



THE ACCESS AND  
DELIVERY PARTNERSHIP

*New Health Technologies for TB, Malaria and NTDs*



# STATUS REPORT 2020



## 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 R&D and to increase access to and delivery of health technologies used to address NTDs, TB and malaria.

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# STATUS REPORT 2020



# CONTENTS

# 4

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Acronyms and abbreviations

# 14

---

Strengthening national health systems:  
ADP country reports

# 7

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Foreword

# 22

---

Extending the impact of ADP:  
regional and global initiatives

# 8

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Introduction

# 28

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Looking ahead

# 12

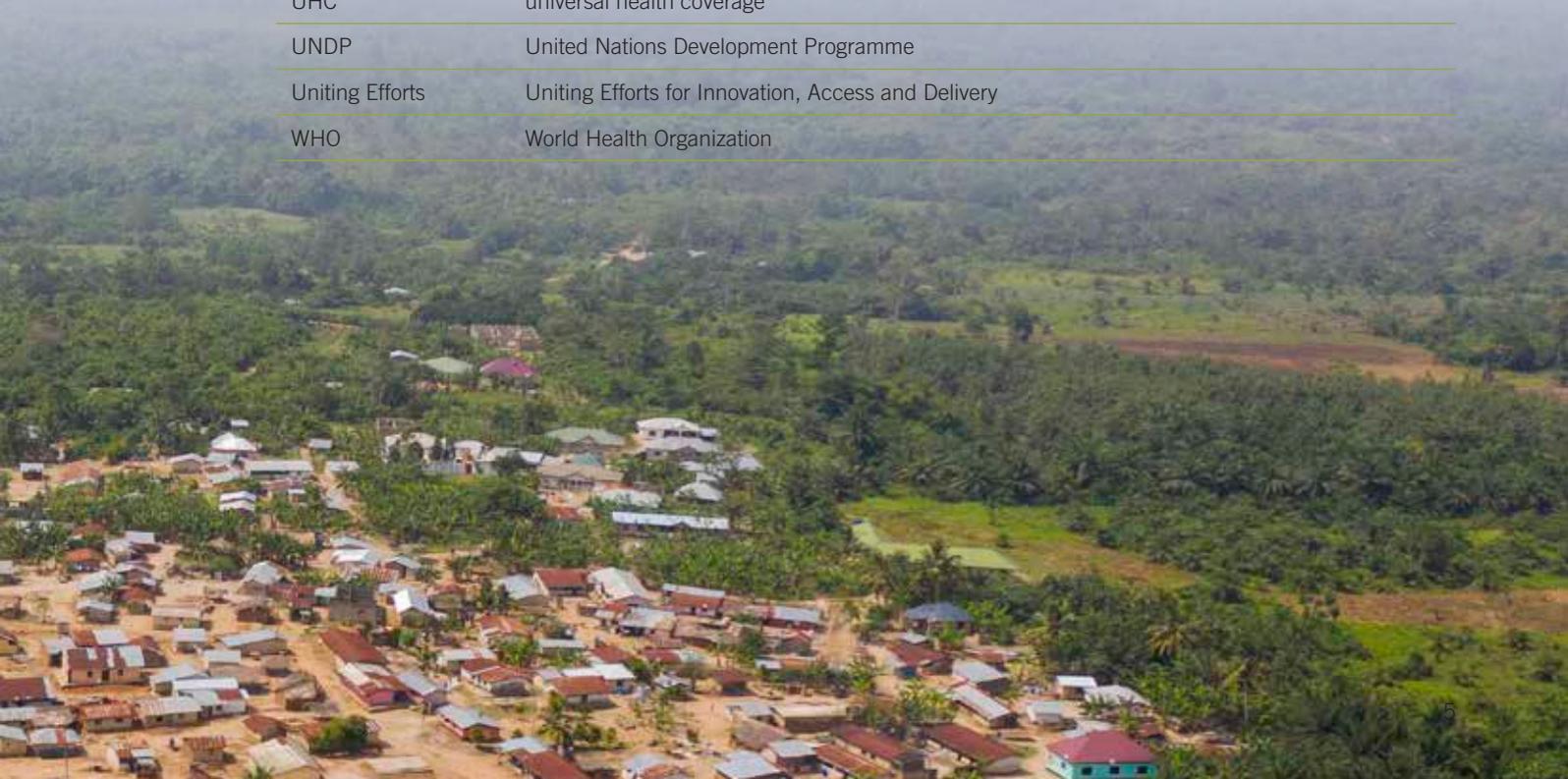
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Strengthening health systems at country and regional levels:  
A snapshot of ADP key results

# ACRONYMS AND ABBREVIATIONS

ADP	Access and Delivery Partnership
aDSM	active drug safety monitoring and management
AU	African Union
AUDA-NEPAD	African Union Development Agency
AU Model Law	AU Model Law on Medical Products Regulation
Badan POM	Badan Pengawas Obat dan Makanan (Indonesia National Agency of Drug and Food Control)
CIP	Coalition of Interested Parties
COVID-19	coronavirus disease
ECOWAS	Economic Community of West African States
DR-TB	drug-resistant tuberculosis
EDL	essential diagnostic list
EHP	essential health package
eVIN	Electronic Vaccine Intelligence Network
FDA	Food and Drug Authority (Ghana) / Food and Drug Administration (Thailand)
GBT	Global Benchmarking Tool
GDP	good distribution practices
GHIT	Global Health Innovative Technology
GMP	good manufacturing practice
HTA	health technology assessment
HITAP	Health Intervention and Technology Assessment Program
IDP	Institutional Development Plan
IR	implementation research
IVD	in vitro diagnostic
LKPP	Lembaga Kebijakan Pengadaan Barang Jasa Pemerintah (Indonesia National Public Procurement Agency)
LMICs	low- and middle-income countries

MCDA	Multiple Criteria Decision Analysis
MDA	mass drug administration
MDGs	Millennium Development Goals
MDR-TB	multi-drug resistant tuberculosis
MHSA	Ministry of Health and Social Action (Senegal)
MoH	Ministry of Health
MoHCGDEC	Ministry of Health, Community Development, Gender, Elderly and Children (United Republic of Tanzania)
NHIF	National Health Insurance Fund (United Republic of Tanzania)
NHIS	National Health Insurance Scheme (Ghana)
NRA	national regulatory authority
NTDs	neglected tropical diseases
PMRA	Pharmacy and Medicines Regulatory Authority (Malawi)
PMS	post-marketing surveillance
QRM	quality risk management
R&D	research and development
RSP	Regulatory Strengthening Programme
SADC	Southern African Development Community
SDGs	Sustainable Development Goals
TB	tuberculosis
TDR	Special Programme for Research and Training in Tropical Diseases
UHC	universal health coverage
UNDP	United Nations Development Programme
Uniting Efforts	Uniting Efforts for Innovation, Access and Delivery
WHO	World Health Organization







# FOREWORD

Despite the global health community being on alert to the potential for a new global pandemic, the emergence of coronavirus disease (COVID-19) has brought about a systemic shock with broad humanitarian and development implications globally.

The pandemic is an unprecedented wake-up call, exposing the inequalities and weaknesses identified in the 2030 Agenda for Sustainable Development. More than ever, it reinforces the critical need for health system strengthening and preparedness.

Like many other health and development programmes, the work of the Access and Delivery Partnership (ADP) was interrupted by the pandemic. ADP partners have swiftly pivoted to make use of digital tools to stay connected and engaged with country stakeholders, to consult and understand the rapidly evolving needs at the country level, to be better able to deliver support as countries come to terms with COVID-19, and also as they take a step back to ensure that other health priorities, programmes and services are not simultaneously neglected.

The individual ADP partners have also been working to deliver support for the global COVID-19 response. The World Health Organization (WHO) leads the coordination of the international community's response to the pandemic. The United Nations Development Programme (UNDP) is working with partners to provide support for health systems and crisis management, alongside addressing socio-economic impacts. As a global programme of scientific collaboration, the Special Programme for Research and Training in Tropical Diseases (TDR) is helping to facilitate, support and influence efforts to combat COVID-19 through clinical research and best practice. PATH experts are partnering with governments to establish emergency operations centres and advising on testing, treating and managing the outbreak.

COVID-19 has been a catalyst for change on several fronts. It has demonstrated that it is possible to rapidly share scientific information and mobilise resources. It has also highlighted the imperative for urgently scaling collaboration, platforms and partnerships for access and delivery of health technologies. ADP is an exemplar of the kind of collaborative effort needed to urgently strengthen health systems in the context of COVID-19 and efforts to achieve universal health coverage.

The current *Status Report 2020* captures the Partnership's operations at a unique moment, demonstrating that despite the present uncertainties, disruptions and swift pace of change in focus countries, the work and impact of ADP remains on track and relevant.

*W. Dhaliwal*

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# INTRODUCTION

The coronavirus disease (COVID-19) pandemic has highlighted the critical importance of ensuring equitable access to health services, as well as increasing availability of medicines, vaccines and diagnostic tools in response to established and emerging health threats. While COVID-19 constitutes an immediate health crisis in all countries, it did not cause the underlying fragility in many health systems – rather, it revealed existing weaknesses. The latest available data show that worldwide access to essential health services was already far below what is needed, with an average of between one third and one half of the world's population with access to essential health services in 2017.<sup>1</sup>

**The COVID-19 pandemic has highlighted the critical importance of ensuring equitable access to health services, as well as increasing availability of medicines, vaccines and diagnostic tools in response to established and emerging health threats.**

Since 2013, the core partners of the Access and Delivery Partnership - the United Nations Development Programme (UNDP), the World Health Organization (WHO), the Special Programme for Research and Training in Tropical Diseases (TDR) and PATH – have supported governments and in-country stakeholders to strengthen health systems through the development of essential policies, human capacities, systems and regulations that help to ensure that new health technologies reach those most in need.

1 (33 percent to 49 percent): Primary health care on the road to universal health coverage: 2019 monitoring report. Geneva: World Health Organization; 2019 ([https://www.who.int/healthinfo/universal\\_health\\_coverage/report/uhc\\_report\\_2019.pdf](https://www.who.int/healthinfo/universal_health_coverage/report/uhc_report_2019.pdf), accessed 10 July 2020).

COVID-19 has highlighted severe fragilities and inequalities within and among nations, but also the importance of resilient health systems and universal health coverage (UHC), which are underpinned by equity.

