



THE ACCESS AND
DELIVERY PARTNERSHIP

New Health Technologies for TB, Malaria and NTDs

STATUS REPORT 2021



World Health
Organization



For research on
diseases of poverty
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the People of Japan

The ADP partners



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From
the People of Japan

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

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LOOKING AHEAD

ACRONYMS AND ABBREVIATIONS

ADP	Access and Delivery Partnership
ADR	adverse drug reaction
aDSM	active drug safety monitoring and management
AEFI	adverse events following immunization
AMDF	Africa Medical Devices Forum
AMRH	African Medicines Regulatory Harmonization
AU	African Union
AU Model Law	AU Model Law on Medical Products Regulation
AUDA-NEPAD	African Union Development Agency
CARN-TB	Central African Regional Network for TB Control
CEMAC	Central African Economic and Monetary Community
COVID-19	coronavirus disease
ECOWAS	Economic Community of West African States
EUL	WHO Emergency Use Listing
eVIN	Electronic Vaccine Intelligence Network
FDA	Food and Drugs Authority
GBT	WHO Global Benchmarking Tool
GHIT	Global Health Innovative Technology
HITAP	Health Intervention Technology Assessment Programme
HTA	health technology assessment
IDP	institutional development plan
IR	implementation research
IVDs	in vitro diagnostics
LMICs	low- and middle-income countries

MDA	mass drug administration
MDR-TB	multi-drug resistant tuberculosis
NHIF	National Health Insurance Fund
NRA	National Regulatory Authority
NTDs	neglected tropical diseases
PV	pharmacovigilance
RTS,S/AS01	RTS,S
SDG	Sustainable Development Goal
SMILE	<i>Sistem Monitoring imunisasi Logistik secara Elektronik</i> (Indonesia)
SOPs	standard operating procedures
SRA	stringent regulatory authorities
TB	tuberculosis
TDR	Special Programme for Research and Training on Tropical Diseases
UHC	universal health coverage
UNDP	United Nations Development Programme
Uniting Efforts	Uniting Efforts for Innovation, Access and Delivery
USSD	unstructured supplementary service data
WARN-TB	West African Regional Network for TB Control
WHO	World Health Organization



FOREWORD

The ongoing coronavirus disease (COVID-19) pandemic is fueling a global health and development crisis of immense proportions. The combined health, social and economic consequences have reversed hard-won gains towards the Sustainable Development Goals. The commitment to “leave no one behind” is being tested by complex layers of inequalities, thrown into sharp relief by the pandemic.

The measures we take now to address the threat of COVID-19 – from tackling the current inequities in global vaccine access, to the existing fragility of national health systems, and the need to protect the vulnerable and marginalized groups within society – will have significant implications for the outlook for sustainable human development.

The *ADP Status Report 2021* outlines how the Access and Delivery Partnership (ADP) has adapted its work in response to the pandemic. Since its inception, ADP has supported governments and stakeholders to strengthen national health systems. The ADP partner organizations work to strengthen institutional and human capacities within the ‘value chain’ of access and delivery – from policy, legal and regulatory frameworks, to research and regulatory capacities, to systems for procurement and supply chain management – to enable people’s access to health technologies.

Such a whole-of-government approach is now also recognized as essential to coordinated and effective COVID-19 responses. During the pandemic, ADP has sought to provide relevant and timely technical advice and information to bolster national COVID-19 responses. At the same time, ADP partners continue to maintain focus on existing health priorities, including tuberculosis, malaria and neglected tropical diseases. These endemic diseases impose health, social and economic burdens within poor and vulnerable populations, and previous gains must be safeguarded.

As you will see from this report, strengthening institutional and technical capacities within national health systems and supporting national responses to the COVID-19 pandemic are two sides of the same coin, each driving access to and delivery of affordable and quality-assured medicines, vaccines and diagnostics towards the achievement of universal health coverage. These investments in strengthening health systems will also have longer-term socio-economic benefits, as well as laying the foundation for greater pandemic preparedness and human security in the future.

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INTRODUCTION

The COVID-19 pandemic is an ongoing global health and development crisis that is reversing decades of progress on poverty, health and education, setting back important gains towards the Sustainable Development Goals (SDGs).

In what is widely regarded as the fastest breakthrough in the development of health technologies, there are now multiple safe and effective COVID-19 vaccines in use. But their availability signals just the start of the long journey towards ending the COVID-19 pandemic. Ensuring sufficient supplies of vaccines – and their equitable access around the world – are proving to be persistent global challenges. As of June 2021, three billion doses of COVID-19 vaccines have been administered but less than 1 percent of people in low-income countries have received a dose. As the vaccines become increasingly available in all countries, it is vital that national vaccination programmes are prepared and able to deliver vaccines to their populations as swiftly and as equitably as possible.

In many low- and middle-income countries (LMICs), however, pre-existing health system fragility and capacity gaps are significant bottlenecks to efficient vaccine delivery. Where they are weak, systems for vaccine distribution, tracking, delivery and administration must be strengthened; where they are lacking, they must be urgently developed.







**New medicines,
vaccines, diagnostics**

Even while tackling COVID-19, it remains vitally important to ensure that other national health priorities – such as those related to combating tuberculosis (TB), malaria and neglected tropical diseases (NTDs) – are also not at risk of neglect. These endemic diseases persist in many LMICs and already impose devastating human, social and economic burdens, predominantly among the most vulnerable populations. It is crucial to adopt measures to both protect previous gains against these diseases and mitigate against any future reversals in progress towards related targets.

The partners of the Access and Delivery Partnership (ADP) are focused on addressing the most pressing and immediate health needs. Maintaining the most critical prevention activities and health care services, and minimizing disruptions during the pandemic, will also significantly reduce the indirect impacts of COVID-19, particularly among poor and marginalized populations. ADP partners have thus adopted a two-pronged strategy: supporting national responses to the COVID-19 pandemic and continuing to bolster national health system capacities – each through the provision of essential technical advice and information.

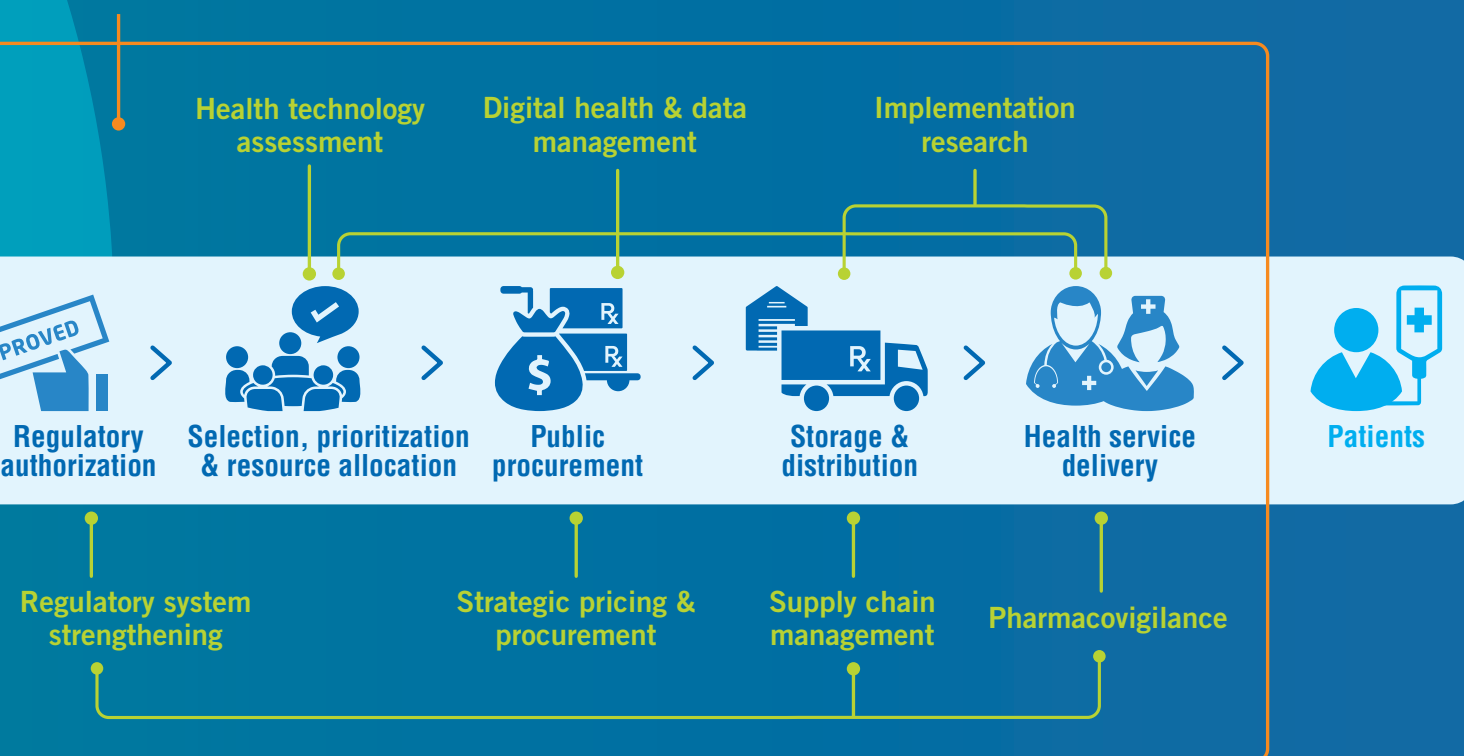
Strengthened institutional and technical capacities help to drive access to and delivery of affordable and quality-assured medicines, vaccines and diagnostic tools. This approach is in line with the overarching ADP goals and underscores the relevance of the specific focus of ADP on strengthening national health systems and their preparedness for health technology introduction. It is also aligned with the 2030 Agenda for Sustainable Development, which calls for efforts to achieve the interlinked targets of eliminating communicable and infectious diseases and achieving real progress towards universal health coverage (UHC). The ADP strategic focus is also consistent with Basic Design for Peace and Health (Global Health Cooperation) of the Government of Japan, which recognizes the need for resilient health systems aimed at forestalling infectious disease outbreaks and other public health emergencies.

