and improve access to quality medicines began in 2012, and focuses on the implementation of policies, enforcement of regulations, adoption of best practices and on the promotion of policy dialogue and strengthening of pharmaceutical sector capacity. It aims to contribute to the achievement of health-related Millennium Development Goals and universal health coverage by improving the availability, affordability and use of safe, effective and quality assured essential medicines for priority communicable and non-communicable diseases.

Ministries of Health lead the implementation in countries. WHO is responsible for coordinating overall planning, implementation and monitoring. The programme is primarily funded by the European Commission.

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