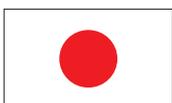




THE ACCESS AND
DELIVERY PARTNERSHIP

New Health Technologies for TB, Malaria and NTDs

STATUS REPORT 2015



From the People of Japan



*Empowered lives.
Resilient nations.*



Copyright © UNDP January 2016

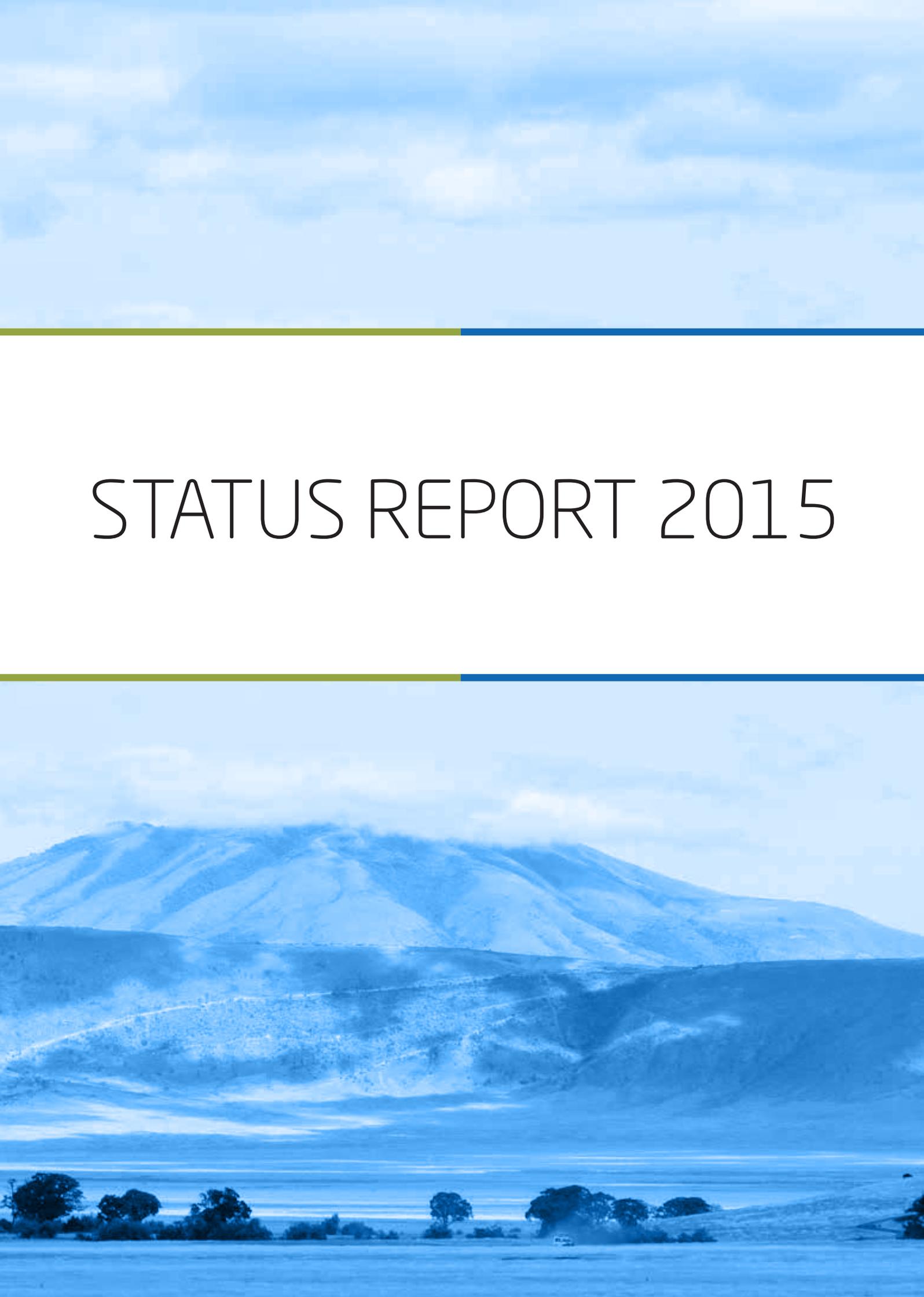
All rights reserved

UNDP, TDR, PATH (2016). The Access and Delivery Partnership: Status Report 2015 (New York).

Disclaimer: The opinions expressed in this publication do not necessarily represent the policies of UNDP or UN Member States.

Design and layout: Inis Communication





STATUS REPORT 2015



Credit: Dominic Chavez/World Bank



CONTENTS

List of abbreviations	ii
About the Access and Delivery Partnership	iii
Partners	iv
The ADP in the sustainable development context	3
How ADP works	4
Country ownership	6
Cross-sectoral and multi-stakeholder collaborations	6
South-South learning and cooperation	7
Achievements and results	9
Ghana.	10
Indonesia	13
Tanzania	16
Regional and cross-cutting initiatives	20
Looking forward	24

LIST OF ABBREVIATIONS

ADP	Access and Delivery Partnership
AMRH	African Medicines Regulatory Harmonization
API	Active Pharmaceutical Ingredients
ARV	Antiretroviral drugs
AU	African Union
COSTECH	Commission for Science and Technology, Tanzania
EAC	East African Community
FDA	Food and Drug Administration
GHIT Fund	Global Health Innovative Technology Fund
HITAP	Health Intervention and Technology Assessment Program, Thailand
HIV	Human Immunodeficiency Virus
HTA	Health Technology Assessment
IHPP	International Health Policy Program, Thailand
LMICs	Low- and Middle-income Countries
MDGs	Millennium Development Goals
MOH	Ministry of Health
MOHSW	Ministry of Health and Social Welfare
NADFC	National Agency for Drug and Food Control
NEPAD	New Partnership for Africa's Development
NGO	Non-governmental Organization
NIMR	National Institute for Medical Research
NTDs	Neglected Tropical Diseases
PMPA	Pharmaceutical Manufacturing Plan for Africa
PSS	Pharmaceuticals Service Section
R&D	Research and Development
SDGs	Sustainable Development Goals
TB	Tuberculosis
TDR	Special Programme for Research and Training in Tropical Diseases
TFDA	Tanzania Food and Drug Authority
UHC	Universal Health Coverage
UN	United Nations
UNDP	United Nations Development Programme
WHO	World Health Organization
WHO-CC	World Health Organization Collaborating Centre for Advocacy and Training in Pharmacovigilance

ABOUT THE ACCESS AND DELIVERY PARTNERSHIP

The adverse impact of tuberculosis (TB), malaria and neglected tropic diseases (NTDs) on development outcomes has resulted in new approaches and partnerships to tackle the global deficiencies in research and development, and treatment access. One such initiative is the strategic partnership between the Government of Japan and UNDP, which promotes research and development, and expedites access to and delivery of health technologies used to address TB, malaria and NTDs. This partnership comprises two complementary components, which reflect the Government of Japan's and UNDP's strategic goals on global health:

The **Global Health Innovative Technology (GHIT) Fund**, which focuses on the promotion of innovation and research through the development of drugs, diagnostics and vaccines for TB, malaria and NTDs. The GHIT Fund stimulates research and development of new health technologies through funding research and product development partnerships between Japanese and non-Japanese organizations.