Since its inception in 2013, ADP has supported governments and national stakeholders to strengthen health systems. This encompasses the value chain of access and delivery – from enabling policy and legal frameworks, implementation research (IR), regulatory approval, procurement and supply chain management, ultimately extending to service delivery and patient safety monitoring. Such a whole-of-government approach is also an essential element of coordinated and effective COVID-19 responses and helps build the foundation for greater pandemic preparedness in the future.



Enabling policy and regulatory framework

ADP: Strengthening capacities of multiple institutions and mechanisms to deliver health technologies to patients in need



Travel and movement restrictions were used to control the spread of COVID-19 in 2020 and continued to be in place in many countries for the first half of 2021. Consequently, organizing in-person ADP meetings or training sessions during the reporting period was difficult. ADP partners continued to use online tools for active engagement with stakeholders in focus countries and conducted virtual meetings and trainings. ADP partners have leveraged their networks of in-country partners and technical experts to ensure ongoing and effective participation in, and commitment to, ADP project activities. ADP partners have also reached stakeholders beyond those in the ADP focus countries using various virtual and regional approaches.

An online ADP community of practice was established. Members of the “ADP Community” include government policymakers and technical experts from ADP focus countries and beyond, ADP partners, and other ADP technical collaborators. This virtual platform is enabling dialogue, rapid flows of information and exchange of country experiences. It will continue to be an avenue for ADP partners to have active engagement with, and provide consistent training and support to, country stakeholders. ADP partners have continued to expand efforts to adjust and adapt to the new situations necessitated by the pandemic and are committed to ensuring delivery of technical support to help focus countries meet priority health needs during the pandemic.

The *Status Report 2021* highlights the work of ADP in its third year of scale-up (April 2020 – March 2021).





IMPACT AT THE COUNTRY, REGIONAL AND GLOBAL LEVELS: A SNAPSHOT OF ADP RESULTS (APRIL 2020-MARCH 2021)





COVID-19: ADP support to the pandemic response

- Delivered *WHO Regulatory Updates on COVID-19*, providing key updates on status of clinical trials and emergency use authorizations of COVID-19 vaccines and diagnostics by stringent regulatory authorities (SRA) and the World Health Organization (WHO) Emergency Use Listing Procedure (EUL).
- Supported the Africa Medical Devices Forum (AMDF) in guiding African Union (AU) Member States on: i) accelerated approval of COVID-19 in vitro diagnostics and medical devices that have received WHO/EUL approval; and (ii) assessment of COVID-19 assays and related market surveillance.
- Conducted a regional risk-based survey to identify prevalence of sub-standard and falsified medicines (e.g. antimalarials, antibiotics and antiviral treatments for COVID-19) to inform regulatory action in the 15 countries of the Economic Community of West African States (ECOWAS).
- Strengthened capacities of health workers and pharmacovigilance (PV) focal points in Ghana, Malawi and Senegal to perform active surveillance and reporting of adverse events for COVID-19 treatments and vaccines.
- Strengthened IR capacity among local researchers and programme implementers in Benin, Burkina Faso and Senegal to identify and address COVID-19 challenges to national TB programmes, and to inform policy measures for sustaining crucial TB services.
- Delivered a three-part webinar series: Using evidence to address health care challenges in LMICs, on application of health technology assessment (HTA) priority-setting principles to optimize national immunization and health service delivery efforts in the context of COVID-19, which brought together participants from 25 countries.
- Revised standard operating procedures (SOPs) for the mass drug administration (MDA) programme for NTDs in Senegal to incorporate measures to address new implementation challenges resulting from the COVID-19 pandemic.
- Documented good practices from India and Indonesia on the use of digital systems to support distribution of COVID-19 vaccines, for transfer of technical knowledge to other LMICs in the process of scaling up their COVID-19 vaccination programmes (including Afghanistan, Bangladesh, Bhutan and Nepal).
- Promoted use of low-cost and easily accessible digital solutions such as the Med Safety mobile application and the unstructured supplementary service data (USSD) mobile platform to strengthen PV systems for COVID-19 vaccines in Ghana and Malawi, respectively.



GHANA

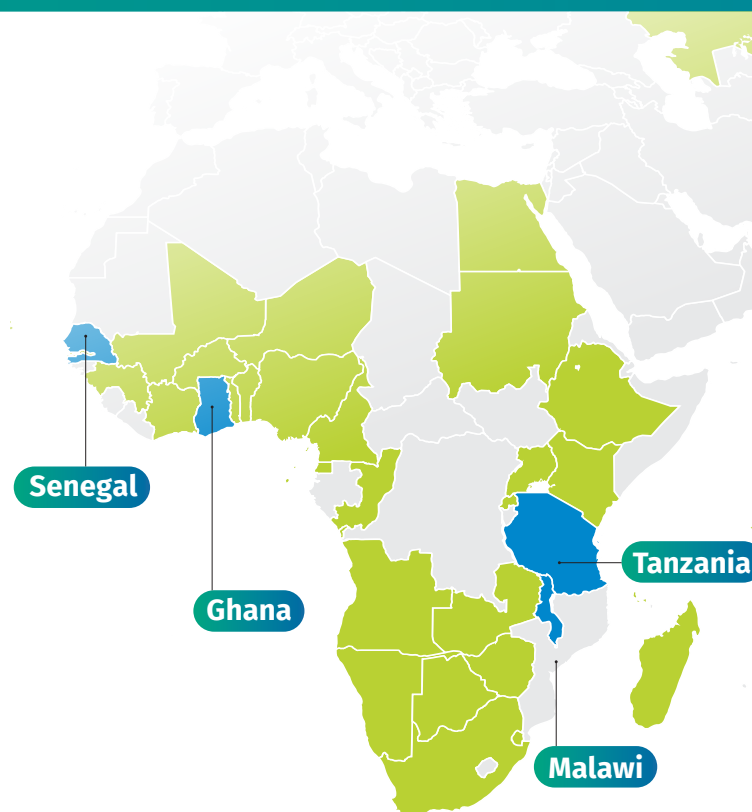
- Established a virtual platform for the SAVING consortium to enable members to engage remotely for integrated planning, coordination and capacity building on the introduction of the RTS,S malaria vaccine.
- Strengthened technical capacities of health workers from 30 lower-level health facilities across six regions to monitor, manage and report adverse drug reactions (ADR) and adverse events following immunization (AEFI).
- Supported the Ghana Food and Drug Authority to conduct a legal and policy review for the domestication of the *AU Model Law on Medical Products Regulation* (AU Model Law).
- Strengthened the capacity of health workers in NTDs in three regions to conduct IR on the influence of gender on equitable access to health services.
- Strengthened the institutionalization of HTAs through development of national HTA guidelines and by providing technical guidance on HTA legislation.
- Supported the National Medicine Price Committee to develop national guidelines and strengthen technical capacities for medicines price regulation and the creation of a medicines price observatory to monitor medicines prices across public and private sector supply chains.

INDONESIA

- Supported the National Quality Control Laboratory of Drug and Food in training the staff of regional laboratories and pharmaceutical industry actors on policy and practice in medicine safety and quality.
- Supported the development of a *National action plan on the implementation of active TB drug safety monitoring and management (aDSM)* to improve safety monitoring of drug-resistant TB treatment.
- Convened training workshops on pharmaceutical pricing strategies and policy to build technical capacity and strengthen decision-making on pharmaceutical price regulation.
- Supported the national public procurement agency on introduction of the multiple criteria decision analysis mechanism to facilitate decision-making on best value selection of health products and vendors for the national e-catalogue.