In line with the overarching approach of the 2030 Agenda for Sustainable Development, ADP adopts a systemic and integrated perspective towards health system strengthening, aimed at the interlinked targets of eliminating communicable and infectious diseases and achieving real progress towards UHC.

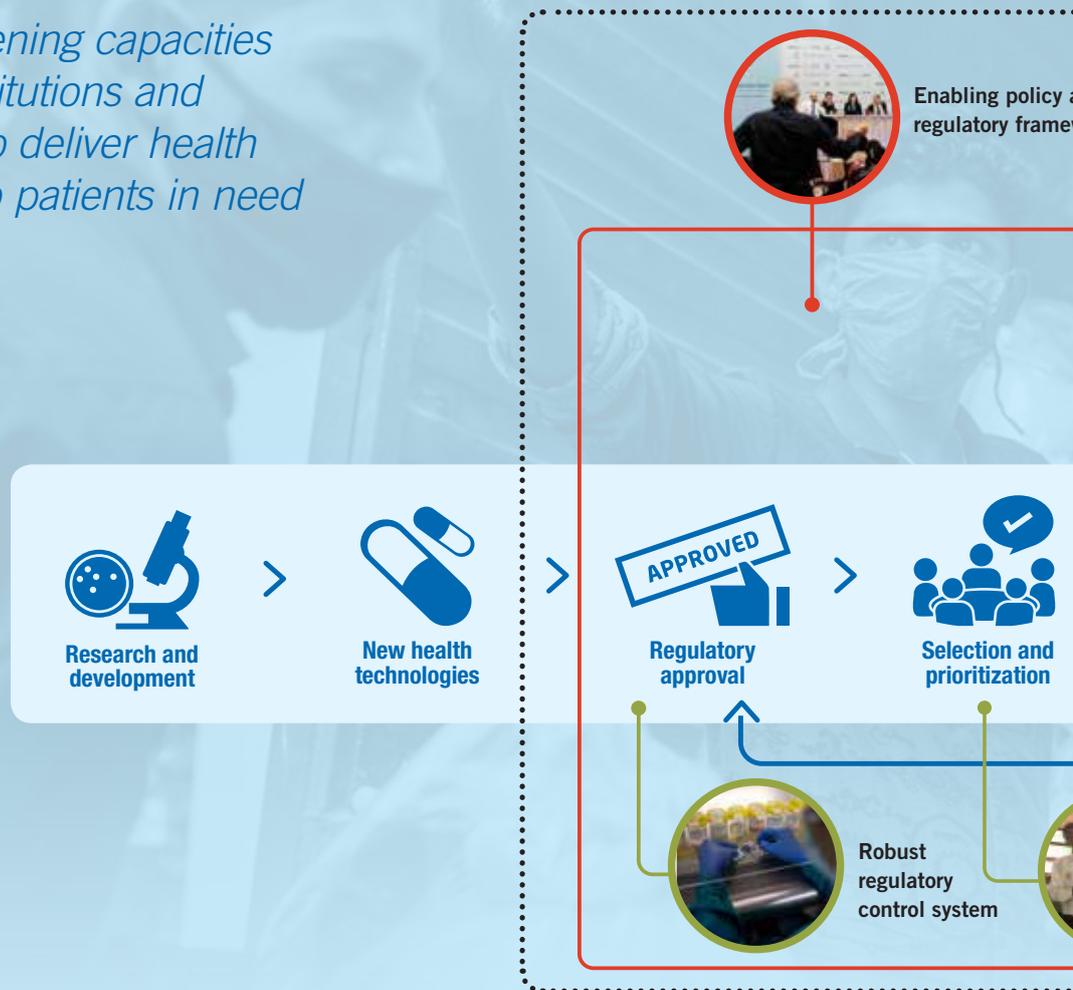
The integrated nature of ADP support – which stretches across the value chain from enabling policy and legal frameworks, implementation research (IR), regulatory approval, procurement and supply chain management, and ultimately reaching service delivery and patient safety monitoring – has placed an increasing number of focus countries in stronger positions to ensure continued access to health technologies for tuberculosis (TB), malaria and neglected tropical diseases (NTDs).

The strengthened capacities to effectively access and deliver health technologies are also critical to driving an effective response to the COVID-19 pandemic.

In launching national COVID-19 responses, countries had very narrow windows of opportunity for initial planning and were forced by circumstances to react rapidly based on early lessons elsewhere and available guidance. Now, as some countries gradually emerge from those rapid responses and lockdowns, the challenges of managing the pandemic are being weighed against the many



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



health, economic and sustainability priorities that countries also face. It is increasingly apparent that even while

**It will be crucial to adopt measures to mitigate any reversal in the progress towards the targets of ending the epidemics of TB, malaria and NTDs, as set out in the SDGs.**

tackling COVID-19, it remains vitally important to ensure that established diseases – such as TB, malaria and NTDs – are not at risk of neglect.

The latest studies suggest that in high-burden settings for HIV (human immunodeficiency virus) and

AIDS (acquired immunodeficiency syndrome), TB and malaria, for example, the resulting health system disruption from COVID-19 could lead to an increase in deaths, over the next five years, by up to 10 percent, 20 percent and 36 percent, respectively.<sup>2</sup> The greatest impact on HIV is assumed to be from interruption of antiretroviral treatment provision, which may occur during a period of high or extremely high health system

<sup>2</sup> Taken from: Report 19: The potential impact of the COVID-19 epidemic on HIV, TB and malaria in low- and middle-income countries (<https://www.imperial.ac.uk/media/imperial-college/medicine/mrc-gida/2020-05-01-COVID19-Report-19.pdf>, accessed 10 July 2020).

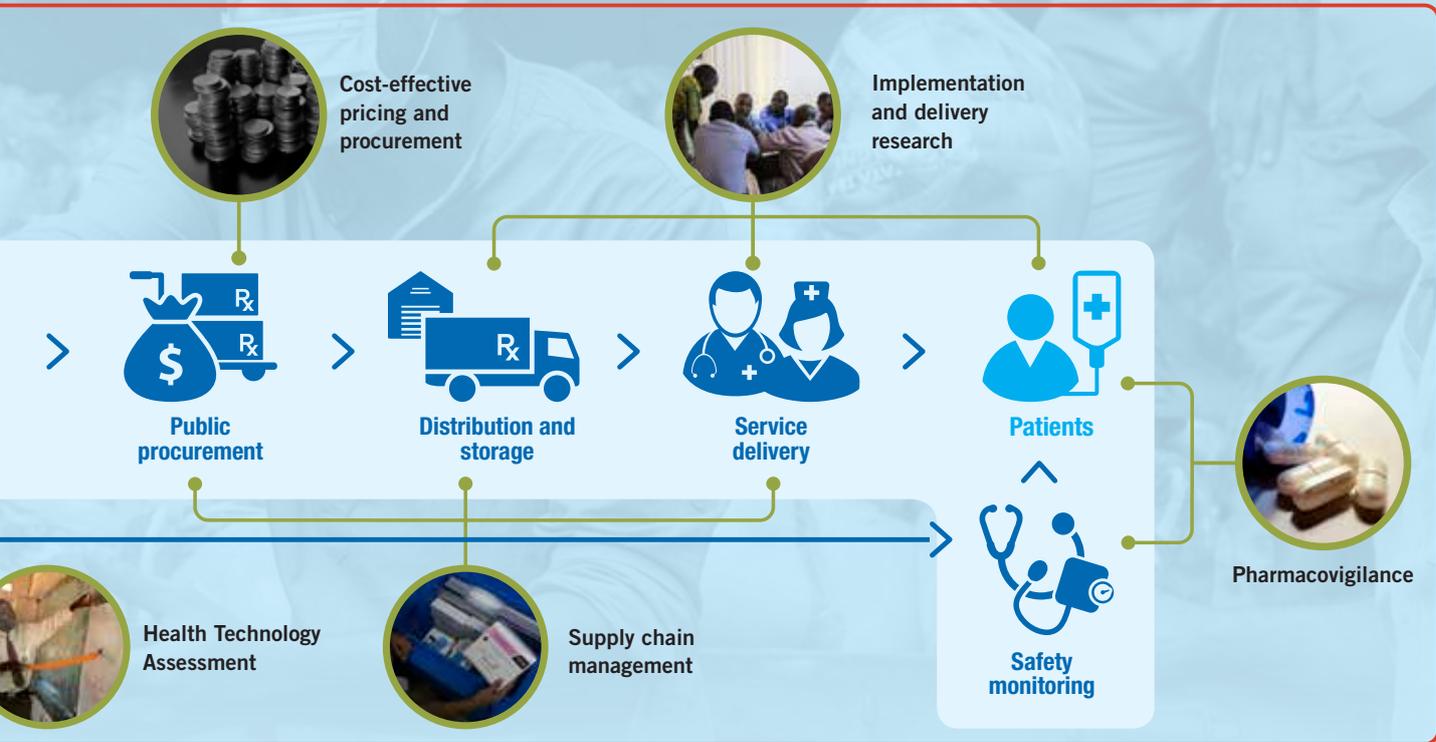
demand; for TB, the greatest impact is likely to be from reductions in timely diagnosis and treatment of new cases and for malaria, the greatest impact would come from reduced prevention activities, including interruption of planned bed net distribution campaigns.

In the longer term, the socio-economic impact of COVID-19 can negatively affect the resources available for addressing TB, malaria and NTDs. As such, the significant gains already made – increased coverage for TB and malaria treatments and declines in maternal and child mortality – may be lost. It will be crucial to adopt measures to mitigate any reversal in the progress towards the targets of ending the epidemics of TB, malaria and NTDs, as set out in the Sustainable Development Goals (SDGs).



## THE ACCESS AND DELIVERY PARTNERSHIP

and work



The SDGs also explicitly acknowledge the links between poverty and major health systems challenges, particularly in low- and middle-income countries (LMICs). Prior to COVID-19, for example, WHO estimated that approximately 1 billion people would be spending at least 10 percent of their entire household budgets on health care by 2020.<sup>3</sup>

Maintaining the most critical prevention activities and health care services for TB, malaria and NTDs will be significant in reducing the indirect impacts of the COVID-19 epidemic on poor and marginalized populations. Strategies that increase access and delivery of health technologies

<sup>3</sup> World Health Statistics 2020: Monitoring health for the SDGs. Geneva: World Health Organization; 2020 ([https://www.who.int/gho/publications/world\\_health\\_statistics/2020/en/](https://www.who.int/gho/publications/world_health_statistics/2020/en/), accessed 10 July 2020).

for neglected diseases, including investments in health systems, will also be essential to strengthen the response to COVID-19 and future pandemics in LMICs. Under such circumstances, exchanging and learning from country experiences is more crucial now than ever; there is a need for rapid flows of information and practical solutions between countries to enable preparedness and decision-making, not least while the need remains for national health systems to mitigate disruptions to essential non-COVID health services.