The **Access and Delivery Partnership (ADP)**, which aims at assisting low- and middle-income countries (LMICs) enhance their capacity to access, deliver and introduce new health technologies for TB, malaria and NTDs.

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

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

The ADP is a five-year project, running from April 2013 until March 2018. This report outlines implementation of Year 2 of the ADP (1 July 2014 – 15 May 2015).



From the People of Japan

PARTNERS



*Empowered lives.
Resilient nations.*

United Nations Development Programme

UNDP works in some 170 countries and territories, helping to achieve the eradication of poverty, and the reduction of inequalities and exclusion. We help countries to develop policies, leadership skills, partnering abilities, institutional capabilities and build resilience in order to sustain development results.



The Special Programme for Research and Training in Tropical Diseases

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



PATH

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



THE ACCESS AND DELIVERY PARTNERSHIP

New Health Technologies for TB, Malaria and NTDs



Credit: Arne Hoel/World Bank

THE ADP IN THE SUSTAINABLE DEVELOPMENT CONTEXT

By focusing on key diseases that hamper sustainable development and by taking an integrated, health systems based approach to strengthening the access and delivery value chain, the ADP project exemplifies the SDG approach to health and development.



The human development impact of TB, malaria and NTDs is significant. These are diseases of poverty and inequality, disproportionately affecting the 836 million people who live below the US\$1.25 per day extreme poverty line¹.

TB remains one of the world's deadliest communicable diseases; in 2014, an estimated 9.6 million people developed, and 1.5 million died from, TB². In the same year, an estimated 3.3 billion people globally were at risk of malaria, with a total of 214 million cases and 438 000 deaths. Malaria is the leading cause

of death among children under five years of age in sub-Saharan Africa³.

NTDs have significant impact across multiple development sectors, including water and sanitation, nutrition, maternal and child health, education, and global and national economic output – therefore, on long-term sustainable development. In 2012, 1.9 billion people were estimated to require preventive chemotherapy for at least one NTD, accounting for a disease burden of at least 26 million disability-adjusted life years (DALYs).³

Despite their impact, few new health technologies have been developed to combat these diseases. For example, during 2000–2011, only

37 (4 percent) of the 850 new therapeutic products registered were for neglected diseases, and only four new chemical entities (1 percent) of the 336 approved during the same period were for neglected diseases.⁴

The recently adopted Sustainable Development Goals (SDGs), explicitly calls for the elimination of TB, malaria and NTDs as a development priority. Under SDG 3, the goal to “Ensure healthy lives and promote well-being for all at all ages”, target 3.3 aims to “end the epidemics of AIDS, tuberculosis, malaria, and neglected tropical diseases and combat hepatitis, water-borne diseases, and other

1 UN, 'The Millennium Development Goals Report', 2015

2 WHO, 'Global Tuberculosis Report 2014', WHO Press, Geneva, 2014.

3 WHO, 'World Malaria Report 2014', WHO Press, Geneva, 2014.

4 Pedrique B., et al. (2013). The drug and vaccine landscape for neglected diseases (2000–11): a systematic assessment. The Lancet Global Health 2013; 1: e371–79



Credit: Lucy Perry/Hamlin Fistula Relief and Aid Fund Australia

communicable diseases”⁵ by the year 2030. The SDGs also advocate a broad, systemic approach to tackling these diseases, underlining the importance for health systems strengthening and universal health coverage (UHC). Target 3.8 aims to, “achieve UHC, including financial risk protection, access to quality essential health care services, and access to safe, effective, quality, and affordable essential medicines and vaccines for all”.

The Government of Japan has led the way in adopting new approaches to address these deficiencies in research and development, and access to health technologies for TB, malaria and NTDs. A twin-pronged approach has been adopted

to ensure the greatest impact; while the GHIT Fund focuses on promoting innovation and research through the development of new health technologies for TB, malaria and NTDs, the ADP complements and supports the GHIT Fund through the building of capacities in LMICs to enable and expand access and delivery of these new health technologies to populations in need.

The SDGs align closely with the Government of Japan’s new global health strategy “Basic Design for Peace and Health”, which emphasizes the need for better health as an indispensable component of human and social development. It commits to assisting LMICs to strengthen health systems, security and resilience, and deliver

UHC by ensuring affordable access to basic health services for all.

The ADP exemplifies the vision of the SDGs and the Government of Japan’s global health strategy. It not only targets the most devastating diseases – TB, malaria and NTDs – afflicting LMICs, but it does so by helping to build long-term capacity in LMICs’ health systems to access and deliver essential new health technologies. It works along the entire access and delivery value chain – from ensuring an enabling policy and regulatory environment and removing bottlenecks and barriers to access, to ensuring that supply chains reach all segments of the population, including the most vulnerable and those in remote locations.

5 <https://sustainabledevelopment.un.org/focussdgs.html>

HOW ADP WORKS

Frameworks for introduction of new health technologies by countries typically involve the innovation or R&D on new technologies stage, which is followed by the introduction or preparation of the new technologies for use by target populations, and finally, the integration phase where new technologies are integrated in routine use within the health system, ensuring that they are able to reach and benefit target populations.

A country's decision-making capacity and processes are critical in each of these phases to enable the successful access to, and delivery of, new health technologies. The ADP approach is thus predicated upon the assumption that strengthening a country's decision-making capacities and processes will improve the uptake of innovative technologies, resulting in increased health impact. Furthermore, the focus on strengthening decision-making processes is based on two important reasons: first, building and strengthening mechanisms for effective decision making is most amenable to long-term improvements to access and delivery; second, this approach allows the ADP to capture learnings and best practices from the focus countries, which will benefit other LMICs, enabling strategic South-South collaboration and learning.