MALAWI

- Strengthened capacity of the National Quality Control Laboratory to monitor medicines quality using the *WHO International Chemical Reference Substances* database and the submission of test samples to the *WHO International Pharmacopoeia*.
- Supported self-benchmarking of the National Regulatory Authority (NRA) and development of an *Institutional Development Plan* (IDP) as a preparatory step towards formal assessment with the WHO Global Benchmarking Tool (GBT).
- Strengthened national capacities to monitor and manage ADR/AEFI through an integrated PV system in five tertiary hospitals and 29 district hospitals.
- Supported the roll-out of a USSD mobile platform: a free, user-friendly digital system to simplify ADR and AEFI reporting for health professionals and consumers.
- Supported an awareness-raising campaign on the importance of reporting ADRs and AEFIs and to raise public awareness of the various reporting channels available.



INDIA

- Facilitated South–South technology transfer from India to ADP focus countries and other LMICs on implementation of the electronic Vaccine Intelligence Network (eVIN), including lessons from ongoing efforts to digitize inventory management of the COVID-19 vaccines and beneficiary tracking.

SENEGAL

- Supported NRA self-benchmarking and development of an IDP, and support to strengthen capacities for regulatory inspection of the pharmaceutical supply chain.
- Established a multisector coordinating platform to plan and implement studies on the impact of the COVID-19 pandemic on national malaria, TB and NTDs control programmes and to inform the development of risk mitigation plans and policy measures.
- Supported evaluation of the national PV system, including development and implementation of a work plan to enable consolidation of the national PV system across disease control programmes.
- Provided PV training to health workers across 22 COVID-19 treatment centres in five regions, enabling collection of active surveillance data from over 5,600 patients to analyse frequency of ADR among COVID-19 patients.
- Adapted best practices into national guidelines, SOPs and a training manual for supply chain management of NTDs medicines in MDA campaigns.

UNITED REPUBLIC OF TANZANIA

- Continued support for the delivery and uptake of paediatric praziquantel formulation for Schistosomiasis (STEPPS) initiative, the multi-stakeholder platform aimed at facilitating integrated planning for the roll-out, in anticipation of regulatory approval.
- Conducted analysis of public sector medicine prices to identify key cost drivers of the National Health Insurance Fund (NHIF), to inform prioritization of the NHIF reimbursement list and enhance the rational use of medicines in the public sector.

The designations employed and the presentation of material on this map do not imply the expression of any opinion whatsoever on the part of the Secretariat of the United Nations or UNDP concerning the legal status of any country, territory, city or area or its authorities, or concerning the delimitation of its frontiers or boundaries.



● ADP focus countries

● Countries that have participated in regional/global activities

- Continued support for regulatory system strengthening to maintain current Maturity Level 3 rating, including technical assistance to review WHO prequalification requirements and good distribution practices for quality assurance of health technologies.
- Contributed to institutionalization of the HTA through support on development of national HTA committee guidelines and advocacy efforts to build commitment of policymakers for wider adoption of the HTA approach.

THAILAND

- Facilitated South–South cooperation through leveraging institutional expertise and experience in Thailand, through partnership with the Health Intervention Technology Assessment Program (HITAP) to provide technical assistance to LMICs on HTA approaches.
- Strengthened capacity of NRA to conduct risk-based regulatory inspection and quality control testing to maintain pharmaceutical quality and integrity standards throughout the supply chain.
- Continued support for implementation of the IDP for the NRA, which has facilitated implementation of 70 percent of formal benchmarking recommendations.

REGIONAL AND SOUTH–SOUTH

- Promoted the use of the *Guidance Document for Domestication of the African Union Model Law on Medical Products Regulation*, jointly developed by the African Union Development Agency (AUDA-NEPAD) and ADP, to inform AU Member States of good practice approaches in domestication of the AU Model Law.
- Supported self-benchmarking of NRAs in six Member States of the Central African Economic and Monetary Community (CEMAC), with the aim of conducting formal GBT assessments in 2021 and 2022.
- Promoted regulatory harmonization for medical devices through support for the AMDF on training national regulators from 25 countries in the Africa region and the development of four guidance documents relating to the manufacturing, regulatory requirements and registration of medical devices and in vitro diagnostics (IVDs).
- Conducted a gender analysis of the WHO *Model List of Essential In Vitro Diagnostics* to provide an evaluation framework on the gender dimensions of access to diagnostic products and *List of Essential In Vitro Diagnostics* to promote equitable access.

- Conducted a comprehensive mapping of capacities and expertise within NRAs and national reference laboratories in 54 countries in the Africa region to identify regulatory gaps and promote collaboration.
- Updated the IR Toolkit with a module on gender and intersectional analysis, to enable a more inclusive and effective response to infectious diseases of poverty.
- Conducted training-of-trainers on the IR Toolkit for French-speaking facilitators, followed by a training of francophone country stakeholders from seven countries in West and Central Africa.
- Facilitated South–South exchanges between national TB programmes and PV units from 27 countries in West and Central Africa on aDSM best practices and systematic use of IR for safe and efficient introduction of new TB treatment strategies.
- Published a guide to support value-based public-sector procurement of medical equipment in LMICs, which will inform the development of a training curriculum for national procurement agencies in Peru and Senegal.
- Convened the ADP South–South Exchange and Learning Platform through a series of four virtual consultations, bringing together government stakeholders and experts from over 20 countries, to promote collaboration and knowledge-sharing and ensure health system preparedness for the introduction of new health technologies.

GLOBAL

- Continued collaboration with the Government of Japan and the Global Health Innovative Technology (GHIT) Fund on the Uniting Efforts for Innovation, Access and Delivery initiative, and published two knowledge products: *Landscape of funding and financing opportunities for access and delivery of health technologies for neglected diseases* and *Guidance note for the development of national investment cases for neglected diseases*, which were launched during interactive webinars.
- Initiated collaboration with the WHO NTDs Department to develop common guidance and tools for NTDs national investment cases to improve financing for health technologies for neglected diseases as a contribution towards the country-led implementation of the new WHO Road Map for NTDs (2021–2030).
- Launched the ADP Community online platform dedicated to strengthening collaboration and learning among stakeholders from ADP focus countries, which has facilitated information flows for timely evidence-based policy and programme planning for COVID-19 and other priority diseases.



SUPPORTING NATIONAL RESPONSES TO THE COVID-19 PANDEMIC

Given the urgent and immediate needs, ADP partners have focused attention on helping LMICs strengthen their national COVID-19 responses. This section reports on the key areas of ADP support in addressing COVID-19-related challenges.



Regulation and safety monitoring of COVID-19 technologies

Through the work of its partner, WHO, ADP helped to ensure that NRAs in LMICs received updated information on the status of clinical trials and authorizations for COVID-19 vaccines. Through regular dissemination of the *WHO Regulatory Update on COVID-19* series,¹ which provides updates on emergency use authorizations of vaccines and diagnostics by SRAs and EULs by WHO, countries have been able to expedite regulatory approval of some COVID-19 vaccines. From these efforts, more than 100 countries approved the AstraZeneca COVID-19 vaccines produced by SK Bio, Republic of Korea, and the Serum Institute of India, within 15 days of EUL by WHO. Ghana,

an ADP focus country, was the first to approve and receive COVID-19 vaccines through the COVID-19 Vaccines Global Access (COVAX) facility.

Support was also provided to the AMDF to develop and share monthly updates to the list of COVID-19 IVDs and medical devices that have received WHO EUL or been authorized by SRAs. The AMDF provided important guidance to AU Member States on the accelerated approval of priority medical products in the context of the COVID-19 response.

Through WHO, ADP also contributed to strengthening capacities and processes to monitor the quality of medicines. A regional risk-based survey was conducted to assess the quality of selected medicines (antimalarials, antibiotics and antiviral COVID-19 treatments) in the 15 countries of the ECOWAS region, including in ADP focus countries Ghana and Senegal, and in Burkina Faso (which will be included as a focus country in the next reporting period).

The study identified the prevalence of sub-standard and falsified medicines across the region, and informed key actions by national regulators to address this problem. The results of the survey will be made available during 2021. In Malawi, ADP supported the National Quality Control Laboratory in conducting market surveillance of a range of medicines – including those for COVID-19 – by helping to procure the International Chemical Reference Substances and the submission of test samples to the WHO *International Pharmacopoeia*.

With the roll-out of COVID-19 vaccines gathering pace in some LMICs, ADP has focused on promoting the active surveillance of adverse events for COVID-19 treatments and vaccines in Ghana, Malawi and Senegal. Through the Special Programme for Research and Training in Tropical Diseases (TDR), ADP supported the strengthening of reporting systems and data management, as well as improved technical capacity and best practices for PV in these countries. In Ghana, 182 health workers from 30 health centres and clinics across six regions were

¹ <https://www.who.int/teams/regulation-prequalification/covid-19> (accessed on 14 September 2021).

designated and trained on vaccine safety monitoring and the use of the Med Safety app to report AEFIs after COVID-19 vaccination. In Malawi, health workers from 26 districts, including PV focal points from the Expanded Programme on Immunisation were also trained on AEFI monitoring. In Senegal, ADP collaborated with the National Pharmacovigilance Centre to implement active surveillance of adverse events in the treatment of COVID-19 in an innovative approach based on a supervisory training programme over a six-month period. Health workers across 22 COVID-19 treatment centres in five regions were provided with formative supervision on PV. Active surveillance data from over 5,600 patients treated for COVID-19 was collected and analysed, providing information on the frequency of ADRs among patients treated for COVID-19.