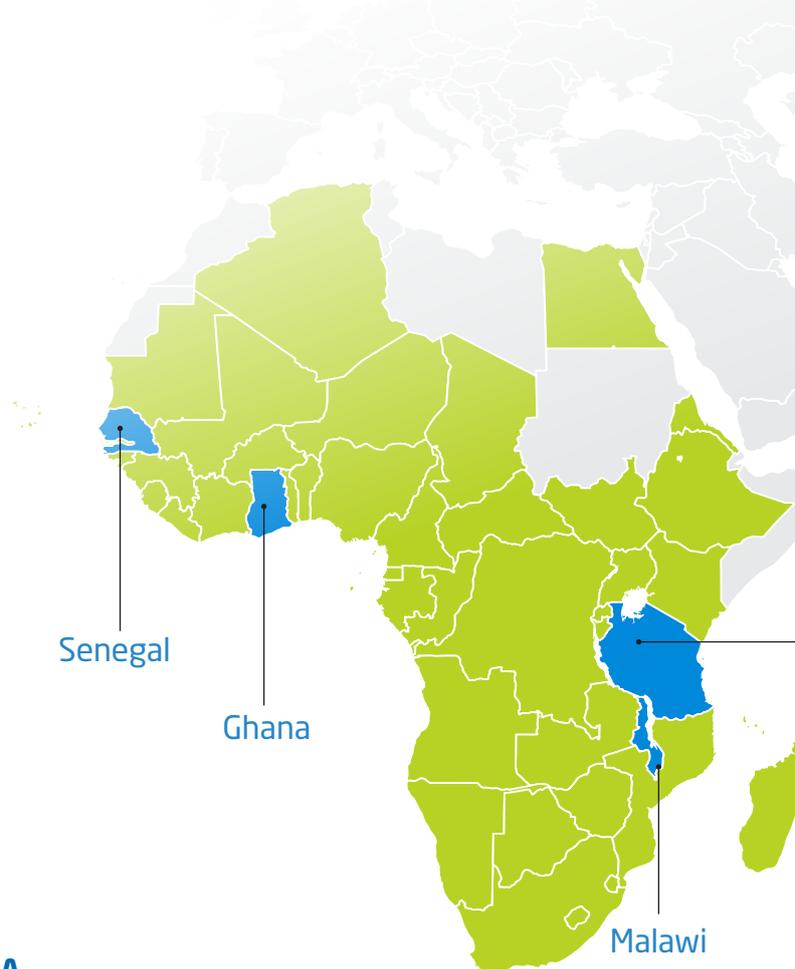
COVID-19 is also accelerating digitization, including in the area of health. While digital technologies can improve access and delivery of health technologies, there is a need for appropriate regulations, policies and practices across the innovation-access-delivery value chain to ensure that

existing inequalities are addressed and not deepened. ADP will aim to provide support to focus countries in this regard, including through the sharing of relevant country experiences.

The diversion of national resources and attention towards tackling the COVID-19 pandemic, along with travel restrictions, have meant some delays in activities planned for the first half of 2020. ADP partners, however, are committed to the continuous delivery of technical assistance to help countries meet their priority health needs during and post-pandemic, including through use of digital technologies and other innovative approaches.

The *Status Report 2020* highlights the work of ADP in its second year of scale-up (April 2019 – March 2020).

# STRENGTHENING HEALTH SYSTEMS AT COUNTRY AND REGIONAL LEVELS: A SNAPSHOT OF ADP KEY RESULTS (APRIL 2019 - MARCH 2020)



## GHANA

- Coordinated introduction of the new RTS,S/AS01 (RTS,S) malaria vaccine across 275 districts by strengthening multisectoral, cross-disciplinary and integrated planning.
- Improved implementation planning for the mass drug administration (MDA) of azithromycin, which will target 90 percent of beneficiaries in three pilot districts, as part of the yaws eradication strategy.
- Continued support to Food and Drug Authority (FDA), which attained “Maturity Level 3” in May 2020, the second country in the WHO African Region to meet the criteria of a stable and well-functioning regulatory system.
- Supported the national roll-out of a new mobile application, MedSafety, which facilitates fast and direct community reporting of adverse drug reactions.

## INDONESIA

- Strengthened the testing capacity of the national quality control laboratories for post-marketing surveillance to improve evaluation of medicines quality.
- Expanded the base of technical capacity within the Ministry of Health and affiliated academic institutions on the use of health technology assessment (HTA) to inform the planning and cost-effective use of vaccines.
- Improved efficiency and integrity of the vaccine cold chain in two pilot districts by introducing a cloud-based electronic logistic management information system (SMILE), which the Ministry of Health has committed to scale up to over 600 health facilities across 11 provinces, reaching 9.4 million beneficiaries in 2020.

## INDIA

- Facilitated South-South technology transfer from India to Indonesia for the implementation of the electronic logistic management information system (eVIN) aimed at increasing efficiency and integrity of the vaccine supply chain.
- Leveraged the expertise of national research institutions to strengthen technical and scientific capacities in vaccinology within national immunization programmes in ten LMICs.

## MALAWI

- Continued support to the multi-sectoral Technical Working Group to improve policy coherence across innovation, access and delivery of health technologies.
- Initiated the process for regulatory system strengthening by supporting the national regulatory authority in conducting a self-assessment using the WHO Global Benchmarking Tool (GBT).
- Strengthened institutional capacity within the new National Pharmacovigilance Centre, as well as in tertiary and districts hospitals to monitor, manage and report adverse drug reactions.

## THAILAND

- Facilitated South-South cooperation by leveraging the institutional expertise and experience on HTA in Thailand to provide technical assistance to LMICs on multidisciplinary research to improve cost-effectiveness of national health insurance packages.
- Strengthened the capacity of the national regulatory authority to conduct risk-based regulatory inspection and quality control testing to maintain pharmaceutical quality and integrity standards throughout the supply chain.



● ADP focus countries

● Countries that benefited from ADP capacity-building initiatives

*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.*

## SENEGAL

- Strengthened technical capacities of relevant national agencies to conduct HTA and health economic evaluation to improve decision-making in the selection of new health technologies.
- Supported the initiation of the self-benchmarking exercise of the national regulatory authority in preparation of the formal WHO assessment, and further strengthened its capacities for regulatory inspection of the pharmaceutical supply chain.
- Established a multidisciplinary coordinating platform to improve stakeholder coordination and policy coherence, and address health system bottlenecks through IR.

## REGIONAL AND SOUTH-SOUTH

- Convened the 'ADP South-South Exchange and Learning Platform' to promote collaboration and knowledge sharing between ADP focus countries and ensure 'health system preparedness' for the introduction of new health technologies.
- Developed key guidance documents and strengthened capacities of legal and regulatory experts from 23 countries on domesticating the African Union (AU) Model Law on Medical Products Regulation (AU Model Law) to meet the AU target of its adoption by 25 Member States by 2020.
- Established regional and country chapters of the Coalition of Interested Parties (CIP) in the WHO African, Western Pacific and South-East Asia regions to coordinate better technical assistance provision for regulatory system strengthening.
- Strengthened capacities of national regulatory authorities in LMICs in Asia and Africa on good manufacturing practices (GMPs), GDPs and quality control/assurance to improve the quality and integrity of medicines throughout the supply chain.
- Convened South-South learning platforms in Africa for ongoing capacity-strengthening and advisory support on applying the IR approach to identify and address barriers within national disease control programmes in 13 countries.
- Developed a guide to support public sector procurement of medical equipment on value-based decision making, as a tool to facilitate South-South exchanges on good practices.

## UNITED REPUBLIC OF TANZANIA

- Supported a national multi-stakeholder platform to plan the integrated roll-out of paediatric praziquantel formulation, in anticipation of marketing approval, to address the treatment gap for 15 million children at risk of schistosomiasis.
- Continued support for regulatory system strengthening to maintain Maturity Level 3 rating, including technical assistance on good distribution practices (GDPs) for quality assurance of health technologies across the entire distribution chain.
- Supported the establishment of the HTA committee, including through the development of national HTA guidelines and processes, and prioritization of research to improve the cost-effectiveness and financial sustainability of the National Health Insurance Fund.

## GLOBAL

- Convened, in partnership with the Government of Japan and the GHIT Fund, the second Global Dialogue of Uniting Efforts for Innovation, Access and Delivery to facilitate strategic discussions on maximizing the critical pathways from health technology research and development (R&D) to access and delivery. Two technical consultations were also held to identify policy and technical solutions relating to access planning early in R&D, and mobilization of investment and financing for access and delivery of health technologies.
- Published, in collaboration with the Liverpool School of Tropical Medicine, a study on the gender dimensions of NTDs with recommendations for addressing gender inequalities to ensure equitable prevention, diagnosis and treatment of NTDs.

# STRENGTHENING NATIONAL HEALTH SYSTEMS: ADP COUNTRY REPORTS

This section describes the impact of ADP in its seven focus countries from April 2019 through March 2020. ADP supported a range of capacity-strengthening interventions, which were in line with the ADP strategic approach of leveraging the expertise of its four core partners and working across sectors to help strengthen and harmonize policies, regulations and systems, as well as build the capacities of key people and institutions.

## GHANA



**The SAVING project will inform the introduction of the new RTS,S malaria vaccine across the country, which will have the potential of averting at least 50,000 malaria cases in its initial roll-out phase.**

Over the past two decades, Ghana has demonstrated its commitment to achieving UHC. By establishing the National Health Insurance Scheme (NHIS) in 2004, Ghana significantly expanded primary health care coverage. There has however, been uneven progress against communicable diseases and maternal and child mortalities, which continue to account for almost half of the nation's annual deaths.