The ADP is focused on three key competencies that define a country's capacity to address these decision-making bottlenecks:

Access and utilization of various **information** are vital to the decision-making process. Such information often relate to existing laws, policies and regulations; efficacy and resource requirements; pricing and procurement issues; clinical guidelines on safety and quality; as well as disease epidemiology.

To support decision making, relevant stakeholders need sufficient **technical expertise and capacity** to understand, interpret and assess information related to these technologies. Technical areas that the ADP focuses on include epidemiology, health technology assessment, cost analysis, legal and policy analysis, market analysis and procurement/forecasting, among others.

Another key requirement is the presence of a well-defined and transparent **decision-making process** and management infrastructure. Typically, decision making on new health technologies involves multiple government agencies and stakeholders within each country. Therefore, the presence of a coordinating mechanism is important in providing coherent policy guidance to facilitate decision making.

By working to strengthen all three competencies related to decision making, the ADP project helps focus countries strengthen country ownership, political will, leadership and commitment to address key national health priorities; and build stronger and more resilient health

systems. In turn, countries are able to accelerate their progress towards universal health coverage, improve health security and eliminate TB, malaria and NTDs.

The ADP project activities have been structured along six strategic, inter-related "Pathways" that help to build capacity in decision-making processes along the entire value chain of access to and delivery of new health technologies.

Pathway 1 strengthens national capacities for developing a coherent and enabling policy and legal environment that properly addresses the intersections of public health and other sectors, including industrial, trade and fiscal policies to ensure affordable access to, and sustainable delivery of, new health technologies. Policy coherence entails balancing and integrating the range of public health, trade, fiscal and other priorities within a country's framework of laws and policies.

Pathway 2 focuses on developing the capacity to identify and address bottlenecks impeding scaled up deployment and use of new health technologies. Health technologies that have been successful in strictly controlled clinical trials may not be as effective when used in real-life contexts of a country's health system. Impediments may be related to the physical environment, socioeconomic or cultural issues, as well as health systems and user characteristics. The focus of Pathway



The Access and Delivery Partnership (ADP) aims at assisting low- and middle-income countries (LMICs) enhance their capacity to access, deliver and introduce new health technologies for TB, malaria and NTDs.

**ADP Pathways
for capacity
building in:**

Developing an enabling policy and legal framework for equitable access and delivery of new health technologies. **1**

Identifying and addressing bottlenecks impeding scaled-up deployment and use of new health technologies. **2**

Improving safety monitoring of new health technologies in real-life contexts. **3**

Promotes evidence-based decision-making on national resource allocation and commercialization of new health technologies. **4**

Strengthen capacity of delivery systems for new health technologies. **5**

Build a base for strategic information and evidence. **6**

To achieve:



**Improved access
to information**



**Enhanced technical
expertise**



**Strengthened
structures for
decision making**

**Country ownership,
leadership and
political will**

**Equitable access to and
sustainable delivery of
health technologies**

**Health systems strengthening to meet
Sustainable Development Goals**



Health Security



Universal Health
Coverage



Disease Elimination
(TB, malaria, NTDs)

2 therefore, is on strengthening the capacity of national stakeholders to systematically identify and address such bottlenecks and barriers.

Pathway 3 strengthens capabilities for monitoring the safety of new health technologies in real-life contexts. The scaled-up deployment and use of new technologies in any population will invariably result in previously unanticipated events and adverse reactions. A functional system that efficiently and effectively detects, assesses, understands and manages or prevents adverse effects, or any other possible drug-related problem within national health systems is crucial.

Pathway 4 promotes evidence-based decision making in relation to national resource allocation and commercialization of new health technologies, including appropriate pricing. As a number of new health technologies come to market, there is a need for national governments to be able to set priorities and rationalize the use of limited resources, including through the conduct of health technology assessments (HTA), to ensure increased access to health technologies at appropriate pricing for maximum health impact. This is particularly important for countries that are moving towards UHC.

Pathway 5 aims to strengthen the capacity of delivery systems, including supply chains for new health technologies. Bottlenecks can occur at any point in the supply chain, but there is often more risk for disruption and delays when introducing a new health technology. This presents significant challenges to LMICs in creating a reliable supply of high-quality medical

commodities, which is critical to prevent disruption of public health programmes and serve the needs of a diverse and dispersed population.

To help tailor the support provided by the ADP, an additional stream of activities, **Pathway 6**, focuses on building a base of strategic information and evidence, which includes development of technical guidance notes and briefing papers to strengthen engagement with policy and legal issues related to access and delivery.

The ADP project partners have identified Ghana, Indonesia and Tanzania as the focus countries for the project based on an assessment of existing in-country/domestic capacity, availability of information, political will and commitment, and the potential for cooperation. Thailand was identified as a partner country for the ADP project in order to leverage the considerable experience of its policy-makers and technical experts on the development of enabling policy and legal environment for access and delivery, and to facilitate South-South learning.

The design and implementation of the ADP activities along the Pathways is informed by strategic approaches that promote country ownership, cross-sectoral collaboration, and South-South learning and cooperation.

Country ownership

The ADP works closely with governments and national stakeholders in focus countries to ensure that the support provided by the ADP is contextually appropriate and effective, and addresses

priorities defined by country stakeholders. By strengthening efforts owned and driven by partner country governments, this approach also helps to secure the long-term sustainability of the processes that ADP activities contribute to.

In Year 1, the ADP focused its efforts on establishing relationships with government stakeholders and champions, building on the comprehensive, context-specific evidence base that the ADP partners have consolidated through extensive consultations and in-country reviews. As a result, while ADP is supporting the governments in all three focus countries Indonesia, Tanzania and Ghana – in their efforts to achieve UHC, the support has focused on different aspects of UHC in each country. For example, in Indonesia, the ADP activities have largely focused on developing legal and policy coherence, as well as capacities for health technology assessments (HTA), whereas in Tanzania, emphasis has been placed on developing implementation research capacities to identify and address bottlenecks in the utilization of new health technologies. In Ghana, the ADP is providing support to ensure effective implementation of the National Medicines Policy, which is a crucial component of the government's efforts towards UHC.