Digital solutions to address COVID-19-related challenges

Especially important during the current pandemic situation, ADP has supported LMICs to identify and adopt innovative solutions to support the digital transformation of health systems to ensure greater efficiency, resilience and sustainability.

In Indonesia, ADP had previously partnered with UNDP Indonesia to support the Ministry of Health and the national immunization programme to pilot a cloud-based digital system for optimizing vaccine supply and delivery, based on the eVIN platform. The success of the pilot led to the adoption of the *Sistem Monitoring Imunisasi Logistik secara Elektronik* (SMILE) system in Indonesia, which has now been scaled up to 10,000 health facilities across the country. During the pandemic, the SMILE system was adapted to support the national distribution of COVID-19 vaccines. It is now widely promoted by the Government of Indonesia as a core digital tool in its COVID-19 vaccination strategy.² In India, the Ministry of Health and Family Welfare also initiated the repurposing and adaptation of eVIN for inventory management of COVID-19 vaccines to ensure delivery to over 300 million individuals.³ ADP, in close collaboration with UNDP Indonesia and UNDP India, has supported the documentation of these digital good practices, strategies and lessons learned from the Indonesia and India experiences. This has helped to facilitate the transfer of knowledge and technical know-how to other LMICs, including Afghanistan, Bangladesh, Bhutan and Nepal, which are now in the process of scaling up their COVID-19 vaccination programmes.

The COVID-19 pandemic has put health systems under significant strain; this has highlighted the importance of innovative models of health care that can help ensure that health services reach those who face geographical, physical or cultural barriers. ADP is consulting government stakeholders to understand the demand for, as well as related challenges to, the scale up of telehealth systems to promote equitable access to quality, cost-effective and essential health services. Technical consultations have been conducted with stakeholders in several countries to gather information on country experiences and good practices to inform the design of the interventions that will support a range of stakeholders in LMICs – within the government, public and private health providers – to implement and scale up these services. ADP is organizing a series of global consultations and webinars in 2021 to understand specific country needs and support development of national policy, regulatory and governance frameworks, and to strengthen health workforce capacity and digital data management.

As part of the efforts to strengthen PV systems for COVID-19 vaccines in Ghana and Malawi, ADP supported the enhanced use of digital mobile applications for monitoring and reporting of AEFI. The Med Safety mobile application in Ghana facilitates the instant reporting of adverse events by patients, caregivers and health care professionals, and dissemination of important health messaging and news alerts. In Malawi, ADP supported the use of the USSD, which is a low-cost and easily accessible tool for the public to report adverse events to the national PV centre.

During the COVID-19 pandemic, ADP support to countries is as critical as ever in building essential capacities and systems. ADP has turned to the use of digital tools to enhance the remote delivery of technical and capacity-building support to country stakeholders. Driven by the strategic focus on South–South learning and exchange, ADP launched an online community platform⁴ that is dedicated to strengthening the coordination, collaboration and learning among stakeholders from ADP focus countries. The ADP Community platform builds on ADP partners' extensive network of stakeholders and key experts, including policymakers, programme managers and civil society – with the aim of enhancing sharing of knowledge, good practices, principles and policies. This has enabled the rapid flow of information and exchange of experiences and use of practical solutions among countries for timely evidence-based policy and programme planning related to COVID-19, as well as other priority disease areas. In the long term, these outcomes will contribute to expanding ADP impact and thought leadership among a growing community of stakeholders.

² See, for example, UNDP, 'Indonesian President highlights the importance of vaccine temperatures ahead of COVID-19 immunization drive', 19 November 2020, <https://www.id.undp.org/content/indonesia/en/home/presscenter/pressreleases/2020/Indonesian-President-highlights-the-importance-of-vaccine.html>, accessed 18 August 2021; A Joint Ministerial Decree (HK.03.01/MENKES/53/2021) on the "Implementation of One Data information system for corona virus diseases 2019 (COVID-19) vaccination" (HK.03.01/MENKES/53/2021) by the Minister of Health and the Minister of Information and Communication.

³ The Times of India, 'eVIN system being repurposed for tracking Covid-19 vaccine delivery: Harsh Vardhan', 20 November 2020, <https://timesofindia.indiatimes.com/india/evin-system-being-repurposed-for-tracking-covid-19-vaccine-delivery-harsh-varadhan/articleshow/79326284.cms>; Al Jazeera, 'India says it may approve COVID-19 vaccine in weeks', 9 December 2020, <https://www.aljazeera.com/news/2020/12/9/india-says-it-may-approve-covid-19-vaccine-in-weeks>, accessed 18 August 2021.

⁴ <https://community.adphealth.org/>

Evidence-based prioritization and resource allocation

Containing health expenditure is particularly pertinent in the context of the COVID-19 pandemic, as financial and human resources within the health system become overstretched along with needs for new treatments, vaccines and medical equipment. ADP convened a series of webinars, in partnership with HITAP, on the application of HTA priority-setting principles for optimizing national immunization and health service delivery efforts in the context of the pandemic. The three-part webinar series, *Knowledge exchange in the time of COVID-19: Using evidence to address health care challenges in low- and middle-income countries*,⁵ explored how evidence can be used to inform specific stages of a typical intervention life cycle – from the identification of priority interventions to procurement and price negotiation, and monitoring of health service delivery. The series brought together participants from 25 countries and was successful in paving the way for continued collaborations and capacity-building on HTA. As a follow-up, consultations are being conducted with ADP focus countries to design and tailor technical support for the institutionalization of HTA and priority-setting strategies as key tools for informed health decision-making.



Mitigating impact of COVID-19 on disease control programmes

The COVID-19 pandemic has had a significant impact on the delivery of essential health services, resulting in significant reductions in screening, testing and diagnosis, as well as onward referral to treatment, for TB, malaria and NTDs.⁶ Those with dual infections of TB and COVID-19 have poorer treatment outcomes, and even a short disruption to TB treatment may cause an increase in the prevalence of drug resistance. A growing body of evidence highlights the urgent need for disease control programmes to adapt to the disruptions caused by the pandemic. ADP is supporting countries to identify the challenges and solutions for COVID-19-related disruptions of critical health services for disease control.⁷ ADP collaborated with the Western and Central African Regional Networks for TB Control (WARN-TB and CARN-TB, respectively) to provide support to local researchers and programme implementers in Benin, Burkina Faso and Senegal towards the design, planning and conduct of 11 IR projects. These projects quantified the impact of the pandemic on human resources, the availability of medicines and diagnostics, and patient care of major disease control programmes; evaluated the effectiveness of a range of innovative interventions, including community-based modalities and new screening algorithms; and explored the use of digital solutions such as telehealth and remote supervision tools for remote monitoring of patient health status, promoting treatment adherence and ensuring the continuum of care. The findings of these studies, expected to be available in late 2021, will inform policy measures for sustaining crucial TB services during the COVID-19 pandemic and contribute to efforts to promote the resilience and pandemic-preparedness of health systems in these countries.

In Senegal, ADP supported the review and revision of the SOPs for the NTDs MDA programme, to incorporate measures to address new implementation challenges resulting from the COVID-19 pandemic. The SOPs provide detailed guidance for programme managers and frontline health workers on the additional measures relating to issues such as the use of personal protective equipment, organization of campaign activities and handling of medical products, which are required to ensure safe implementation of routine MDA campaigns.

⁵ <https://adphealth.org/hitap-webinar/>

⁶ https://www.theglobalfund.org/media/10776/covid-19_2020-disruption-impact_report_en.pdf

⁷ <https://tdr.who.int/newsroom/news/item/24-03-2021-research-to-ensure-continuity-of-tb-care-amid-COVID-19>



STRENGTHENING NATIONAL HEALTH SYSTEMS: WORKING ACROSS THE VALUE CHAIN

ADP capacity support has focused on two broad themes: (1) developing coherent policy and legal frameworks for innovation, access and delivery; and (2) strengthening technical capacities of, as well as enhancing the interactions between, the range of institutions involved in supporting access and delivery of health technologies. Availability of a new medicine, diagnostic tool or vaccine represents the first step; successful introduction and delivery requires that multiple relevant institutions coordinate their functions across the health system, within an enabling policy and legal framework. ADP has leveraged relevant technical expertise within each of its partner organizations to deliver capacity support for effective functioning across the value chain of introduction, access and delivery of new health technologies.

Policy coherence and integrated planning

The ADP implementation experience has shown that having a consistent multisectoral forum across government agencies – from health and regulatory authorities, to finance, investment and industry, as well as science and technology agencies – can enable institutions to work together to identify effective responses to shared gaps in policy and capacity. ADP has supported the establishment or strengthening of such multisectoral forums in its focus countries.