Integrated approaches are recognized as instrumental to progress towards UHC, as is the active engagement of decision-makers, researchers and those delivering health services. ADP support has strengthened integrated approaches and multi-sectoral coordination; as demonstrated in the revision and implementation of the National Medicines Policy, and through strengthening of the national capacities for monitoring and response on safety issues associated with new health technologies and for IR among disease control programmes.

### Results and impact

ADP support for national multisectoral coordination has been instrumental in developing an integrated plan for the roll-out of the new RTS,S malaria vaccine across Ghana. The multisectoral working group, convened by the University of Health and Allied Sciences, the Ministry of Health, Ghana National Drugs Programme and the Food and Drugs Authority (FDA), with ADP support, successfully mobilized a 2.1 million euro grant from the European and Developing Countries Clinical Trials Partnership to implement the roll-out plan. This project – *Building capacity to address implementation challenges for sustainable access and delivery of new vaccines in Ghana (SAVING)* – will inform the introduction of the new RTS,S malaria vaccine across the country, which will have the potential of averting at least 50,000 malaria cases in its initial roll-out phase.<sup>4</sup> The integrated approach of the

SAVING platform provides a model for enhanced access and delivery of new health technologies, and will be critical in informing the introduction and roll-out of other medicines, vaccines and diagnostics.

Ghana has also prioritized the roll-out of community-based MDA of azithromycin – in line with the WHO Morges strategy for global yaws eradication – with the target of covering over 90 percent of the at-risk population in three pilot districts. In support of this priority, ADP strengthened national capacities in IR, pharmacovigilance and integrated planning. In partnership with the Ghana Health Service, ADP supported training of trainers and frontline health workers on key aspects of MDA implementation – disease recognition, mapping and management. Through these means, important operational challenges, including the effective use of rapid diagnostic tests and

<sup>4</sup> <https://www.afro.who.int/news/ghana-announces-roll-out-malaria-vaccine-implementation-programme-mvip>, World Health Organization, 11 April 2019 (accessed on 13 July 2020).



sample collection, and the need for community mobilization to prevent gender- and stigma-related barriers, were identified. These findings will also be used to inform the next phases of MDA to improve further the yaws eradication effort.

ADP continued to support regulatory system strengthening in Ghana, which plays a critical role in the effective introduction and roll-out of any health technology. Through WHO, ADP support - from the formal assessment using the GBT for the evaluation of national regulatory authorities, to the development and implementation of the Institutional Development Plan (IDP) – contributed to the efforts of FDA Ghana in achieving a stable, well-functioning and integrated regulatory system.

In May 2020, WHO announced the attainment of “Maturity Level 3” – the second highest in the four-tiered WHO classification of national medicines regulatory systems – by FDA Ghana.<sup>5</sup> Ghana and the United Republic of Tanzania are the only two of the WHO African Region’s 47 countries to have attained a Maturity Level 3 ranking.

There has also been close collaboration with FDA Ghana to strengthen country

capacity for safety monitoring of new health technologies, including the establishment of a national electronic management system for individual case safety reports, the Safety Watch System. The system incorporates health care provider and consumer reporting portals, as well as allowing submission of reports by marketing authorization holders. ADP has further supported the introduction of a new mobile application, MedSafety, which facilitates fast and direct community reporting of adverse reactions. As part of the national roll-out, ADP is in the process of supporting FDA Ghana in designing and implementing an evaluation of the use and impact of MedSafety, as well as the deployment of information, education and communication materials to raise public awareness of the various reporting channels available in instances of adverse drug reactions.

ADP has supported the institutionalization of HTA and promotion of effective pricing regulation and policies to inform decision-making within the context of the NHIS, which will contribute towards ensuring access to cost-effective medicines and the sustainability of the NHIS.

ADP supported the Ministry of Health to develop the terms of reference for the HTA committee and a work plan to prioritize HTA implementation. The national HTA committee was launched in late 2019 and has requested further support from ADP on the institutionalization process.

ADP also supported the ongoing work of the National Medicine Price Committee and the finalization of the national guidelines for price regulation. Working with national partners, ADP will continue to support the implementation of the pricing policy in Ghana, including strengthening capacities for reference pricing and strategic procurement approaches, and the development and operationalization of a system for monitoring prices of medicines across the supply chain.

<sup>5</sup> See <https://www.afro.who.int/news/ghana-foods-and-drugs-authority-fda-attains-maturity-level-3-regulatory-status>, World Health Organization, 18 May 2020 (accessed on 10 July 2020).

# INDONESIA



Since its national health insurance scheme (JKN) was established in 2014, Indonesia has made remarkable progress towards its goal of achieving UHC, with coverage now reaching an impressive 82 percent of the population. However, persistent challenges remain. The national per capita health expenditure remains relatively low compared to other middle-income countries, and insufficient to deliver an essential UHC package.

Addressing these systemic issues – as well as ongoing health challenges such as maternal mortality and one of the world's highest TB burdens – will be essential to expanding UHC in Indonesia. ADP support in Indonesia thus focuses on reinforcing policy approaches and strengthening technical capacities that enable improvements in efficiency and value-for-money, equity and quality in the delivery of health services.

## Results and impact

Adopting best practices for the selection and prioritization of health technologies can help increase sustainability of JKN and continued progress towards UHC. In Indonesia, ADP support for strategies that promote cost-effective selection, prioritization and procurement of health technologies have included a regional price comparison study to identify improvements in pricing policies and practice; development of guidance and training for procurement of medical and laboratory equipment; and strengthening the use of HTA to inform decision-making. ADP has contributed to expanding the base of technical capacity for HTA in Indonesia, through regional exchanges and national trainings for personnel in the Ministry of Health and affiliated academic institutions.

Since 2014, ADP has partnered with the Indonesia National Agency for Drug and Food Control (Badan POM) to strengthen the national regulatory system. As Indonesia piloted the introduction of the new TB medicine, bedaquiline, for multidrug-resistant disease (MDR-TB) in adults – one of the first countries to do so – ADP collaboration with Badan POM and the national TB programme helped to establish an active safety monitoring

## ADP supported the national immunization programme to pilot SMILE in two districts and across 55 health facilities, reaching over 850,000 beneficiaries during the pilot period.

system that was instrumental in the inclusion of bedaquiline in the national standard treatment guidelines for TB. ADP is working with Badan POM and the National Pharmacovigilance Centre to further strengthen pharmacovigilance data management in MDR-TB treatment programmes, through the digital linkage between the WHO Global aDSM database (used for the surveillance of adverse events in patients under MDR-TB regimens) and eMESO (the electronic system used by Badan POM for adverse drug reactions reports).

Following the GBT assessment of Badan POM in 2018, ADP support has focused on addressing the capacity gaps identified, including on the role of national quality control laboratory in post-marketing surveillance (PMS) and the strategic concept of risk-based testing, to improve laboratory testing capacities to evaluate the quality of medicines.

In light of the transfer of responsibility for public procurement of health products from the National Public Procurement Agency of Indonesia (LKPP) to the Ministry of Health in 2020, ADP is working with both institutions and Badan POM to plan for the introduction of a Multiple Criteria Decision Analysis (MCDA) mechanism for medicines and medical equipment procurement. The MCDA is a process to evaluate multiple criteria – including price, quality, reliability of supply and health impact – in a decision-making process designed to inform the best overall value selection of health products and vendors for the national e-catalogue. Planning consultations with the three agencies to pilot the MCDA methodology were postponed due to the COVID-19 pandemic, but ADP is exploring options for supporting a situation analysis and capacity strengthening activities to enhance key stakeholders' readiness to use MCDA in the procurement process.

ADP supported the national immunization programme to pilot the Electronic Vaccine Intelligence Network (eVIN) in two districts and across 55 health facilities over the period of 2018–2019. The cloud-based digital application – eVIN, which is branded as “SMILE” in Indonesia – enables improved efficiency and integrity of vaccine cold-chains to

optimize vaccine supply, delivery and access. The SMILE system tracked 1.4 million doses of vaccines and reached over 850,000 beneficiaries during the pilot period. Within the first 12 months of implementation, vaccine stockouts were reduced by 55 percent and the ‘vaccine availability index’ reached 99 percent. Meanwhile, the level of over-stocking and stock wastage dropped by over 50 percent and 90 percent, respectively. With this success, SMILE will be scaled up in 2020 to over 600 health facilities across 11 provinces, reaching 9.4 million beneficiaries. Funding for the scale up has been secured via a grant of US\$2.3 million from GAVI, the Vaccine Alliance and a co-financing commitment from the Indonesia Ministry of Health. SMILE was rapidly deployed in the pilot districts, through a South-South technical exchange facilitated by ADP to share learnings from the success of the national scale up of eVIN in India.

Since 2014, ADP has collaborated with the Ministry of Health and Universitas Gadjah Mada on IR capacity strengthening, including the launch a national strategy on prioritization of health system research and training for TB, malaria and NTD management and control. Building on these efforts, ADP is supporting the Provincial Centre for Health Research and Development in Papua to build IR capacity. Dispersed communities present challenges for health services access in Papua, which is the largest province in the country with a relatively high burden of TB, malaria and NTDs. Strengthened research capacities will help optimize implementation of evidence-based health interventions in Papua. Capacity building activities are planned in 2020, using the ADP IR Toolkit as a resource, to identify and address barriers for effective disease control programmes for leprosy, helminthiasis, malaria and arbovirus.

# MALAWI



## Priorities for ADP support were identified in three key areas: establishing an enabling legal and policy environment; regulatory systems strengthening; and improved procurement policy and planning.

A heavy communicable disease burden, characterized by high prevalence of diseases such as HIV, TB, malaria and NTDs, and a rising epidemic of non-communicable diseases, are key challenges in Malawi.

The national Health Sector Strategic Plan (HSSP) II 2017–2022 outlines the goal of achieving UHC in Malawi, with the strategic approach providing an essential health package (EHP) to enable equitable access to quality health care by covering the costs of essential services. The HSSP II has highlighted the need for sustainable health care financing mechanisms, given that the cost of implementing the EHP exceeds available resources. As the Government of Malawi strives to meet the goal of equitable and affordable UHC, it also faces the challenge of increasing the human resources for health and strengthening institutional capacities for prevention and control of diseases. The work of ADP in Malawi has thus focused on supporting national institutions and strengthening the technical capacities involved in disease prevention and control, as well as the delivery of health services.