Cross-sectoral and multi-stakeholder collaborations

The ADP promotes an integrated approach and cross-sectoral collaborations in recognition of the fact that actions outside the health

sector are critical in addressing the broader determinants of health. This approach is particularly pertinent to activities under Pathway 1, which aim at ensuring coherence between policies and laws across sectors such as health, trade, industrial development and science and technology, among others, to enable improved access to and delivery of new health technologies. However, this approach is applied in activities across all the Pathways, whenever applicable.

In addition to working across sectors, the ADP also seeks to bring together perspectives from a wide array of stakeholders in the access and delivery value chain, such as policy makers, researchers, technical experts, civil society and the private sector.

The ADP also seeks to catalyze strategic partnerships between national governments and global stakeholders, including the UN agencies and other development partners, to help strengthen access and delivery systems for new health technologies. For example, in Indonesia, the ADP collaborated with the National Drug Regulatory Agency and the WHO Safety and Vigilance department in conducting a workshop on pharmacovigilance and cohort event monitoring, which not only strengthened routine pharmacovigilance systems but also facilitated networking between pharmacovigilance experts and staff of public health programs. In Ghana, the ADP has made substantial contributions to reducing duplication in malaria research by bringing together health research and academic institutions, the private sector and development



partners such as the WHO country office, UNDP and the Roll Back Malaria partnership.

South-South learning and cooperation

The ADP prioritizes mutual exchange of knowledge and learning between the focus countries and with other LMICs that have successfully implemented processes to enable better access to, and delivery of, new health technologies. For example, the ADP successfully leveraged the experience of policy-makers and technical experts in Thailand on key aspects of health governance, particularly in relation to health technology assessment and the strengthening of an enabling policy and legal environment for access to health technologies.

Another example of South-South learning facilitated by ADP is the collaboration between two regional training centres – at the Universitas Gadjah Mada, Indonesia, and the School of Public Health at the University of Ghana – who are jointly developing an assessment tool for implementation research capacity.

Furthermore, the ADP aims to bridge the gap between national level efforts in focus countries and broader regional, continental and international frameworks and initiatives. The ADP has convened several regional level activities and workshops in Asia and Africa to enable knowledge-exchange and sharing of learning between regional and national initiatives. It is also providing technical assistance to governments of focus countries to align their laws, policies and processes with regional and international frameworks.

For example, in Ghana the ADP is supporting the government's objective of implementing the African Union's Pharmaceutical Manufacturing Plan for Africa (PMPA) by helping to develop policy coherence between various national sectors relevant to domestic manufacturing and public health. In Tanzania, which is part of the East African Community (EAC) initiative for regulatory harmony for medicines, the ADP supported a study which assessed the level of integration of continental and sub-regional initiatives related to access and delivery.



Vulgaires
Machins

Ghana

“The support the Ghana National Drug Programme has received from the ADP in reviewing the [new] National Medicines Policy has been very valuable and timely. This policy is set to change the face of the pharmaceutical sector of Ghana”

Edith Gavor, Programme Manager,
Ghana National Drugs Programme,
Ministry of Health, November 2015



The Primate's World Relief and Development Fund (PWRDF)

Indicator	Data
Human Development Index Ranking	140
Population total (millions)	26
Gross national income per capita (USD)	3,852
Population living below \$1.25 a day (%)	29
Public health expenditure (% of GDP)	5
Life expectancy at birth (years)	61
Under-5 mortality rate (per 1000 live births)	78
International Trade (% of GDP)	89
Incidence of TB (per 100,000 population) ^a	165
Total deaths due to TB (per 100,000 population) ^a	52
Total deaths due to malaria (per 100,000 population) ^b	54
No. of school age children treated for Soil Transmitted Helminths / treatment coverage (%) ^c	2,289,325 / 100%
No. of people treated for Lymphatic filariasis / treatment coverage (%) ^c	7,859,416 / 77%
No. of people treated for Onchoceriassis ^c	3,495,861

All data are from 2013 and derived from UNDP (2014) Human Development Report unless where stated

- a WHO (2015). Global Tuberculosis Report 2015 (data from 2014). Retrieved on 15 December 2015 from https://extranet.who.int/sree/Reports?op=Replet&name=%2FWHO_HQ_Reports%2FG2%2FFPROD%2FEXT%2FTBCountryProfile&ISO2=TZ&LAN=EN&outtype=html
- b WHO (2015). World Malaria Report 2015 (data from 2013). Retrieved on 15 December 2015 from <http://www.who.int/malaria/publications/world-malaria-report-2015/en/>
- c WHO Global Health Observatory Data Repository. Retrieved on 15 December 2015 from <http://apps.who.int/gho/data/node.country.country-GHA?lang=en>



Credit: Neil Palmer/CIAT



Credit: Neil Palmer/CIAT



Credit: Stefano Peppucci/Flickr



Credit: Dominic Chavez/World Bank



Credit: Stefano Peppucci/Flickr

The ADP has promoted multi-sectoral coherence through its support for the effective implementation of the National Medicines Policy, which expresses the government’s commitment to universal access to affordable medicines. It is also providing technical assistance to help align Ghana’s national manufacturing policies with the African Union’s Pharmaceutical Manufacturing Plan. The ADP is helping to move implementation research up in the policy agenda and developing long-term training facilities on implementation research for Ghana and the region.

In Ghana, the ADP has focused on Pathways 1, 2 and 3 – strengthening policy coherence, addressing bottlenecks to deployment of new health technologies and developing capacities to monitor the safety of newly introduced health technologies.

To ensure sustainable access to new health technologies that will meet country needs, the ADP has promoted policy coherence and alignment between the various national sectors relevant to health, medicines regulation and industry. In Year 2, the ADP collaborated

with the Ministry of Justice and the Attorney-General’s office to conduct an assessment of the current policy and legal framework in Ghana to enhance coherence of policies relating to innovation, public health and access to health technologies. The ADP proposes further work in this area with the Ministry of Justice and the Attorney-General’s office to on strengthening the capacity of Parliamentarians for integrating public health considerations in the legal framework in the country. The ADP’s efforts on promoting legal and policy coherence is in synergy

with the government’s objective of implementing the African Union’s Pharmaceutical Manufacturing Plan for Africa (PMPA).