In Ghana, ADP continues to support the multisectoral working group for the introduction of the RTS,S malaria vaccine, which has the potential of averting at least 50,000 malaria cases in its initial roll-out phase.⁸ ADP had previously supported the working group in its successful mobilization of a EUR2.1 million grant from the European and Developing Countries Clinical Trials Partnership to implement the project: Building capacity to address implementation challenges for sustainable access and delivery of new vaccines in Ghana (SAVING). The SAVING consortium is using the IR approach to enable effective introduction of the new RTS,S malaria vaccine across the country. ADP has further supported the establishment of a digital communication platform for the consortium.

Building on the experience in Ghana, ADP is also supporting the National Institute for Medical Research in the United Republic of Tanzania in convening a multi-stakeholder platform to facilitate health system preparedness for the introduction of a paediatric formulation of praziquantel once it is available and approved for use. Children under five years of age – who make up a significant proportion of the estimated 15 million Tanzanians at risk of schistosomiasis – are not currently covered by MDA campaigns due to the lack of an appropriate formulation for their age group. The Delivery and uptake of pediatric praziquantel formulation for schistosomiasis (STEPPS) initiative brings together stakeholders across disciplines and national agencies to develop plans and strategies collectively in anticipation of availability of the pediatric formulation.

The SAVING and STEPPS initiatives exemplify the multidisciplinary and systemic approach to identifying implementation challenges and prioritizing research questions that are key to improving access and delivery of new medical interventions. They can provide useful models for the introduction and roll-out of other medicines, vaccines and diagnostics. In the context of COVID-19 vaccines, these platforms provide a foundation for the multi-sectoral coordination needed for effective vaccine roll-out.

⁸ World Health Organization, 'Ghana announces the roll out of malaria vaccine implementation programme (MVIP)', 11 April 2019, <https://www.afro.who.int/news/ghana-announces-roll-out-malaria-vaccine-implementation-programme-mvip>, accessed 18 August 2021.

Strengthening institutional and technical capacities for access and delivery

Regulatory system strengthening

An important component of ADP capacity support is regulatory system strengthening and harmonization, which are critical for ensuring the safety, efficacy and timely market entry of new health technologies. With a range of complementary expertise among its partners, ADP is well placed to provide such integrated support: UNDP supports countries to strengthen their policy and regulatory frameworks, WHO conducts benchmarking of NRAs to identify gaps and strengthen capacities and processes, and TDR provides technical support to NRAs on strengthening PV systems and safety monitoring capacities.

Benchmarking of national regulatory authorities

Through WHO, ADP has supported NRAs in focus countries to assess their regulatory functions using the WHO GBT. Subsequently, WHO assists in developing IDPs designed to address technical and capacity support needs so that NRAs can meet benchmarked international standards. During the reporting period, ADP supported the self-benchmarking and development of IDPs for NRAs in ADP focus countries Malawi and Senegal, as well as Burkina Faso (a potential new ADP focus country). This exercise is the preparatory step towards formal benchmarking of the NRAs, which are scheduled in the next 12 to 18 months. As part of its regional approach, ADP also supported the self-benchmarking of NRAs in the six Member States of CEMAC (Cameroon, Central African Republic, Chad, Congo, Equatorial Guinea and Gabon) and Djibouti with the aim of conducting formal GBT assessments during 2021 and 2022.

ADP continues to provide capacity support for IDP implementation in other ADP focus countries – Ghana, Indonesia, Thailand and the United Republic of Tanzania – which have completed their formal benchmarking exercise. ADP efforts have contributed towards stable, well-functioning and integrated regulatory systems in these countries. In May 2020, WHO announced that the Ghana Food and Drugs Authority (FDA) had attained Maturity Level 3, the second highest in the four-tiered WHO classification of national medicines regulatory systems.⁹ The Tanzania Medicines and Medical Devices Authority is the only other agency in the Africa region to have attained this classification (in 2018). In Thailand, over 70 percent of the recommendations from the formal benchmarking have been implemented. A final review is planned for the last quarter of 2021, with the possibility of a classification upgrade to Maturity Level 3 for the Thailand FDA.

Mapping of regulatory and laboratory capacities for medical devices (including in vitro diagnostics)

A comprehensive mapping of capacities and expertise within NRAs and national reference laboratories was conducted for all 54 countries in the Africa region, with the aim of promoting collaboration and leveraging existing expertise. Considerable gaps relating to regulatory controls for medical devices, including IVDs, with only eight countries found to have minimum-level controls and enforcement recommended by the WHO *Global model regulatory framework for medical devices*. These findings have increased awareness of the need to establish a regulatory framework for medical devices, including IVDs, to prioritize assessment of the regulatory authorities in this area and to establish clear roles and responsibilities among relevant institutions.

Medicine quality assurance across the supply chain

Ensuring that the quality and integrity of medicines is maintained throughout the supply chain is a key function of NRAs; hence, ADP support is aimed at consolidating and integrating international standards and best practices on distribution into national guidelines and operations. During the reporting period, ADP continued to provide technical support to regulatory inspectors from the Africa (Burkina Faso, Ghana, Malawi, Senegal and the United Republic of Tanzania) and the Asia and Pacific (Bangladesh, Bhutan, India, Indonesia, Kazakhstan, Maldives, Myanmar, Nepal, Sri Lanka, Thailand and Timor-Leste) regions. This support follows from earlier regional workshops on good distribution practices, which provided training on the conduct of regulatory inspections and quality risk management principles, and implementation of the minimum standards required to ensure the quality and integrity of the pharmaceutical supply chain.

ADP also supported a regional risk-based survey to assess the quality of selected medicines (antimalarials, antibiotics and antiviral COVID-19 treatments) in 15 countries within the ECOWAS region, including ADP focus countries Burkina Faso, Ghana and Senegal. The study identified the prevalence of sub-standard and falsified medicines across the region, and informed key actions by national regulators to address this problem. The results of the survey will be made available in late 2021.

In Malawi, ADP strengthened the capacity of the national quality control laboratory to monitor quality of medicines by enabling access to and use of the WHO International Chemical Reference Substances (ICRS) database. The ICRS are used as primary standards for physical and chemical tests and assays and will be used by the quality control laboratory in ongoing activities for market surveillance

⁹ See World Health Organization, 'Ghana Foods and Drugs Authority (FDA) attains maturity level 3 regulatory status', 18 May 2020, <https://www.afro.who.int/news/ghana-foods-and-drugs-authority-fda-attains-maturity-level-3-regulatory-status>, accessed 18 August 2021.



of medicines used for TB, malaria, HIV and NTDs, as well as COVID-19-related treatment and antibiotics. In Indonesia, ADP supported the National Quality Control Laboratory of Drugs and Food, which is responsible for developing analytical methods for routine laboratory testing of pharmaceutical products and food, to train local experts from regional laboratories and pharmaceutical industry on policy and practice in controlling safety and quality, and on the validation of methods for pharmaceutical analysis.

Safety monitoring of new health technologies

The introduction and use of new health technologies invariably encounters previously unanticipated events and/or adverse reactions – underscoring the importance of a functional system that can detect, assess and manage (or prevent) adverse effects. ADP, through TDR, has supported national regulatory authorities, disease control programmes and health providers to strengthen technical capacity and implement best practices for PV, with a focus on the rollout of COVID-19 vaccines.

In Ghana, ADP continues to support the digitization of the safety surveillance system, through the introduction of the Safety Watch System, a national electronic management system for individual case safety reports, and the Med Safety app that facilitates fast and direct community reporting of ADRs and AEFIs. Both systems have increased reporting by over 30 percent between 2016 and 2019. During this reporting period, ADP supported the Ghana FDA in the decentralization of PV activities, by strengthening technical capacities of health providers at the primary health care level (i.e., health centres and clinics) to monitor, manage and report ADRs and AEFIs. Institutional focal points from 30 lower-level health facilities across six regions were designated and trained on PV, including vaccine safety monitoring and the use of the Med Safety App to report AEFIs after COVID-19 vaccination.

In Indonesia, ADP has built on its previous support on active safety monitoring provided to the national regulatory authority (BPOM) and the national TB programme. This initial support had led to the introduction of a new medicine, bedaquiline, for multidrug-resistant TB (MDR-TB) in adults – one of the first countries in the world to do so. ADP supported a situation analysis of active TB drug safety management and monitoring in Indonesia, which has identified key areas for improving effective flow of information on ADRs, from peripheral health facilities to national PV authorities. ADP supports the development of a National Action Plan, which aims at integrating and implementing aDSM for MDR-TB into existing treatment protocols and PV structures.