### Results and impact

When ADP first commenced its work in Malawi, consultations with national policymakers and government stakeholders from multiple sectors identified priorities for ADP support in three key areas: establishing an enabling legal and policy environment; regulatory systems strengthening; and improved procurement policy and planning.

ADP has continued to provide support to the multi-sectoral Technical Working Group within the Ministry of Justice and Constitutional Affairs, mandated with the task of recommending policy and legal reforms, and ensuring policy coherence across innovation, access and delivery of health technologies.

For regulatory system strengthening, ADP is working with the newly established Malawi Pharmacy Medicines Regulatory Authority (PMRA, formerly the Pharmacy,

Medicines and Poisons Board of Malawi) to identify areas of strengths and opportunities to further improve regulatory functions. Following the self-benchmarking of PMRA as part of the Southern African Development Community (SADC) Regulatory Harmonization Programme, specific capacity gaps within the regulatory system were identified. ADP will provide the corresponding support to guide capacity-strengthening activities, including a formal benchmarking exercise using the GBT and the development of an IDP.

PMRA recently established the National Pharmacovigilance Centre to enhance safety monitoring of medicines and vaccines in Malawi. ADP has focused its efforts to strengthen the institutional and human capacities within the Centre and PMRA. This included support for the development and implementation of a national work plan to integrate pharmacovigilance systems within public health programmes and the strengthening of reporting channels. By fostering collaboration and harmonization between the PMRA, public health programmes, and the central and district hospitals, ADP has also contributed to enhancing the pharmacovigilance capacities within public health programmes and reference hospitals.

Pharmacovigilance focal points have now been 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 pharmacovigilance system across all levels of the health system. ADP will continue to support the training of health workers at these hospitals on pharmacovigilance and the efficient reporting of adverse events. These interventions will contribute to enhanced safety monitoring and data management, in turn strengthening the national pharmacovigilance system that is crucial to ongoing roll-out of the new malaria vaccine.

There is also ongoing work with national agencies, including the Public Procurement and Disposal Agency

and the Central Medical Stores Trust, to develop capacity-strengthening interventions in procurement planning. This builds on country priorities identified by Malawi on procurement policy reform and planning at a global workshop convened by ADP, which brought together public health procurement stakeholders from eight LMICs from Asia and Africa, including Malawi.

On disease prevention and control, ADP supported the capacity-strengthening of the Ministry of Health and Population in conducting IR to identify and address barriers to health service access and uptake of new health technologies. Efforts included training on the application of IR concepts and the multidisciplinary approach to research involving biomedical and social scientists and health programme implementers involved in disease control, immunization, health service delivery, disease surveillance and laboratory testing. These training programmes focused on the identification and prioritization of implementation challenges as well as the development of research protocols and funding proposals for studies that aim to overcome barriers to more effective access, utilization and scale up of health interventions.

# SENEGAL



## **ADP supported capacity strengthening of the National Agency of Universal Health Financial Protection and Ministry of Health and Social Action for the institutionalization of HTA as a systematic approach to priority-setting and selection of new health technologies for UHC.**

The Government of Senegal has made a clear commitment to focus on specific priorities in realizing UHC: improving the quality of health-care provision; strengthening the health workforce; and protecting its citizens from catastrophic health expenditure.

As a measure to increase protection against catastrophic health expenditures – and reduce the health system's dependence on out-of-pocket spending – the government initiated a programme for universal health financial protection. Senegal now has three types of financial protection schemes: for formal sector employees; free health-care initiatives; and community-based health insurance as the strategic approach to reach the informal sector and rural areas. The latest data indicate that around half of citizens currently benefit from one of several existing protection mechanisms. In this context, one key area of ADP support has been in the provision of technical assistance for priority-setting and sustainable resource allocation.

### **Results and impact**

Given the goal of the Government of Senegal to achieve UHC by 2022, a critical priority for the country is the institutionalization of HTA as a systematic approach to evidence-informed priority-setting and selection of new health technologies for UHC. In this connection, ADP has supported the strengthening of technical capacities of personnel from the National Agency of Universal Health Financial Protection and Ministry of Health and Social Action (MHSA). Stakeholders were introduced to best practice tools and models for conducting health economic evaluation and obtained a better understanding of the evolving role of HTA in the context of UHC policymaking. Furthermore, ADP has leveraged its partnership with the Health Intervention and Technology Assessment Program (HITAP) in Thailand to explore a potential partnership with Hitotsubashi University (Japan) and the Japan International Cooperation Agency

(JICA) in providing further technical and capacity-building support on HTA. The MHSA 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 on-going to design interventions and develop work plans, with the aim of implementing activities when the COVID-19 travel restrictions are lifted.

In the previous reporting period, ADP collaborated with MHSA to establish a multidisciplinary coordinating platform to identify and address barriers that hinder implementation of national disease control programmes. ADP provided technical support to the platform, which involved government policymakers and technical experts from across national and subnational agencies, to identify the main bottlenecks in health programmes that could be addressed through operational research and IR.

In response to the health research priorities identified by the coordinating platform, ADP has focused its support on building the capacity of relevant stakeholders on principles and best practices in conducting IR and implementation of a programme designed to share related tools and approaches to strengthen the health system. The programme targets key personnel including programme managers, department heads, researchers, senior managers and members of regional and district health teams, as well as actors from public health institutions. In light of the COVID-19 travel restrictions, ADP partners are exploring online options for conducting training and capacity strengthening activities.

ADP increased its support to MHSA and the national regulatory body – Direction de la Pharmacie et du Médicament – in strengthening the regulatory system, by addressing several priorities identified by national stakeholders. First, ADP helped to identify the interventions and technical support required for the domestication of the AU Model Law,

which provides a strategic framework to guide systematic and speedier approval of new health technologies. Another priority area identified was the need to strengthen the reporting of adverse drug reactions and data management, as well as improving technical capacity and best practices for pharmacovigilance. ADP supported the development and implementation of a work plan aimed at strengthening the consolidation of the national pharmacovigilance system across the major disease control programmes. During 2020, existing safety monitoring tools used by these programmes will be updated according to current best practice, and regional focal points will be trained.

In addition, ADP supported the national regulatory body in performing a self-benchmarking exercise to identify key capacity gaps within the national regulatory system. The findings helped with preparations for formal benchmarking of the national regulatory system and functions using the GBT to identify capacity gaps and necessary interventions. The formal benchmarking, which was planned as an in-country exercise, has been re-scheduled due to the COVID-19 pandemic. ADP has also strengthened the capacity of regulatory inspectors, hospital pharmacists and suppliers on conducting regulatory inspection using GDP and quality risk management (QRM) principles. These new capacities will improve risk-based regulatory inspection and implementation of the minimum standards required to ensure quality and integrity of the pharmaceutical supply chain.

# UNITED REPUBLIC OF TANZANIA



**ADP collaborated with the Ministry of Health, Community Development, Gender, Elderly and Children and the National Institute for Medical Research to coordinate a multi-stakeholder platform to enhance planning and preparedness for the introduction and scale-up of new health technologies.**

A significant challenge to the Government's UHC commitment is the increasing financial burden to the National Health Insurance Fund (NHIF). In addition, the quality of health services remains another major challenge, hampered by insufficient health infrastructure and fragmentation of services. The Tanzania Health Sector Strategic Plan III (2015–2020) acknowledged the need for systems to improve quality as well as the need to address the fragmented health delivery system. As such, ADP has focused on supporting interventions that help to link up the value chain for access and delivery as a means of integrating the fragmented health delivery system.

## Results and impact

Children under five years of age – although a significant proportion of the 15 million Tanzanians at risk of schistosomiasis – are not currently covered by the mass treatment campaigns. This is due to the lack of a formulation of praziquantel appropriate for their age group. Anticipating the approval of a paediatric formulation of praziquantel, ADP collaborated with the Ministry of Health, Community Development, Gender, Elderly and Children (MoHCDGEC) and the National Institute for Medical Research (NIMR) to coordinate a multi-stakeholder platform to enhance planning and preparedness for the introduction and scale-up of new health technologies. The resulting integrated work plan addresses the fragmented health delivery system by building the systems and technical capacities necessary for fast-track introduction and deployment of new health technologies. While the work plan uses paediatric praziquantel as a model, it will also serve as a template for use in the introduction of other health technologies.

Building on this work and to address the gap in inventory management, ADP will support coordinated supply planning and forecasting of medical commodities at the primary health care level. While the COVID-19 pandemic has delayed this activity, ADP partners

are exploring options to provide technical support via online tools.

ADP support for regulatory system strengthening contributed to the Tanzania Medicine and Medical Devices Authority (TMDA) achieving “Maturity Level 3” in 2018, being the first country in Africa to do so. Since then, ADP has continued to support TMDA in addressing priority issues identified in the IDP, including the provision of technical assistance to TMDA for reviewing WHO prequalification requirements and for the re-inspection of the TMDA quality control laboratory, which is needed to maintain the national laboratory's rating at Maturity Level 3. During this exercise, ADP facilitated the participation of laboratory experts from Kenya and Zimbabwe to share their experience and knowledge on good laboratory practices with their Tanzanian counterparts.

To ensure sustainability of the national health insurance scheme, ADP had provided technical support for the review and revision of standard treatment guidelines and the national Essential Medicines List, which contributed to cost-effectiveness and increased coverage of the national health insurance benefits package, which now covers over 12 million beneficiaries. Building on these achievements, ADP is supporting the newly established HTA committee in Tanzania by facilitating the technical exchange and transfer of knowledge from the counterpart HTA committee in Ghana. This has helped to build political will and commitment among policymakers for the institutionalization of HTA, which are critical elements for the effective functioning and sustainability of the HTA committee. ADP supported the development of national HTA guidelines, drafting of HTA committee terms of reference, and the prioritization of HTA research topics. A draft HTA guideline is now under review by MoHCDGEC and awaiting approval.

In addition to the use of HTA to improve cost-effective selection of components within the national health insurance

benefits package, the need to contain costs of health technologies is also recognized. Following up on previous support to MoHCDGEC on sustainable and equitable pricing strategies, ADP supported a pricing analysis of medicines, which represent the highest cost drivers for the NHIF. Preliminary findings have identified some anomalies in pricing and opportunities for cost reductions, as well as helping to improve understanding of medicine consumption and costs. Further data collection and analysis will continue in 2020, and once completed, will inform decision-making and prioritization of the NHIF reimbursement list, improve the rational use of medicines and increase cost-savings and coverage of the NHIF.