To further strengthen policy coherence, the ADP is also supporting the MoH on the effective implementation of the National Medicines Policy (NMP). The NMP covers a broad range of issues, from medicines selection, access and pricing, and sustainable supply issues to the development of pharmacovigilance capacity, all of which will facilitate the government’s efforts towards achieving UHC. The ADP is helping to develop key tools for the effective implementation of the NMP, including an implementation plan and cost estimates, a monitoring and evaluation plan to measure implementation progress, and an advocacy and communications plan to create greater awareness of the policy goals and objectives.

To identify and address implementation bottlenecks in the utilization of new health technologies, the ADP is leveraging the network of regional health research centers of the Ghana Health Service (GHS) to focus on strengthening capacity to meet country-specific health system needs. In collaboration with the GHS, along with the national malaria, TB, yaws and NTDs control programmes, the ADP is sensitizing key decision makers on the importance of implementation research; and strengthening the capacity of national stakeholders, including health care providers, program managers and researchers, to identify and address implementation bottlenecks that limit the effectiveness of health interventions, strategies and policies. Through a process of analysis of the key challenges, available resources and capacities using a standard scale, a series of implementation research questions that are appropriate in meeting country needs were developed and prioritized. In Year 3, a high level meeting on implementation research has been planned to prioritize implementation challenges and setting of the national health research agenda.

The ADP's approach to bringing together diverse stakeholders on implementation research in Ghana has also resulted in reduced duplication and maximized efficiencies in malaria research. By working with health research and academic institutions, the GHS, the private sector and development partners (WHO country office, UNDP and the Roll Back Malaria partnership), the ADP supported the mapping and documentation of all ongoing, and planned malaria research in Ghana.

In order to ensure sustained capacity building and continued growth of human resource on implementation research in the country, the ADP has been working with the GHS and the School of Public Health, University of Ghana (UOG) to provide technical support in establishing regional training centres for health research, with specific emphasis on implementation research. Furthermore, the ADP is strengthening human resource capacity on implementation research by supporting UOG researchers to participate in TDR's global training scheme for LMICs on implementation research

on malaria, TB and NTDs. The ADP also facilitated South-South collaboration between two regional training centres at Universitas Gadjah Mada, Indonesia, and UOG, who are jointly developing an assessment tool for implementation research capacity at country level.

Lastly, to help improve safety monitoring of new health technologies, during Year 2 the ADP began supporting the Regional Centre of Regulatory Excellence in Pharmacovigilance and Pharmacoepidemiology in Ghana on improving systems and piloting innovative approaches for safety monitoring at the community level. A proposal to pilot the use of mobile technology for safety monitoring at the community level is being developed with the help of the ADP and the study should begin by early 2016.

Indonesia



Credit: Lorrie Graham DFAT/Flickr



Credit: Anna & Michal/Flickr

Credit: J Moses Ceaser/Center for International Forestry Research (CIFOR)

“The objectives and proposed activities of the ADP are consistent with the approaches that we have taken in addressing TB, malaria and NTDs. I am confident that the work of the Partnership will make an important contribution to the efforts of the government.”

Prof. Agus Purwadianto, Former Senior Adviser to the Minister of Health Indonesia, Government of Indonesia, February 2014

Indicator	Data
Human Development Index Ranking	110
Population total (millions)	253
Gross national income per capita (USD)	9,788
Population living below \$1.25 a day (%)	16
Public health expenditure (% of GDP)	3
Life expectancy at birth (years)	69
Under-5 mortality rate (per 1000 live births)	29
International Trade (% of GDP)	50
Incidence of TB (per 100,000 population) ^a	399
Total deaths due to TB (per 100,000 population) ^a	49
Total deaths due to malaria (per 100,000 population) ^b	3
No. of school age children treated for Soil Transmitted Helminths / treatment coverage (%) ^c	614,510 / 1%
No. of people treated for Lymphatic filariasis / treatment coverage (%) ^c	24,425,649 / 25%
No. of people treated for Schistosomiasis / treatment coverage (%) ^c	10,392 / 56%

All data are from 2013 and derived from UNDP (2014) Human Development Report unless where stated

- a WHO (2015). Global Tuberculosis Report 2015 (data from 2014). Retrieved on 15 December 2015 from https://extranet.who.int/sree/Reports?op=Replet&name=%2FWHO_HQ_Reports%2FG2%2FPRD%2FEFT%2FTBCountryProfile&ISO2=TZ&LAN=EN&outtype=html
- b WHO (2015). World Malaria Report 2015 (data from 2013). Retrieved on 15 December 2015 from <http://www.who.int/malaria/publications/world-malaria-report-2015/en/>
- c WHO Global Health Observatory Data Repository. Retrieved on 15 December 2015 from <http://apps.who.int/gho/data/node.country.country-GHA?lang=en>

The ADP's close collaboration with national stakeholders in Indonesia has contributed to a cross-sectoral approach for addressing barriers to effective access to and delivery of new health technologies. Key successes have included active engagement with a range of government agencies to facilitate greater coherence in the policy and legal framework, improved safety monitoring and enhanced capacity in health technology assessments, which are important elements for achieving Indonesia's national goal of universal health coverage.

In Indonesia, the ADP activities spanned Pathways 1 to 5. A notable achievement for the ADP has been its active engagement with a network of national stakeholders to develop an integrated multi-sectoral approach to improve access and delivery of new health technologies. As part of its efforts on strengthening the integration of public health perspectives into policy and legal frameworks, the ADP has collaborated with the Ministry of Law and Human Rights (MoLHR) and a cross-section of other government actors whose various areas of responsibilities affect domestic research and development, pharmaceutical production and access to health technologies. These actors include policy-makers and experts from the Ministries of Health, Trade, Industry, Development Planning, MoLHR and the Food and Drug Authority.

The ADP is contributing to capacity strengthening of MoLHR staff members on integrating public

health perspectives within policies and laws in various sectors by supporting the development of a training curriculum. The ADP is also currently supporting the MoH to conduct a mapping of stakeholders, technical assistance providers and donors in the public health arena and the access and delivery value chain to identify key actors and areas for further strengthening of policy coherence. This mapping exercise is ongoing and findings will be available in Year 3.

Introduction of a new treatment for multidrug-resistant TB, bedaquiline, was identified as a key national priority for Indonesia during Year 1 of the ADP. This priority prompted the ADP to support both the scale up of new health technologies relating to TB diagnosis (GeneXpert, Digital X-ray) and treatment (bedaquiline) and in strengthening capacities for active safety monitoring and pharmacovigilance.