ADP has also focused on strengthening the institutional and human capacities within the recently established National Pharmacovigilance Centre in Malawi. Through the development of a national work plan and fostering collaboration and harmonization between the NRA, public health programmes, and central

and district hospitals, ADP contributed towards an integrated PV system across all levels of the health system. PV focal points were designated within five tertiary hospitals and 29 district hospitals to operationalize systems for data flow and sharing, which form the foundations of an effective and integrated PV system. Training sessions on the PV system were also conducted for over 500 health workers, retail pharmacists and PV focal points for specialized health programmes, including TB, NTDs and immunization.

ADP also supported PV capacity-strengthening of pharmacists and medical doctors working in public health programmes in Burkina Faso and Senegal through enrolment in a regional e-training course provided by the Anti-Poison and Pharmacovigilance Centre of Morocco, a WHO Collaborating Centre.

As part of its support to promote the use of digital technologies for active safety monitoring, ADP supported the evaluation of the use and impact of the Med Safety App in Ghana. A survey of users, primarily health workers, found an overwhelming positive response to the app, with key areas of improvements identified. These findings, to be published in a peer-reviewed journal in 2021, will help improve the scale up of Med Safety in Ghana and inform the implementation of other similar mobile applications in other countries. In Malawi, ADP supported the launch of an USSD mobile platform that simplifies the process for health professionals and consumers to report ADRs/AEFIs.

ADP also supported awareness-raising campaigns in Ghana and Malawi on the importance of reporting adverse reactions. Information, education and communication materials were developed and deployed to raise public awareness of the various reporting channels available.

Regulatory harmonization

AU Model Law on Medical Products Regulation

ADP continues to collaborate with its longstanding partner, AUDA-NEPAD, in its effort to promote the domestication of the AU Model Law on Medical Products Regulation¹⁰ (AU Model Law) at the national level. The AU Model Law provides a comprehensive framework for an integrated and harmonized approach for medicines regulation; when effectively implemented at the national level, it will significantly contribute towards the goal of the African Medicines Regulatory Harmonization (AMRH) initiative and streamline regulatory approval processes across the region.

Having provided initial expert legal advice and technical support for the drafting of the AU Model Law, ADP now collaborates with AUDA-NEPAD to support AU Member States and regional economic communities to adopt the AU Model Law into national and regional legal frameworks. To guide the technical assistance to AU Member States, ADP developed the *Guidance document for domestication of the African Union Model Law on medical products regulation*, planned for AUDA-NEPAD/ADP joint publication in 2021.

¹⁰ The AU Model Law provides a comprehensive framework to guide AU Member States in enhancing regulatory system capacity and promoting an integrated and harmonized approach to medicine regulation. Please see section on 'Strengthening medicine regulatory capacity and harmonization' for more details.

ADP has continued with country-level technical assistance for the domestication of the AU Model Law in Ghana and Senegal. Following legal and policy reviews in the two countries, the legal drafting process will commence in late 2021. ADP is also responding to a request from the Secretariat of the Economic Community of Central African States (ECCAS) to conduct a survey of five countries (Angola, Burundi, the Democratic Republic of the Congo, Rwanda and Sao Tome et Principe), with the aim of capturing the status of legal and policy frameworks related to medicines regulation. The findings of the survey will enable AUDA-NEPAD to identify and provide the needed technical support in these countries to domesticate the AU Model Law.

Joint regulatory assessments

Through the work of its core partner, WHO, ADP has promoted joint regulatory assessments as an integral part of regulatory harmonization efforts. Learning from the ongoing ZaZiBoNa initiative, ADP has facilitated South-South technical exchanges to promote joint regulatory assessment of new medicines. These efforts include technical exchange between the Southern African Development Community Secretariat and the Association of Southeast Asian Nations Joint Assessment Coordination Group to discuss and share best practices for regulatory convergence and harmonization, and the implementation of coordinated joint assessments. WHO has also facilitated participation of regulatory experts from Ghana and the United Republic of Tanzania in the assessment of quality and safety of priority medicines and vaccines, including the WHO EUL for COVID-19 vaccines, conducted by the WHO Medicines Prequalification Programme. These assessments have provided strategic opportunities to increase the knowledge and experience of regulators from the ADP focus countries, who in turn, were able to contribute to the effort of the African Vaccines Regulators Forum to enable the timely approval of the COVID-19 vaccines in participating countries in the region.

Regulatory harmonization on medical devices

The regulatory harmonization efforts of ADP also include support to the AMDF, which is a technical committee of regulatory experts aimed at building country capacity on harmonization of the regulation of medical devices, including IVDs, among AU Member States. To advance these objectives, ADP supported AMDF in delivering a training workshop for national regulators from 25 countries, including ADP focus countries Burkina Faso, Ghana, Malawi, Senegal and the United Republic of Tanzania. The initiative also led to the development of four important guidance documents: *Guidelines for importation and exportation of medical devices*; *Guidelines for inspection of manufacturing site(s) for assessment of the quality management system of medical devices based on ISO 13485*; *Guidelines on regulatory requirements for issuance of market authorization of medical devices*; and *In vitro diagnostic medical devices and guidelines for registration of medical devices establishments*. These guidance documents are currently being finalized and will be submitted to the AMRH Steering Committee for endorsement in 2021.

To promote regulatory convergence among NRAs, six virtual meetings were held with regulators from the WHO regions

to discuss and develop tools and guidance documents on key regulatory capacities, including quality assurance of pharmaceutical products and the implementation of good manufacturing, regulatory and reliance practices.

Global and regional coalitions for regulatory system strengthening

For increased coordination and effectiveness in regulatory system strengthening efforts, ADP has facilitated, through WHO, the establishment of a Coalition of Interested Parties. This approach aims to improve harmonization, coordination and consistency in the provision of technical and capacity-building support. Through its networks in the WHO Africa, Western Pacific and South-East Asia regions, the Coalition coordinates efforts to address capacity gaps within national and regional regulatory bodies and networks, and promotes harmonization, work-sharing and reliance.

Implementation research to address barriers in disease control programmes

Large-scale deployment of health technologies can encounter a range of barriers in access, delivery and use, particularly within the resource-limited health systems of many LMICs. Failure to address these barriers will affect the effective uptake and penetration of health technology. Through TDR, ADP has supported national research institutions, national disease control programmes and health researchers in focus countries to systematically apply IR principles to identify and address barriers to the effective introduction and use of health technologies. Central to this work has been the establishment of South-South learning platforms and the use of a comprehensive IR Toolkit to guide capacity-strengthening efforts at the regional and country levels.¹¹

In Ghana, ADP had previously supported the national NTDs programme by strengthening national capacities for the roll-out of community-based MDA of azithromycin for the prevention and treatment of yaws. Important operational challenges were identified, including the effective use of rapid diagnostic tests and sample collection, and the need for community mobilization to prevent gender- and stigma-related barriers. ADP provided further support in strengthening the capacity of NTDs programme staff and health workers in three regions on the gender dimensions of NTDs and the use of IR. ADP supported the development of research protocols to investigate the influence of gender on health service accessibility and on the perception of gender-related stigma among women with skin-affected NTDs (including yaws). These studies, which ADP will continue to support moving forward, will contribute to efforts to address the barriers to effective implementation of MDA campaigns and will inform subsequent efforts for improving the strategic approach of the NTDs programme.

ADP is strengthening the IR capacity of the Provincial Centre for Health Research and Development in Papua, the largest province in Indonesia. Strengthened research capacities will

¹¹ <https://adphealth.org/irtoolkit/>

help optimize the implementation of evidence-based health interventions. Capacity-building activities are planned in 2021, using the ADP IR Toolkit as a resource, to identify and address barriers to effective disease control programmes for leprosy, helminthiasis, malaria and arbovirus.

Building on earlier success of South–South learning platforms for IR, an online training-of-trainers on the IR Toolkit was organized for French-speaking facilitators, followed by a training session for a broader group of francophone country stakeholders from West and Central Africa (Benin, Burkina Faso, Cameroon, Côte d'Ivoire, Guinea, Senegal and Togo). These virtual sessions introduced the IR Toolkit to a new cohort of health system researchers, who gained the knowledge and skills for designing IR studies and developing research proposals.

In Malawi, ADP supported the Ministry of Health and Population in building national capacity on the application of IR and the multidisciplinary approach to health systems research. A training was conducted for biomedical and social scientists and health programme implementers involved in disease control, immunization, health service delivery, disease surveillance and laboratory testing.

Integrating gender dimensions into access and delivery

A better understanding of both the similarities and differences in how people of all genders and sexes are vulnerable to and experience the impact of diseases such as TB, malaria and NTDs can inform national health systems and enable development partners to deliver equitable prevention, diagnosis and treatment services. ADP published the 2019 discussion paper *The gender dimensions of neglected tropical diseases*,¹² which provided a set of recommendations to address challenges arising from gender inequalities related to NTDs.

ADP conducted a gender analysis of the second WHO *Model List of Essential In Vitro Diagnostics* aimed at developing a framework to evaluate the gender dimensions of diagnostic products. To achieve UHC, investments in essential diagnostics that will support equitable access to health technologies are needed. If equitable access to diagnostic tools is to be achieved, a transparent and intentional effort to investigate and mitigate gender barriers to health is needed. *Universal health care, essential diagnostics lists and gender equity* will be published in 2021.