Guidelines developed by ADP for supply chain management of NTD-focused MDA campaigns have been adopted by the national NTD programme for training of frontline health workers. Building on this achievement, ADP has broadened its support to other areas of the health supply chain. ADP co-convoked the Health Supply Chain Summit – which brought together over 300 participants from national health programmes, public and private health facilities, academia, supply chain implementing partners, and donors – to identify strategies to strengthen performance across each segment of the health supply chain. Identified priorities include strengthening alignment and coordination across the fragmented health supply chain, and enhancing data quality, analytics and linkages across national health programmes. There is also a need to promote enabling legal, regulatory and policy frameworks conducive to an efficient and reliable supply chain, including frameworks for price control and procurement. These priorities will inform the ADP work plan in 2020 and beyond.

# ADP RESOURCE COUNTRIES

India and Thailand play important roles as ADP resource countries, whereby their repositories of experience and technical expertise have been leveraged for the benefit of the ADP focus countries and other LMICs. A range of policymakers and technical experts from India and Thailand have been identified and drawn from the public and academic sectors to share their experience and expertise. ADP partners have also facilitated linkages between technical institutions in these two countries with those in other ADP focus countries.

This approach to capacity-strengthening has been valuable to build both policy and technical capacities, especially in the areas of HTA, digital health and IR, and has facilitated the replication of successful approaches and a greater depth of support in ADP interventions.

## INDIA



**ADP collaborates with the Ministry of Health and Family Welfare to promote South–South dialogue among LMICs on the adoption of HTA and digital health solutions as effective approaches for health system strengthening to achieve UHC.**

Significant challenges persist in the health system of India, including gaps in health care infrastructure, with stark differences in rural and urban services. Service delivery in India is also highly fragmented, with large numbers of mainly small providers delivering over 64 percent of health care.

But in less than two years since it was launched, the ambitious national health protection scheme in India – Ayushman Bharat – has moved the country a significant step closer to the goal of UHC. In that time, the scheme has reached close to 4 million people and saving an estimated \$1.6 billion for families. This represents concrete progress in India, where out-of-pocket household expenditure currently makes up about two thirds of all health care spending in India.

ADP has successfully leveraged the significant and innovative policy and programmatic experience of India in several ways. First, ADP is collaborating with UNDP India to enable the transfer of knowledge from the national roll-out of eVIN – an innovative digital technology platform for strengthening the vaccine cold-chain system – to address key infrastructure and information management constraints across the vaccine cold-chain. Building on the success of India in scaling eVIN across the entire country to improve vaccine availability and reductions in wastage, ADP facilitated South–South technical cooperation and technology transfer to enable the accelerated uptake of the system in Indonesia, and its forthcoming expansion to a further 600 health centres in 23 districts, reaching nearly 7 million beneficiaries (see section on Indonesia). Learning the lessons from India guided the successful mobilization of \$2.3 million funding from Gavi, the Vaccine Alliance, and a co-financing commitment from the national health budget for the scale up of eVIN in Indonesia. ADP is exploring further South–South technical

exchanges between India and other interested LMICs, with a view towards improving policymaking and planning for the introduction of new vaccines.

Secondly, to improve evidence-based policymaking and good practice related to epidemiology and surveillance, clinical trials and health economics of vaccines, ADP has also leveraged the expertise and experience of India in clinical and policy research related to vaccinology to improve capacities of national immunization programmes in ensuring safety, efficacy and cost-effectiveness of vaccines. Through its technical partner, HITAP, ADP has collaborated with the Translational Health Science and Technology Institute and the Jawaharlal Institute of Postgraduate Medical Education and Research in India to design and implement the ‘Vaccinology for Clinical and Public Health Practice’ course, which built scientific and technical capacity in vaccinology and promoted the institutionalization of evidence-informed policymaking among policymakers, programme managers and health professionals in 10 LMICs (see section on ‘Promoting cost-effectiveness and sustainability of UHC’).

ADP collaborates with the Ministry of Health and Family Welfare to promote South–South dialogue among LMICs on the adoption of HTA and digital health solutions as effective approaches for health system strengthening to achieve UHC. The plan is to leverage the relevant expertise and experience from key Indian institutions in an international conference. The conference was planned for February 2020 but has now been postponed until early 2021 due to the COVID-19 pandemic.

# THAILAND



**ADP has collaborated with HITAP to strengthen technical capacities across ADP focus countries on conducting multidisciplinary research to inform selection of health technologies for the national health insurance package and coverage under UHC programmes.**

The UHC policy of Thailand, now established for almost 20 years, has enabled the provision of essential preventive, curative and palliative health services to the whole population, and at all life stages.

As with countries in the process of establishing UHC systems today, however, there are constant challenges, including that of balancing increasing demands and rising costs. Several strategies have been adopted to lower excessive spending without lowering net health service delivery or impact.

It is building on this experience that ADP has collaborated with HITAP to strengthen technical capacities across ADP focus countries on conducting multidisciplinary research examining the cost, clinical effectiveness and other implications (e.g. sociocultural and ethical issues) to inform selection of health technologies for the national health insurance package and, hence, coverage under UHC programmes. As

part of ADP support to focus countries and its South-South strategy, ADP has partnered with HITAP to meet requests from government stakeholders in Bhutan, Indonesia, Kenya, Lao People's Democratic Republic and Senegal for support on the technical aspects and institutionalization of HTA in these countries (see section on 'Promoting the cost-effectiveness and sustainability of UHC').

In addition to leveraging expert resources from Thailand, ADP has also contributed to strengthening the capacities of Thai health institutions and systems. ADP, through WHO, supported the further development of the regulatory system, starting with a capacity assessment of the Food and Drug Administration (FDA) using the GBT. The benchmarking exercise identified specific capacity needs of the regulatory system that were prioritized in an IDP. To address the identified capacity gaps, ADP strengthened

the regulatory inspection function of the FDA Thailand by building the capacities of drug inspectors on several key technical areas. In the previous reporting period, capacities to implement best practices for inspection of clinical trials were highlighted to help ensure data quality and safety of human subjects. More recently, ADP supported FDA Thailand to strengthen capacities related to the use of the risk-based GDP regulatory inspection, as well as the functions of quality control laboratories and their role in PMS, to ensure that minimum standards of pharmaceutical quality and integrity are maintained throughout the supply chain (see section on 'Strengthening medicines regulatory capacity and harmonization'). The capacity for risk-based regulatory inspection of GMP was also strengthened according to WHO-recommended best practices and standards, ensuring full enforcement of GMP for medicines and vaccine manufacturers in Thailand.



# EXTENDING THE IMPACT OF ADP: REGIONAL AND GLOBAL INITIATIVES

The implementation experience of ADP, since its inception in 2013, provides a rich source of learning. ADP partners have therefore sought to leverage South–South learning to extend the impact of the Partnership’s work across an increased number of countries. Focusing on the common challenges across different health systems, South-South exchanges between focus countries have delivered both policy lessons and technical solutions.

## ADP South–South Exchange and Learning Platform

ADP established the South–South Exchange and Learning Platform in 2019 to facilitate the sharing of country experience from ADP focus countries, and to leverage lessons learned for a greater depth of national-level capacity-strengthening.

The second meeting of the South–South Exchange and Learning Platform in February 2020 brought together over 50 government stakeholders from the seven ADP focus countries – as well as Bhutan, Burkina Faso and Kenya. The meeting focused on sharing lessons learned from malaria and NTD control and prevention initiatives, with a view to identifying good practices for improved disease control and prevention. Aside from the representatives of the national disease programmes, participants also heard from the WHO Department of Control of Neglected Tropical Diseases on the new NTD Roadmap for 2021–2030 and the Malaria Vaccine Implementation Programme (MVIP), which coordinates

and supports the phased introduction of the RTS,S malaria vaccine in Ghana, Kenya and Malawi.

A key message arising from the discussions was the need for cross-sectoral and integrated planning to ensure “health technology preparedness” in LMICs. The meeting also allowed stakeholders to identify key country priorities and initiate joint planning with ADP partners. With the limitations imposed by the COVID-19 pandemic during the first half of 2020, ADP will explore the use of digital tools for the South–South Exchange and Learning Platform to serve as a forum for networking and exchange. A series of online ADP consultations will take place during July and August 2020, following up on the February 2020 meeting, to enable country stakeholders and partners to continue activity planning and the exchange of country experiences. The digital platform will also be a means for ADP partners to leverage innovative digital approaches in delivering and extending ADP technical support to countries.

## REGIONAL AND GLOBAL PLATFORMS

ADP has also initiated, or contributed to, several regional and global platforms that bring together policymakers and technical experts from LMICs to catalyse knowledge generation and learning on specific issues. The work and impact of these platforms are described below:

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### 1. Strengthening medicines regulatory capacity and harmonization

An important objective of ADP support to focus countries is regulatory system strengthening and harmonization, which is a critical component for access to quality-assured and safe health technologies. An estimated 10 percent of medical products in LMICs is either substandard or falsified, and up to 158,000 additional deaths from malaria could be caused every year by substandard and falsified antimalarials in sub-Saharan Africa.<sup>6</sup> 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 national regulatory systems to identify gaps and strengthen capacities and processes, and TDR provides technical support to national regulatory authorities on strengthening pharmacovigilance systems and related capacities.

### AU Model Law on Medical Products Regulation

ADP has been a long-standing partner of the African Union Development Agency (AUDA–NEPAD) in the efforts to strengthen regulatory harmonization

<sup>6</sup> [https://www.who.int/news-room/detail/28-11-2017-1-in-10-medical-products-in-developing-countries-is-substandard-or-falsified#:~:text=A%20second%20model%20done%20by,52.4%20million\)%20to%20patients%20and,World Health Organization, 28 November 2017 \(accessed on 13 July 2020\).](https://www.who.int/news-room/detail/28-11-2017-1-in-10-medical-products-in-developing-countries-is-substandard-or-falsified#:~:text=A%20second%20model%20done%20by,52.4%20million)%20to%20patients%20and,World Health Organization, 28 November 2017 (accessed on 13 July 2020).)

across the African region. One area of focus is the AU Model Law on Medical Products Regulation (AU Model Law). The AU Model Law is a key pillar of the African Medicines Regulatory Harmonization initiative, which aims to create an enabling policy and regulatory environment for timely access to quality-assured health technologies.