The ADP worked in collaboration with the National Drug Regulatory Agency (NDRA), the national TB program and the pharmacovigilance teams in hospitals to ensure early detection and proper management of adverse drug reactions. In conjunction with the NDRA and the WHO Safety and Vigilance Department, the ADP conducted a workshop that strengthened routine pharmacovigilance systems and networking between pharmacovigilance staff and public health programs, as well as introducing participants to cohort event monitoring. The efforts in strengthening the systems and capacities related to the introduction of bedaquiline provided an entry point for the ADP to support



Credit: Ben Pederick, Good Morning Beautiful Films/Depart

relevant stakeholders on developing and utilizing the tools for active surveillance of not only bedaquiline, but also of other innovative drugs that will be entering the market in the future.

Legal and policy frameworks that promote the access to, and delivery of, new health technologies need to be complemented by evidence-based decision making on national resource allocation for, and prioritization of, new health technologies. Therefore, the ADP is contributing to capacity development of Indonesia's Health Technology Assessment (HTA) unit within the Ministry of Health (MoH) to undertake systematic, multi-disciplinary evaluation of new health technologies. This will help ensure that introduction of new technologies



ment of Foreign Affairs and Trade

are based on sound assessments of country needs and cost-effective allocation of resources. These processes are also critical for generating the most ‘value for money’ and equity within the health system and inform the development of a health financing strategy for delivering the appropriate benefits package as Indonesia moves towards UHC.

As part of strengthening the capacity for implementing HTA in Indonesia, the ADP also facilitated South-South knowledge-exchange involving Thailand’s Health Intervention and Technology Assessment Program (HITAP) and South Korea’s National Evidence-Based Healthcare Collaborating Agency (NECA), which shared their experience and technical knowledge on

establishing and institutionalizing HTA in their countries. The ADP worked with HITAP to design an appropriate training curriculum that focuses on developing skills and building experience on conducting economic evaluations and implementing appropriate financing mechanisms, and developing policy recommendations relating to public health program design and investment decisions. In Year 3, the ADP will provide support on addressing the capacity gaps in the MoH and implementation of the next steps for piloting and scaling up the HTA approach in Indonesia.

In order to improve deployment of new health technologies, the ADP, in consultation with national stakeholders, has helped identify key bottlenecks, challenges and

capacity gaps in procuring new medical equipment. The challenges in Indonesia include a lack of product knowledge for developing specifications, limited information on quality standards and limited information on market prices of new health technologies. Geographically remote locations were found to be particularly restricted in their access to technical resources. As a result of these findings, the ADP supported the MoH develop a capacity building action plan and training tools, in collaboration with relevant government agencies and development partners.

Tanzania



Credit: William Hertha/www.hertha.com

“The ultimate results of [ADP-supported capacity-building] effort shall be a strong and integrated health system and also increased access to and efficient delivery of new technologies for health.”

Dr Mwelecele N Malecela
Director General, National Institute for
Medical Research, March 2015

Indicator	Data
Human Development Index Ranking	151
Population total (millions)	51
Gross national income per capita (USD)	2,412
Population living below \$1.25 a day (%)	44
Public health expenditure (% of GDP)	7
Life expectancy at birth (years)	65
Under-5 mortality rate (per 1000 live births)	52
International Trade (% of GDP)	50
Incidence of TB (per 100,000 population) ^a	327
Total deaths due to TB (per 100,000 population) ^a	112
Total deaths due to malaria (per 100,000 population) ^b	32
No. of school age children treated for Soil Transmitted Helminths / treatment coverage (%) ^c	563,423 / 4.2%
No. of people treated for Lymphatic filariasis / treatment coverage (%) ^c	17,114,802 / 42.9%
No. of people treated for Schistosomiasis / treatment coverage (%) ^c	2,882,418 / 27.59%

All data are from 2013 and derived from UNDP (2014) Human Development Report unless where stated

a WHO (2015). Global Tuberculosis Report 2015 (data from 2014). Retrieved on 15 December 2015 from https://extranet.who.int/sree/Reports?op=Replet&name=%2FWHO_HQ_Reports%2FG2%2FPROD%2FFEXT%2FTBCountryProfile&ISO2=TZ&LAN=EN&outtype=html

b WHO (2015). World Malaria Report 2015 (data from 2013). Retrieved on 15 December 2015 from <http://www.who.int/malaria/publications/world-malaria-report-2015/en/>

c WHO Global Health Observatory Data Repository. Retrieved on 15 December 2015 from <http://apps.who.int/gho/data/node.country.country-GHA?lang=en>



The ADP is providing policy support to stakeholders in Tanzania for the effective integration of regional access initiatives with national efforts, as well as the initiation of a priority setting process to inform on health technology introduction. The ADP activities are also making important contributions to capacity development in Tanzania in the areas of implementation research and supply chain management.

In Tanzania, a key area of work identified by country stakeholders is the need for improved legal and policy coherence to promote innovation, access and delivery of new health technologies. The ADP conducted an assessment of the level of integration of continental and sub-regional initiatives within national frameworks; as well the level of coordination and coherence of national laws and policies on science and technology, R&D and innovation, industrial development and drug regulation. This study identified potential linkages and alignment

between sub-regional efforts and national level implementation, and provided key recommendations for policy and legal reforms aimed at increasing access to medicines and diagnostics within the public supply chain system, including through measures to promote production, innovation and technology transfer.

Another important area of work for the ADP in Year 2 has been in capacity building of health professionals on implementation research in order to ensure effective deployment of new health technologies and

effective implementation of health interventions.

The ADP also supported the development of a national implementation research agenda and related action plans and research protocols in collaboration with the National Institute for Medical Research (NIMR), the Ministry of Health and Social Welfare (MOHSW) and national disease control programmes, as well as national health researchers and academics. This implementation research agenda will play an important role in informing future training initiatives in the country.

In Year 2, the ADP invested significant effort in strengthening the capacity of the health workforce to improve pharmacovigilance of new medicines. The ADP worked with the Tanzania National Drug



Credit: Math Mattern/Flickr



Credit: Yoni Lerner/Flickr



Credit: Tim Cronin/CIFOR

Regulatory Authority (TDFA) in establishing a cohort of trainers by conducting a series of Training of Trainers (TOTs) for staff members from public and private facilities, disease control programmes (HIV, TB and malaria) and regional pharmacovigilance centres from 7 regions around the country. In Year 3, these trainers will lead regular trainings on pharmacovigilance for health care workers at public and private health facilities, with support from the ADP. The ADP also supported two key TDFA staff members by pairing them up with New Zealand’s medicines and medical devices safety authority to learn about technical and organizational best practices.