The 2019 discussion paper also called for improved IR on NTDs-related initiatives to identify gender- and sex-related risks and barriers to prevention and access to treatment. To address this gap, ADP has updated the IR Toolkit with a module on gender and intersectional analysis. The new gender module will enhance the IR toolkit's role as a training resource for the development of IR proposals incorporating gender equity and gender dynamics at multiple levels of the health care system. The new module is expected to be published in 2021.

Promoting safe and efficient roll-out of new TB treatment regimens

Building on previous initiatives to strengthen IR capacities, ADP worked with individual countries to identify and address needs and priorities for further country-level technical support and capacity-building in relation to the implementation of new guidelines for the treatment of MDR-TB patients. WHO treatment guidelines for MDR-TB now recommend aDSM and the use of IR to maximize the efficient and safe introduction of new TB treatment strategies. In line with these guidelines, ADP supported the training of – and South–South exchanges between – national TB programmes and PV units from 27 countries across West and Central Africa, as well as in Indonesia, to enhance technical capacities on aDSM best practices relating to PV and the systematic use of IR.¹³ Experiences, expertise and materials on active TB drug-safety monitoring and management was shared within the network. From these discussions, the WARN-TB and CARN-TB networks integrated developing country-specific aDSM implementation plans into their 2021 action plans.

Health technology assessment

Even as governments commit to UHC, national health systems come under pressure to balance the expanding needs of UHC with limited resources. ADP promotes sustainable, evidence-based resource allocation through priority-setting processes and institutions, that allow LMICs to evaluate the implications of the introduction and use of new health technologies. One such approach is HTA, a multidisciplinary process to systematically evaluate the social, economic, organizational and ethical impact of a health intervention or health technology.

ADP has supported efforts to build technical capacities and institutionalization of HTA in focus countries, particularly Ghana, Indonesia, Senegal and the United Republic of Tanzania. In a collaboration between UNDP, PATH and technical partner, HITAP, ADP has supported the



¹² See https://adphealth.org/upload/resource/2523_ADP_Discussion_Paper_NTDs_211119_web.pdf

¹³ <https://tdr.who.int/newsroom/news/item/23-03-2021-understanding-and-addressing-barriers-to-tb-drug-safety-monitoring-in-west-and-central-africa>

institutionalization process of HTA in focus countries, including through the establishment of dedicated national HTA units. This has been supplemented with ongoing technical support, such as training workshops and intensive experiential learning and mentoring, as well as the design and implementation of HTA studies.

In Ghana, ADP supported the newly inaugurated National HTA Committee to establish a steering committee and related technical working groups and the implementation of the evidence-informed deliberative approach for the development of process guidelines, workplans and terms of references. ADP will continue its support for the upcoming phase, which will include development of the national HTA guidelines (finalized in mid-2021). ADP support also included technical legal guidance on HTA legislation, which will mandate the systematic use of HTA in health decision-making and policymaking, as well as help ensure effective functioning and sustainability of the committee.

Learning from the experience in Ghana, ADP facilitated a technical exchange with the National HTA Committee in the United Republic of Tanzania. This transfer of knowledge has helped build political will and commitment, and promoted the wider adoption of the HTA approach, among policymakers in Tanzania. ADP continued to support advocacy efforts targeting stakeholders and decision-makers and helped draft the process guidelines for the National HTA Committee.

In Senegal, ADP has leveraged its partnership with HITAP to explore a potential partnership with Hitotsubashi University (Japan) and the Japan International Cooperation Agency to provide capacity-building support to the National Agency of Universal Health Financial Protection and the Ministry of Health and Social Action on best-practice tools and models for conducting health economic evaluation.

The Ministry has also requested ADP to facilitate knowledge exchange with stakeholders and experts from Ghana on the establishment of the HTA committee and national guidelines. Consultations are ongoing to design interventions and develop work plans.

In Indonesia, ADP continues to work with the national public procurement agency (LKPP), the Ministry of Health and the national regulatory authority on introducing a multiple criteria decision analysis mechanism for the procurement of medicines and medical equipment.

A regional HTA platform

In collaboration with HITAP, ADP convened a regional HTA knowledge platform to facilitate country stakeholders' access to critical resources and expertise in establishing national HTA mechanisms. The knowledge platform, which includes collaboration with the School of Public Health at the National University of Singapore and the International Decision Support Initiative, also facilitates South–South exchanges between policymakers, regulators and technical experts in LMICs to build a network of HTA practitioners sharing country experiences and best practices.



Value-based procurement policy and practice

Through PATH, ADP has focused on increasing awareness of strategic approaches for value-based planning and procurement of medical equipment in the public sector – to help governments balance increasing health needs, safeguarding the availability of health technologies and containing rising costs. Country procurement policies can have a significant direct impact on the ability to access health technologies and commodity supply chains efficiently; as the global procurement landscape evolves, national procurement policies will need to reflect developments. To promote the incorporation of health-related requirements into national procurement policy frameworks, ADP has initiated the development of a guide on the next generation of procurement policies. A global meeting to validate the guide will be organized in 2021.

Capacity gaps in medical equipment planning and procurement practices in LMICs are illustrated by studies showing that at any given time, between 40 percent and 70 percent of medical equipment is broken, unused or unfit for purpose.¹⁴ To address this challenge, ADP published a guide to support value-based public-sector procurement of medical equipment in LMICs. Based on the training module ADP developed with the national procurement agency of Indonesia for use in the country's national procurement training programme, the guide aims to promote value-based decision-making that takes account of the full life cycle of medical equipment and highlights the importance of planning and procurement processes that identify and address health, clinical and facility needs. The guide, available in French and Spanish, has been used to inform the development of a training curriculum and other capacity-building activities for national procurement agencies in Peru and Senegal planned for the last quarter of 2021.



Strategic pricing of health technologies

Medicines and other health technologies make up a significant proportion of health expenditure; effective cost-containment can contribute to promoting affordable and equitable access to health technologies, and the sustainability of national health insurance systems. Recognizing the need, ADP has supported efforts to strengthen strategic approaches to pricing of health technologies in the public sector.

Following on from recent ADP-supported regional and global initiatives – including a global training workshop on affordable, sustainable and equitable pharmaceutical pricing policies; and a multi-country study comparing prices of government-procured essential medicines – ADP focus countries have identified effective policies and methodologies to strengthen pharmaceutical price regulation and have subsequently requested technical support from ADP to address institutional and capacity gaps.

In Ghana, ADP is providing ongoing support on advancing the objectives of the Ghana National Medicines Policy that defines the priority of optimizing pharmaceutical prices. ADP supported the National Medicine Pricing Committee in developing and implementing a set of national guidelines, as well as building technical capacities on various price-setting methodologies for medicines price regulation. ADP supports the creation and operationalization of a price observatory to enhance capacity to monitor medicines prices across public and private sector supply chains.

In Indonesia, an ADP-commissioned regional study in 2019 found significant price discrepancies between Indonesia and other countries in the region for single- and multi-source medicines. To address the technical gaps highlighted in this study, ADP supported the Ministry of Health in convening a series of training workshops to assist national policymakers and stakeholders in identifying pricing strategies and approaches appropriate to the Indonesian context and planning key policy action to improve pharmaceutical price regulation in Indonesia.

In the United Republic of Tanzania, ADP commissioned an analysis of medicine prices in the public sector to identify key cost drivers of the expenditure of the NHIF. The study provided an overview of medicine consumption and costs in the public sector and identified opportunities and options for cost reductions. ADP will continue working with the Ministry to integrate the recommendations of the study into decision-making and prioritization of the NHIF reimbursement list, with a view to enhancing rational use of medicines in the public sector and increasing coverage of the NHIF.

¹⁴ Diaconu, K., Chen, Y.-F., Cummins, C. et al., Methods for medical device and equipment procurement and prioritization within low- and middle-income countries: findings of a systematic literature review, *Globalization and Health* 2017; 13(59).



SOUTH–SOUTH AND GLOBAL INITIATIVES

ADP has sought to leverage the experiences and expertise from its network of stakeholders in the ADP focus countries as a source of South–South learning and exchange. Focusing on common challenges across different health systems, exchanges between focus countries have delivered both policy lessons and technical solutions, as well as driven synergies and collaborations between key national agencies in different countries.

Leveraging the experience and expertise from ADP resource countries

As ADP resource countries, India and Thailand have played important roles in sharing their country experiences and technical expertise with other ADP focus countries.

The experience of India in the re-purposing of eVIN for inventory management and delivery of the COVID-19 vaccines, as well as for tracking of vaccine recipients to ensure delivery to over 450 million individuals, offers valuable lessons for other countries. ADP had collaborated with UNDP India to facilitate South–South technical cooperation and technology transfer to enable the accelerated uptake of the SMILE system in Indonesia, which reached nearly 7 million beneficiaries in 2021. ADP continues to enable further South–South technical exchanges between India and other interested LMICs, with a view to improving policymaking and planning for the introduction of new vaccines, particularly for those exploring digital solutions to support distribution of COVID-19 vaccines.