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 for medicines regulation.

ADP provided expert legal advice and technical support for the drafting of the AU Model Law. With the adoption of the AU Model Law by AU Heads of State, the partnership between ADP and AUDA-NEPAD is now focused on supporting AU Member States and regional economic communities to adopt the AU Model Law into national legal frameworks.

In collaboration with AUDA-NEPAD, ADP organized technical seminars and training workshops for regulators and legal experts from the regional economic communities and AU Member States to accelerate the process of domestication. A regional training workshop was organized in May 2019 for legal and regulatory experts from SADC and the Economic Community of West African States (ECOWAS) to provide technical assistance to the AU Member States for their AU Model Law adoption processes.

Through a survey conducted jointly with AUDA-NEPAD, ADP was able to provide the first comprehensive update on the domestication status and assess the technical assistance needs of AU Member States. This enabled the development of a key document that will be used by AUDA-NEPAD and other partners to guide their capacity-strengthening activities to reach all 55 AU Member States.

Given the shared target of 25 AU Member States to adopt the AU Model Law by 2020, ADP support to AUDA-NEPAD and AU Member States will be instrumental in ensuring continued progress towards the target.

In turn, this will contribute towards medicines regulatory harmonization for faster, more predictable and transparent approval of medical products in Africa.

## Building global and regional coalitions for regulatory system strengthening

In conjunction with the work on the AU Model Law, ADP has supported capacity-strengthening of national regulatory authorities (NRAs), which are responsible for the oversight of the quality and safety of medical products, particularly through an assessment of regulatory functions using the GBT and development of IDPs that aim to bring NRAs up to benchmarked international standards.

While an increasing number of organizations are now active in contributing to capacity-strengthening of NRAs, there has been little coordination of such support. To achieve greater coordination and effectiveness in medicines regulatory system strengthening efforts, ADP has facilitated, through WHO, the establishment of a Coalition of Interested Parties (CIP). This coalition-focused approach aims to improve harmonization, coordination and consistency in the provision of technical and capacity-building support, leading to a more efficient use of overall resources, greater consistency in standards and approaches, improved outcomes and impact, and less burdensome interventions for regulatory authorities.

Through its networks in the WHO African, Western Pacific and South-East Asia regions, the CIP coordinates

the efforts of the various partners and stakeholders in addressing capacity gaps within national and regional regulatory bodies and networks, work-sharing and harmonization. The CIP provides a web-based information-sharing platform that reaches countries and regional networks of NRAs in these regions. ADP has convened multiple stakeholder consultations to validate the principles and procedures of this new model for regulatory system strengthening and significant progress has been made in the establishment of the regional CIP chapters in Africa and Asia. For example, ADP supported AUDA-NEPAD in establishing and operating the Africa CIP chapter through the convening of the African Medicines Regional Harmonization Partnership platform.

ADP will support the launch of the comprehensive Global CIP framework in 2020. This framework includes a digital platform for easy sharing of information, resources and coordination. Regional meetings will also be convened across all three chapters to validate the CIP framework for regulatory system strengthening and develop work plans for their respective regions.

As part of harmonization efforts, ADP supported countries in the SADC region by co-organizing with the SADC Secretariat a meeting to promote joint assessment of new



medicines for marketing authorization in the region. Regulatory experts from Indonesia and Thailand were also invited, as part of a South-South technical exchange, to discuss and share best practices for regulatory convergence and harmonization, and the implementation of coordinated joint assessments.

ADP has also contributed to the Indo-Pacific Regulatory Strengthening Programme (RSP), which aims to enhance cooperation and coordination across the WHO Western Pacific and South-East Asia regions by identifying priority areas for regulatory strengthening, and to mobilize capacity-building assistance to national regulatory authorities. The RSP is led by the national regulatory authority of Australia, the Therapeutic Goods Administration, and currently covers seven countries: Cambodia, Indonesia, Lao People's Democratic Republic, Myanmar, Papua New Guinea, Thailand and Viet Nam. ADP contributed to the development of the RSP framework and technical understanding of GMP principles, the use of laboratory testing in quality assurance, efficient product registration business processes and pharmacovigilance frameworks.

## Strengthening capacities of national regulatory authorities in Africa and Asia

Ensuring that the quality and integrity of medicines is maintained throughout the supply chain is a key function of national regulatory authorities. ADP support in this area is aimed at consolidating and integrating international standards and best practices on distribution into national guidelines and operations.

ADP supported regional workshops on GDP for regulatory inspectors from Africa (Burkina Faso, Ghana, Malawi, Senegal, and the United Republic of Tanzania) and Asia (Bangladesh, Bhutan, India, Indonesia, Kazakhstan, Maldives, Myanmar, Nepal, Sri Lanka, Thailand, and Timor-Leste). The capacity of inspectors on the use of a risk-based approach and QRM principles during GDP regulatory inspections was strengthened to ensure that the quality and integrity of medicines is maintained throughout the supply chain. These national regulatory authorities are now equipped to ensure the quality of pharmaceutical products during all aspects of the distribution process.

ADP also supported a multi-stakeholder platform that brought together government officials, regulators, manufacturers and other stakeholders to discuss key enabling factors for the promotion of domestic pharmaceutical manufacturing capacity with a focus on quality assurance and GMP, good submission and regulatory practices, and leveraging on policy and business enablers to strengthen local production of medical products towards quality and sustainability, among other topics.

ADP also supported the strengthening of technical capacities of NRAs and quality control laboratories – from Burkina Faso, Ghana, India, Indonesia, Kenya, Malawi, Senegal, Thailand and the United Republic of Tanzania – on a range of technical protocols related to laboratory management, the evaluation of quality of medicines and the detection of substandard and falsified medicines. These capacity-building events, including the Annual Network of Official Medicines Control Laboratories (NOMCoL)–Asia-Pacific, the African Medicines Quality Forum and the Global Health Protection Programme Drug Quality Assurance training, facilitated common understanding and consensus on acceptable standards of practice. The African Medicines Quality Forum provided the opportunity to improve harmonization of quality control standards and practices, eventually leading to mutual recognition of quality control test results among African countries. Furthermore, ADP supported country participation at other platforms, including the Scientific Conference on Medical Products Regulation in Africa and the African Medicines Regulators Conference, which also promoted regulatory harmonization by strengthening partnerships between NRAs, alignment of regulatory networks and advancing discussions related to the establishment and operationalization of the African Medicines Agency.

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## 2. Promoting safe and efficient roll-out of new DR-TB treatment regimens

WHO treatment guidelines for drug-resistant tuberculosis (DR-TB) – that incorporate the shift towards oral regimens with new medicines such as bedaquiline – now recommend active TB drug safety monitoring and management (aDSM) and use of IR to maximize the



efficient and safe introduction of new TB treatment strategies. In line with these guidelines, ADP has supported training and South–South exchanges between national TB programmes and pharmacovigilance units in West Africa to enhance technical capacities on aDSM best practices relating to pharmacovigilance and the systematic use of IR.

Building on these efforts, ADP conducted follow up with individual countries to identify and address needs and priorities for further country-level technical support and capacity-building in relation to implementation of new guidelines for treatment of MDR-TB patients. As part of its South-South outreach, ADP provided support to the national TB programme in Burkina Faso on the management of adverse events and advocacy for the inclusion of alternative health care providers in pharmacovigilance. The planned follow up for a formal evaluation of systems and the development of a work plan for the national pharmacovigilance centre in Burkina Faso was delayed by the COVID-19 pandemic but ADP is exploring available options, including the use of online tools, to continue the technical support.

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### 3. Implementation research to address barriers to the introduction of new health technologies

ADP supports the expanded use of IR approaches as a means of identifying and addressing barriers to access, delivery and effective use of new health technologies in LMICs. Central to this approach is the use of the comprehensive *Implementation Research Toolkit (IR Toolkit)*, coupled with lessons learned and good practices of ADP support and activities in the focus countries, to strengthen capacities of health researchers and national disease programme managers.

The IR toolkit has also been translated into French to enable the training

of national malaria programme managers from ECOWAS countries on prioritizing research questions, designing appropriate methodologies and developing proposals for research funding. Building on these results, ADP convened two more South–South learning platforms in the Africa region. These platforms facilitated cross-country learning and exchange on policy, programmatic and technical issues representing common challenges across different health systems. A total of 16 multidisciplinary country teams representing 13 countries<sup>7</sup> participated at these platform workshops. Country teams were made up of policymakers, implementers, programme managers and academics working on disease control, medicines regulation, health procurement and health service delivery.

Guided by the IR Toolkit, participants were able to systematically apply key IR principles to formulate appropriate research questions for identifying and addressing barriers to health programme implementation encountered by the national disease control programmes in their own countries. Each country team developed a research proposal and an integrated work plan that aimed to address problems faced by the health systems in real life contexts, and which incorporated gender dimensions into the IR framework. Country teams have been able to leverage the IR platforms for ongoing advisory and implementation support for the development of research proposals and work plans, as well as mobilization of resources to implement the proposed research study. The regional learning platforms have also contributed to expanding the cohort of competent resource persons and experts who are available to sustain ongoing technical and capacity-building efforts in the African region. An online training-of-trainers module on the IR Toolkit for French-speaking facilitators will be held in 2020 so that

<sup>7</sup> Cameroon, Democratic Republic of the Congo, Ethiopia, Ghana, Kenya, Malawi, Nigeria, Rwanda, Somalia, Uganda, United Republic of Tanzania, Zambia and Zimbabwe



they can provide subsequent training to a broader group of francophone country stakeholders.

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## 4. Promoting the cost-effectiveness and sustainability of UHC

Priority-setting mechanisms and procedures can help ensure sustainable health resource allocation; particularly as national health systems seek to balance between the demands of expanding UHC benefits packages and limited resources.

ADP, in collaboration with HITAP, promotes health priority-setting through a knowledge platform that facilitates country stakeholders' access to critical resources and expertise in establishing national HTA mechanisms. The knowledge platform also facilitates South–South exchanges between policymakers and technical experts in LMICs, with a view to building a network of HTA practitioners sharing country experiences and best practices as a means of enhancing and sustaining capacity-development.