In order to ensure efficient allocation of national resources and improve access to new health technologies, the ADP is supporting the government of Tanzania on strategy development for local production and improving capacity for implementation of the HTA mechanism. A key identified gap is the limited market intelligence on priority products and pricing, which impact production strategy. Working closely with the Pharmaceutical Services Section (PSS), the ADP is conducting research on the local and regional market competition of the pharmaceutical sector. This study will be completed during Year 3 and the findings will inform implementation planning and strategy development of

the Government of Tanzania’s Pharmaceutical Sector Action Plan 2014–2020, as well as the plan for the roll out of the African Union’s PMPA.

In April 2015, the ADP collaborated with the PSS, Directorate of Health Quality Assurance, HITAP (Thailand) and PRICELESS (South Africa), to jointly hold an introductory workshop to help strengthen capacity to develop a priority setting process, including potential utilization of the HTA mechanism, to inform policy development related to the introduction and inclusion of appropriate health technologies within Tanzania’s plans for UHC. The workshop identified potential areas in which the ADP and its



Credit: PWRDF/Flickr



Credit: Zahur Ramji (AKDN)/USAID

partners could provide support, including the integration of a priority setting process in the revision of the National Essential Medicines List (NEML) and the composition of the benefits package under UHC.

Lastly, the ADP collaborated with PSS on improving supply chain performance by strengthening of communication and coordination between different actors along the supply chain, as well as improved understanding on structured planning and procurement processes for the introduction of new health technologies. Through a series of workshops, the ADP is helping to develop an action plan on supply chain management, which will become an official component

of the Tanzanian National Pharmaceutical Action Plan.

The ADP also developed guidelines for the supply chain management of NTDs medicines for mass drug administration (MDA) campaigns, in collaboration with central-level decision makers at the PSS, the Medical Stores Department, Neglected Disease Control Program and MOHSW, as well as health professionals from the district, facility and community levels. These will be distributed to guide pharmacists, frontline health workers and community drug distributors on various aspects of supply chain management of NTDs medicines in the lead up to the next scheduled MDA campaign

in February 2016. Building on lessons learned in Year 2, the ADP will continue to work with global stakeholders, including the WHO Department of Control of Neglected Tropical Diseases, to contribute to the evidence base for global best practices in NTDs supply chains. The ADP also began working on a trainer of trainer's curriculum for supply chain management of NTDs during MDA campaigns, which will be pilot tested in late 2015.

REGIONAL AND CROSS-CUTTING INITIATIVES

“ADP takes a systemic approach to improve the decision-making capacity of countries to choose, develop and deliver health technologies that are suited to that particular country’s context. This approach is very much in line with the holistic approach taken by the AU Commission.”

Dr. Marie-Goretti Harakeye, Head of Division, Social Affairs Department, African Union Commission, April 2015

Beyond country level activities, the ADP has enabled South-South learning and exchange through regional activities and workshops in Africa and Asia and is helping to build a robust knowledge base on the introduction of new health technologies related to TB, malaria and NTDs.

Enabling South-South learning

In Year 2, the ADP organized a number of regional activities as a

means of enabling South-South exchanges and learning between countries in the two regions. Given that growing numbers of LMICs have been able to implement innovative approaches in issues such as policy coherence, improving local production, implementation research and health technology assessment, the regional meetings and workshops facilitated fruitful discussion and sharing of a cross-section of experiences, strategies and good practices. The regional meetings provided a useful forum to share information on the ADP’s approach, which has generated demand for technical support and knowledge products within ADP focus countries and beyond.

Furthermore, in light of constraints around human and financial resources in LMICs, the regional meetings were valuable in strengthening communication, collaboration and technical and learning networks, among high-level policy makers and technical experts across national, regional and international levels. Members of these networks were able to identify common priorities and needs, which promoted a more integrated approach towards decision making on matters impacting public health innovation and access to health technologies.

In partnership with the Ministry of Foreign Affairs of Indonesia and the

Non-Aligned Movement Centre for South-South Technical Cooperation (NAM CSSTC), the ADP supported a workshop in November 2014 with over 70 policy makers from agencies of health, trade and foreign affairs from member states of the Association of South East Asian Nations (ASEAN). This workshop built greater awareness among policy makers of the implications of existing health policies, and trade and investment agreements, on innovation and access to medical technologies; and promoted a better understanding of the intersections of these issues at the global, regional and national levels. Furthermore, the workshop provided a forum for ASEAN policy makers to explore the possibility of a regional approach within ASEAN to address the challenges to innovation in public health and equitable access to medical technologies; which prompted participants to identify opportunities for improved collaboration across sectors for a more integrated approach towards decision making and key strategic areas for possible South-South exchange and collaboration relating to access and delivery.

In May 2015, as a follow-up to the ASEAN-NAM meeting, the ADP organized a regional consultation in Bangkok, Thailand on integrating public health considerations into innovation and industrial frameworks in LMICs. The meeting



Credit: Albert González Farran/UNAMID

brought together 30 participants from China, Indonesia, Malaysia, Thailand and Vietnam. Based on a guideline produced by the ADP, the consultation meeting strengthened the technical and decision-making capacities of technical officers from health ministries and drug regulatory authorities to ensure appropriate balance of public health priorities and the promotion of innovation.

An African regional meeting on promoting policy coherence for innovation in and access to health technologies took place in April 2015 in Addis Ababa, Ethiopia. Working in partnership with the UNDP Regional Centre for Africa and the African Union Commission, this meeting brought together over 90 delegates from 12 Anglophone countries in sub-Saharan Africa. Participants included high-level government representatives from multiple

sectors, including health and drug regulation, trade and industry, science and technology, finance and business, and foreign affairs, as well as representatives from academia, research institutes and regional bodies. The involvement of stakeholders from multiple sectors enhanced understanding of the need for alignment within policy and legal frameworks to ensure innovation for, and access to, new health technologies.