ADP has also leveraged the extensive experience of Thailand in implementing a sustainable UHC system and adopting innovative policies and strategies to lower excessive spending without lowering net health service delivery or impact.

ADP South–South exchange and learning platform

ADP established the South–South exchange and learning platform in 2019 to facilitate the sharing of country experiences between stakeholders from ADP focus countries and to leverage lessons learned for a greater depth of national-level capacity strengthening. The platform has strengthened the ADP network of focus countries and regional partnerships and created demand for the range of ADP technical expertise and service offerings.

During the reporting period, ADP convened four virtual stakeholder consultations.¹⁵ Government stakeholders and experts from over 20 countries came together to identify health system challenges and solutions across critical dimensions of the access and delivery value chain: integrated and multisectoral planning; value-based planning and procurement; regulatory preparedness; and digital health interventions. The virtual consultations provided critical opportunities for stakeholders to exchange and learn about effective approaches in addressing emerging health system challenges related to the COVID-19 pandemic. They were also helpful in ensuring continued engagement between ADP partners and country stakeholders at a time when the COVID-19 pandemic restricted international travel and in-person meetings. The consultations further highlighted the importance of ensuring that other health priorities, programmes and services, including those for TB, malaria and NTDs, are not neglected while countries respond to COVID-19.



¹⁵ <https://www.adphealth.org/south-south-stakeholder-online-consultations/>

ADP online community platform

Following the success of the ADP South–South platform, and building on existing ADP networks of key experts, policymakers and civil society, ADP established a dedicated online community platform¹⁶ to achieve the following goals: (1) facilitate remote delivery of ADP technical and capacity support; (2) foster collaboration and coordination; and (3) promote South–South knowledge exchange and sharing of best practices. The ability to share lessons, experience and information rapidly between stakeholders has contributed to evidence-based policy and programme planning related to COVID-19. Closer engagement with country stakeholders has allowed ADP to be more responsive to shifting country needs and emerging health system priorities, which has proven critical during the COVID-19 pandemic, where travel restrictions have slowed the delivery of traditional in-person technical support.

Uniting Efforts for Innovation, Access and Delivery

The Uniting Efforts for Innovation, Access and Delivery (Uniting Efforts) initiative – the global platform jointly coordinated by ADP, the GHIT Fund and the Government of Japan since 2019 – reflects the partners' commitment to strategic collaboration to inform policy deliberations and practice in global health to help address persistent inequities in health.¹⁷ The three partners of Uniting Efforts continue to strengthen their collaboration with the aim of driving aligned action across the innovation–access–delivery continuum, and promoting preparedness in LMICs to introduce new health technologies rapidly. Aligned action that drives accelerated research and development and product development of new health technologies and ensures rapid access and delivery of these health technologies, is a vital contribution towards achievement of UHC and in turn, human security.

With the emergence of the COVID-19 pandemic, Uniting Efforts shifted to online and virtual modes to follow up and build on the recommendations from partners and stakeholders, which arose from the deliberations of the Uniting Efforts Second Global Dialogue held

in February 2020. These included the publication and dissemination of knowledge products to facilitate further exchanges among the stakeholders. During this reporting period, Uniting Efforts published and launched two knowledge products through interactive webinars, to enable broad dissemination and dialogue on their use.

The first webinar – Financing for access and delivery amid a global crisis: Innovative approaches to maintain momentum on neglected diseases (July 2020) – brought together policymakers and experts to discuss innovative financing approaches for access and delivery of lifesaving treatments, diagnostics and other health technologies in developing countries, including the findings and recommendations in the Uniting Efforts Discussion Paper: *Landscape of funding and financing opportunities for access and delivery of health technologies for neglected diseases*.¹⁸

A second webinar, in November 2020 – Making the case for neglected diseases: Leveraging national investment cases to unlock financing for access and delivery of health technologies, launched the *Guidance note for the development of national investment cases for neglected diseases*.¹⁹ This dialogue brought together neglected disease and investment case experts to discuss the opportunities and challenges involved with using investment cases as an evidence-based strategy to mobilize financing.

The partners of Uniting Efforts are encouraged by the interest and active participation of a broad diversity of stakeholders in both webinars. There were over 100 participants in each event, representing governments (both donor and endemic country governments), innovators, funders, access and delivery specialists, civil society, affected communities, academics and the stakeholders within multilateral and United Nations agencies.

In one concrete follow-up, Uniting Efforts partners have initiated a collaboration with the WHO NTDs Department to develop common guidance and tools for NTDs national investment cases to improve financing and funding for access and delivery of health technologies for neglected diseases. This is expected to be an important contribution towards the country-led implementation of the new WHO roadmap on NTDs, *Ending the neglect to attain the Sustainable Development Goals: A road map for neglected tropical diseases 2021–2030*.



¹⁶ <https://community.adphealth.org/>

¹⁷ <https://www.unitingeffortsforshealth.org/>

¹⁸ https://adphealth.org/upload/resource/2795_ADP_Uniting_Efforts_discussion_paper_neglected_diseases.pdf

¹⁹ https://adphealth.org/upload/resource/2849_ADP_Uniting_Efforts_Guidance_Note_171120_final.pdf



LOOKING AHEAD

As ADP looks towards the next project year of 2021–2022, the issue of access to COVID-19 vaccines is likely to remain on centre stage. Delayed access to vaccines will prolong the pandemic, with costs to lives and a deepening of socio-economic impacts. New COVID-19 variants are causing concern about COVID-19 surges, including in LMICs where vaccinations have been limited by uneven global supply.

As the global community seeks to overcome the urgent challenge of ensuring greater vaccine supplies, efforts must also be made to enable national health systems to respond effectively and quickly. The pandemic continues to strain national health systems. With each COVID-19 surge, hospitals and health systems in hard-hit areas are overwhelmed by the influx of COVID-19 patients with significant pressures on health workers, supplies and other services, as well as patient beds.

In this context, the ADP focus on strengthening health systems to ensure enhanced access to, and delivery of, health technologies is more important today than ever. The pandemic has put health systems under significant stress, but it has not fundamentally changed the underlying need for increased capacities to perform essential health system functions. These are prerequisites for UHC, but also crucial for pandemic preparedness and response, and ultimately, human security.

The pandemic has accelerated digital transformation in the health sector in many countries. The use of digital technologies has played a crucial role in the roll-out of the COVID-19 vaccines. As demonstrated by eVIN, CoWIN (Covid Vaccine Intelligent Network) in India and SMILE in Indonesia: the data-driven vaccine supply chain management systems were rapidly adapted to support COVID-19 vaccination in these countries. There are further examples of digitization in the vaccination effort – from vaccination registration and scheduling, to reporting and monitoring of adverse events. Artificial intelligence and big data analytics are also supporting decision-making and targeting of the most vulnerable for vaccination.

ADP will look towards increasing support to focus countries on the implementation of digital solutions for vaccine delivery. This complements the UNDP global approach to support national COVID-19 vaccine deployment plans,

which focuses on three core elements: digital solutions for vaccine delivery and systems strengthening; integrated data analytics to support decision-making for vaccine equity; and greening of COVID-19 vaccination, including through solar and smart facilities.

Beyond vaccines, the use of digital tools has been identified as a vital means to increase efficiency, resilience and sustainability of health systems. ADP will therefore continue to support national efforts to identify and use digital tools to address broader health system challenges. This includes building on previous support for the use of digital mobile applications for PV and safety monitoring, and on conducting operational research to understand the success factors for implementation. Another focus area is the scale up of tele-health systems to promote equitable access to essential health services. ADP will further its work in this area, to improve understanding of specific country needs and to support development of related national policies, regulatory and governance frameworks, strengthening of health workforce capacity and digital data management.

Digital transformation should be regarded as an investment for strengthening health systems and accelerating progress towards attaining UHC, and thus achievement of SDG 3 (Good Health and Well-being).

In this context, ADP will support countries to help ensure local ecosystem readiness, and identify digital health interventions that are appropriate, cost-effective and sustainable. In doing so, ADP will link with relevant initiatives, such as the UNDP/Draper University Impact Venture Acceleration and Scaling Initiative, which seeks to drive the digital response to and recovery from the COVID-19 pandemic through venture capital funding for accelerating the development, market entry and impact scaling of digital technologies appropriate for LMICs.

This is also in line with the United Nations Secretary General's *Roadmap for digital cooperation*, the WHO *Global strategy on digital health* and the UNDP *Digital strategy*. In June 2021, the Group of 7 (G7) Health Ministers reaffirmed the importance of international collaboration on health and recognized the importance of digital health solutions in transforming health care, noting the need for solutions that are inclusive, comprehensive and equitable.







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