Through this platform, ADP has been able to leverage technical expertise to support HTA capacity-building, research studies and institutionalization processes across a range of countries, including Bhutan, Ghana, India, Indonesia, Kenya and Lao People's Democratic Republic. Responding to a request from the Bhutan Ministry of Health, technical experts from HITAP and Hitotsubashi University have initiated a collaboration with the Ministry of Health to design a HTA study to estimate a cost-effectiveness threshold that will inform



sufficient flexibility for decision-making that addresses the specific needs of the health sector, including ensuring best value-for-money.

the expansion of the UHC package in Bhutan. The HTA knowledge platform also includes an ongoing collaboration with the School of Public Health, National University of Singapore, and the International Decision Support Initiative (iDSI) that has convened several regional training programmes for senior regulators, health policymakers and practitioners from across Africa and Asia. The HTA training sessions focused on providing a comprehensive perspective on the use of HTA, from the policy and application level, as well as promoting a multi-disciplinary approach to prioritizing and implementing health policies and programmes.

## 5. Value-based procurement policy and practice

As LMICs accelerate towards UHC, governments are grappling with meeting competing health needs and safeguarding the availability of needed health technologies, while attempting to contain costs. ADP is thus focusing its efforts to increase awareness of strategic approaches for 'value-based' planning and procurement of medical equipment in the public sector.

Value-based planning and procurement approaches help maximize the impact of limited resources and help move countries towards both the achievement and sustainability of UHC. The global procurement landscape is rapidly changing and new insights around procurement policies specific to health commodities are needed to improve procurement and health system efficiency. While procurement policies in LMICs aim to promote transparency and accountability, and reduce corruption in public procurement processes, such policies and practices may not allow

ADP has initiated a South-South exchange among national procurement authorities and health ministries in ADP focus countries and other LMICs to enhance understanding of policy, strategic and methodological approaches, with the aim of promoting the incorporation of health-related requirements into national procurement policy frameworks. To this end, ADP is also developing a guide on the next generation of procurement policies, including good practice examples and country experiences, to inform and support public procurement agencies and ministries of health in LMICs on procurement policy reform.

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.<sup>8</sup> ADP has developed a guide to support public sector procurement systems in LMICs. Based on the training module ADP developed with the Indonesia national procurement agency (LKPP) for its use in the national procurement training programme of Indonesia, the guide aims to promote value-based decision-making, which takes account of the full medical equipment lifecycle and highlights the importance of planning and procurement processes that identify and address health, clinical and facility needs. The guide will be published in 2020 and will be a resource for national procurement agencies to support training of procurement personnel at the national and sub-national levels.

8 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).

## ADP GLOBAL CONTRIBUTIONS

### Uniting Efforts for Innovation, Access and Delivery

Since 2018, ADP, in close partnership with the GHIT (Global Health Innovative Technology) Fund and the Government of Japan, has coordinated a global platform for technology delivery preparedness- Uniting Efforts for Innovation, Access and Delivery (Uniting Efforts).<sup>9</sup> The Uniting Efforts global platform convenes key stakeholders in funding, innovation and access and delivery of health technologies for neglected diseases, to drive greater collaboration and progress for aligned action across the innovation-access-delivery continuum. The aim is to promote LMIC preparedness to introduce new health technologies as they become available, through identification and early planning of the strategies and needed interventions to access and deliver the technologies.

Following up on priority issues identified during the inaugural Global Dialogue, held in January 2019, Uniting Efforts convened over 50 key experts and partners at two technical sessions in September 2019 to provide substantive inputs for the priorities, policies and strategies that improve preparedness for technology access and delivery. Three key knowledge products and tools were identified and commissioned to support early-stage planning for health technology access and delivery during the R&D phase, and strategies to improve innovative and sustainable financing for access to and delivery of neglected disease interventions.

The Second Global Dialogue was held in February 2020 and brought together over 100 stakeholders from multiple

9 See: [www.uniteffort sforhealth.org](http://www.uniteffort sforhealth.org) (accessed on 11 July 2020).

disciplines, including governments (both donor and endemic country governments), innovators, funders, delivery specialists, civil society, academics and other stakeholders, including multilateral and United Nations agencies. Discussions centred around improving critical pathways and coherent policies governing progress from basic science and R&D, to eventual access and delivery at the community level. The Second Global Dialogue facilitated discussions and sharing of good practices around planning for access and delivery in R&D for neglected diseases, as well as strategies to improve financing. The discussions also highlighted the relevance of the three key knowledge products identified during the September 2019 technical sessions: a review of access policies and practices in R&D, a landscape of funding for access and delivery of health technologies for neglected diseases, and a framework for investment cases for neglected diseases. There was consensus that these knowledge products will help enhance decision-making for policymakers, with positive impact on strategies and investments across the innovation, access and delivery continuum. As such, ADP, the GHIT Fund and the Government of Japan will focus efforts on validating these knowledge products and their eventual use. The aim is to enable their effective use so that a common approach towards innovation, access and delivery may be engendered across the global network of product development partnerships and delivery-focused organizations.

This collaborative initiative with the GHIT Fund and the Government of Japan will continue to be a major focus for ADP in transforming the way that health technologies for neglected diseases are financed, discovered, developed and delivered. Specific efforts will continue to strengthen the linkage between the global platform and other relevant efforts in 2020, including the Global Action Plan for Healthy Lives and Well-Being for All (SDG3-Global Action Plan), the WHO Roadmap for Neglected Tropical Diseases

2021–2030 and the planned 2020 Kigali Summit on Malaria and NTDs.

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## Integrating gender dimensions into access and delivery

Communicable diseases disadvantage people of different genders, including women and girls, in different ways, depending on prevailing context and individual health status. Environmental and structural factors, including sub-standard living conditions and a lack of safe water and sanitation, intersect with biological, social, economic and cultural factors to shape vulnerability to and experiences of TB, malaria and NTDs. By understanding similarities and differences in how people of all genders and sexes are vulnerable to and experience these diseases can inform national health systems and enable development partners to deliver equitable prevention, diagnosis and treatment services.

ADP commissioned two studies that explored the gender dimensions of NTDs and how gender impacts NTD risks and outcomes. In collaboration with the Liverpool School of Tropical Medicine, ADP published the Discussion Paper on The Gender Dimensions of Neglected Tropical Diseases<sup>10</sup> that analyses gender inequalities related to NTDs and provides a set of recommendations that address these challenges to deliver equitable prevention, diagnosis and treatment services. The paper reviews evidence on how sex and gender impact NTD risks and outcomes, highlighting current data as well as implementation gaps. Recommendations in the paper include a call for greater investment in sex-disaggregated data and implementation research in NTD-related initiatives to explain the impact of sex and gender on NTD risk, prevention

and access to treatment. The paper was launched during a dedicated symposium at the Annual Meeting of the American Society of Tropical Medicine and Hygiene in November 2019.

ADP is also conducting a gender analysis of the second Model List of Essential In Vitro Diagnostics published by WHO in 2019 and the equivalent national EDLs in several LMICs. Recognizing the essential role that in vitro diagnostics (IVDs) play in advancing UHC, the goal of these EDLs is to increase access to appropriate, affordable and quality-assured IVDs for the most common conditions, as well as a number of priority diseases. The exploratory research is focused on gender equity and gender dynamics at multiple levels in relation to the listed diagnostics and aims to develop a framework for evaluating the gender dimensions of diagnostic products for the gender sensitization of EDLs. The analytical tools for the study have been developed, and data collection is currently underway.

<sup>10</sup> See: [https://adphealth.org/upload/resource/2523\\_AD\\_P\\_Discussion\\_Paper\\_NTDs\\_211119\\_web.pdf](https://adphealth.org/upload/resource/2523_AD_P_Discussion_Paper_NTDs_211119_web.pdf) (accessed on 11 July 2020).



# LOOKING AHEAD

Travel restrictions and lockdowns across the world have temporarily interrupted how ADP works. Nevertheless, ADP core partners have been able to continue their engagement with country stakeholders throughout the current reporting period – including through virtual consultations and face-to-face dialogues.

While the current circumstances require a new level of agility on the part of ADP partners, they have not undermined the main purpose and goals of ADP. Rather, in many countries, the COVID-19 pandemic has shone an intense light on the importance of expanding coverage of health services and improving access to quality-assured diagnostics, medicines and vaccines. It has also underlined how fragmented processes for innovation, access and delivery of health technologies strain the ability of health systems to provide full and affordable access to quality health care, particularly in times of crisis.

The notable alignment between ADP objectives, focus and approach and the exigencies of the COVID-19 pandemic are a strong validation: Health system strengthening for greater access and delivery of health technologies is more important today than ever. Pandemic responses add to these needs, but do not fundamentally alter them.

Moving ahead, common capacity gaps across the health technology value chain of many LMICs are likely to become increasingly evident as COVID-19-related health technologies become available and fast-track options are sought to ensure their timely introduction in countries. The ongoing focus of ADP on access and delivery will therefore continue, cognizant of the need for national health systems to achieve a balance between minimizing the impact of COVID-19 and, at the same time, mitigating disruptions to other essential health programmes and services – such as those addressing TB, malaria and NTDs. Maintaining the most critical prevention activities and health care services for such diseases will significantly reduce the indirect impacts of the COVID-19 pandemic on poor and marginalized populations.

National lessons learned along the ADP innovation–access–delivery value chain should be shared and utilized to help countries grappling with this dual priority; highlighting the need for rapid flows of information and practical solutions among countries to enable evidence-based preparedness and decision-making.

During July and August 2020, ADP will hold a series of virtual consultation events to enable country stakeholders and other partners to collectively

identify shifting country needs. This is part of the ADP partners' efforts to provide continuous support to LMICs to enable access and delivery of vital health technologies. It will build on the February 2020 meeting of the ADP South-South Exchange and Learning Platform, wherein a cross-disciplinary meeting of experts and country stakeholders considered how integrated, multisectoral engagement can improve access to and delivery of new health technologies. The ADP South–South Stakeholder Online Consultation series will also offer a starting point for assessing available options that can promote sustainability and resilience of health systems. This will include developing opportunities to leverage other innovative digital approaches in delivering and extending ADP support to countries. ADP will provide a digital platform for LMICs to exchange country experiences and technical solutions for the strengthening of health systems in the context of the COVID-19 pandemic.

While vital, the digital evolution of the work of ADP also underscores the importance of optimizing and leveraging the already existing networks and partnerships that have been fostered by ADP over the past seven years.

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