In order to leverage South-South cooperation on implementation research capacity building, the ADP provided technical support to establish the Universitas Gadjah Mada (UGM) in Indonesia as a regional training centre for health research, with specific emphasis on implementation research, for the South East Asia region. The ADP also helped promote South-South

collaboration between the two regional training centres at UGM and UOG, who are jointly developing an assessment tool for implementation research capacity at country level. The sustainability and scope of South-South learning will be further strengthened in Year 3 when the ADP facilitates exploration of potential areas of research collaboration and synergies between UGM and the Noguchi Memorial Institute for Medical Research in Ghana.

The ADP contributed to improved understanding, new knowledge and advancement of the methodological approach to pharmacovigilance by organizing a regional discussion on Cohort Event Monitoring (CEM), which is one of the key strategies for adverse events surveillance, especially in the early phase of product launch. Effective implementation of CEM is critical

for new drugs, in particular new TB medicines in the pipeline, but this approach needs further development. The outcome of the discussions informed the improvement in the effectiveness of CEM for new drugs.

Capacities and strategies related to scaling-up of a new seasonal malaria chemoprevention (SMC) and safety monitoring systems in 10 sub-Saharan African countries were promoted by the ADP. Representatives from national malaria control programmes and pharmacovigilance centres participated in a regional workshop at the end of 2014 on preparing for the upcoming SMC campaigns. This workshop provided the opportunity to analyse the situation in each country; identify the specific needs in resources, capacities and strategies for active pharmacovigilance at the community level in the context of SMC; and learn lessons from countries like Ghana, which have in the past piloted innovative approaches for safety monitoring.

Contributing to the knowledge-base on new health technologies

In order to develop the knowledge base on access to and delivery of new health technologies, the ADP commissioned a number of global studies. In Year 2, a mapping of pipeline technologies for TB, malaria and NTDs was conducted. This product pipeline analysis identifies the drugs, diagnostics and vaccines expected to be ready

for market introduction by 2020. The analysis also provides a better understanding of the implications of introducing new health technologies in resource-limited settings, by highlighting the additional requirements or burdens on existing health systems in LMICs, particularly where they relate to establishment of new regulations on active pharmacovigilance systems; to supply, distribution and storage processes; and to health workforce training. The analysis also identifies key issues related to requirements at international policy level such as recommendations, endorsements, prequalification and monitoring on the introduced innovations.

The ADP also commissioned a series of case studies to document “good-practice” examples from select LMICs that have successfully demonstrated the re-shaping of conventional governance structures to facilitate multi-sectorial, inclusive and participatory processes, leading to coherent policies and laws that are public-health sensitive. Because experiences in complex health systems may not be easily transferred from one country to another, these case studies placed an emphasis on trying to understand how the context shapes the practices in LMICs, with a view for extrapolating lessons and identifying the necessary conditions and incentives to stimulate such South-South exchanges in the future.

A review of laws and policies on requirements for mandatory reporting of adverse drug reactions (ADR) by health professionals was also commissioned by the ADP. While this review will help to identify enabling factors and challenges



Credit: Enea Pestelacci/Flickr

for the introduction of mandatory reporting of ADR in the context of Indonesia, the findings will be used to inform the strengthening of laws and policies in the other ADP focus countries, as well as other LMICs.

As a means of disseminating the ADP knowledge products to a global audience, a public website for the ADP project was launched in Year 2 (www.adphealth.org). Targeted outreach to development partners, public health practitioners and policy makers is also being undertaken through the use of social media tools such as Twitter, blogs and electronic newsletters.



THE ACCESS AND DELIVERY PARTNERSHIP

HOME ABOUT APPROACH FOCUS COUNTRIES UPDATES CONTACT US

THE ACCESS AND DELIVERY PARTNERSHIP

New Health Technologies for TB, Malaria and NTDs

Scroll Down

www.adphealth.org

LOOKING FORWARD



Credit: James Maiden/Center for International Forestry Research (CIFOR)

In Year 3, the ADP will continue to build on the achievements and lessons learned in the past two years. Under the guidance of its Advisory Group, the ADP will continue to work with focus countries, while facilitating the sharing of lessons and tools with other countries to expand the project's impact.

The ADP will continue to showcase its integrated approach, which will be particularly pertinent in the context of the broad, systemic approach

adopted by the SDGs for addressing the interlinkages of health and development. The ADP project represents a new development paradigm that can help address 'silos' in decision and policy-making. These silos traditionally prevent coherent approaches in the public health and broader development frameworks. In order to further this integrated, innovative approach, the ADP will actively engage with community groups and civil society actors as important stakeholders, building

their capacity on issues around access to health technologies. This engagement will provide added value by broadening the input into the ADP and into broader discussions with relevant product development partnerships.

The ADP will focus on increasing the sustainability and scope of capacity building at the country level. In addition to implementing the range of capacity-building activities and interventions in focus countries, the



ADP will strengthen its engagement with, and support the optimization of, existing regional and global platforms/networks to enhance South-South learning. Collaborations with technical partner country, Thailand, will be further strengthened in order to optimize the existing resources and competencies and learn from their approaches and experiences.

To create demand and generate impact beyond the focus countries, engagement with global and

national stakeholders will be further strengthened. The ADP will seek to document experiences and lessons from the implementation process through case studies, guidance notes and other types of knowledge products. These knowledge products will help to disseminate the learnings from the ADP focus countries to LMICs more broadly and ensure maximum impact.

ADP ADVISORY GROUP MEMBERS

Garry Aslanyan

Amie Batson

Samir Kumar Brahmachari

Pedro Conceição

Mandeep Dhaliwal (Chair)

Peter J. Hotez

Marie-Goretti Harakeye Ndayisaba

Shiba Phurailatpam

Suwit Wibulpolprasert

CONTACTS

For additional information about the Access and Delivery Partnership, please contact:

Tenu Avafia

Team Leader

Law, Human Rights and Treatment Access

HIV, Health and Development Team

United Nations Development Programme

304 East 45th Street, FF-10108B

New York, NY 10017

tenu.avafia@undp.org

Cecilia Oh

Programme Advisor

HIV, Health and Development Team

United Nations Development Programme

Bangkok Regional Hub

3rd Floor, UN Service Building

Rajdamnern Nok Avenue

Bangkok, Thailand

cecilia.oh@undp.org



*Empowered lives.
Resilient nations.*

HIV, Health & Development Team
Bureau for Policy and Programme Support
United Nations Development Programme
304 East 45th Street, 10th Floor
New York, NY10017
USA

www.undp.org
www.adphealth.org

