STATUS REPORT 2016
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## ACRONYMS AND ABBREVIATIONS

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full Form</th>
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<tbody>
<tr>
<td>ADP</td>
<td>Access and Delivery Partnership</td>
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<tr>
<td>AIDS</td>
<td>Acquire Immune Deficiency Syndrome</td>
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<tr>
<td>BPOM</td>
<td>National Agency for Drug and Food Control (Indonesia)</td>
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<tr>
<td>GHIT Fund</td>
<td>Global Health Innovation and Technology Fund</td>
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<td>GHS</td>
<td>Ghana Health Service</td>
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<tr>
<td>Global Fund</td>
<td>Global Fund to Fight AIDS, Tuberculosis and Malaria</td>
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<tr>
<td>HITAP</td>
<td>Health Intervention and Technology Assessment Programme (Thailand)</td>
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<tr>
<td>HIV</td>
<td>Human Immunodeficiency Virus</td>
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<tr>
<td>HTA</td>
<td>Health Technology Assessment</td>
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<td>HTAC</td>
<td>Health Technology Assessment Committee (Indonesia)</td>
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<tr>
<td>KPPU</td>
<td>National Competition Authority (Indonesia)</td>
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<tr>
<td>LF</td>
<td>Lymphatic filariasis</td>
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<tr>
<td>LKPP</td>
<td>National Public Procurement Agency (Indonesia)</td>
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<tr>
<td>LMIC</td>
<td>Low- and middle-income country</td>
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<tr>
<td>MDA</td>
<td>Mass drug administration</td>
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<tr>
<td>MDR-TB</td>
<td>Multidrug-resistant tuberculosis</td>
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<tr>
<td>MOH</td>
<td>Ministry of Health</td>
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<tr>
<td>MOH-CDGEC</td>
<td>Ministry of Health, Community Development, Gender, Elderly and Children (Tanzania)</td>
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<td>MoLHR</td>
<td>Ministry of Law and Human Rights (Indonesia)</td>
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<td>NEML</td>
<td>National Essential Medicines List</td>
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<td>NIMR</td>
<td>National Institute for Medical Research (Tanzania)</td>
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<td>NMP</td>
<td>National Medicines Policy</td>
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<td>NPC</td>
<td>National Pharmacovigilance Centre (Indonesia)</td>
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<td>NTDs</td>
<td>Neglected tropical disease</td>
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<td>PC</td>
<td>Preventive chemotherapy</td>
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<td>PDP</td>
<td>Product development partnership</td>
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<td>R&amp;D</td>
<td>Research and development</td>
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<tr>
<td>SAC</td>
<td>School-aged children</td>
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<td>SCH</td>
<td>Schistosomiasis</td>
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<tr>
<td>SDG</td>
<td>Sustainable Development Goal</td>
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<tr>
<td>STH</td>
<td>Soil-transmitted helminths</td>
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<tr>
<td>TB</td>
<td>Tuberculosis</td>
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<tr>
<td>TDR</td>
<td>Special Programme for Research and Training in Tropical Diseases</td>
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<td>TFDA</td>
<td>Tanzania Food and Drug Authority</td>
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<tr>
<td>UGM</td>
<td>Universitas Gadjah Mada</td>
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<td>UHC</td>
<td>Universal health coverage</td>
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<td>UNDP</td>
<td>United Nations Development Programme</td>
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<tr>
<td>UN ESCAP</td>
<td>United Nations Economic and Social Commission for Asia and the Pacific</td>
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<td>WHO</td>
<td>World Health Organization</td>
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ABOUT THE ACCESS AND DELIVERY PARTNERSHIP

In recent years, we have seen a number of developments narrowing the innovation gap for health technologies to address tuberculosis (TB), malaria and neglected tropical diseases (NTDs). For example, two new chemical compounds for TB have been approved, representing the first new TB medicines in over 50 years. The first malaria vaccine also received conditional approval for use in 2015. But even where promising health technologies have been developed, the complications of getting these to patients in need are enduring challenges. The ability to deliver treatment and care, in a timely manner, to all who need them remains a struggle for many low- and middle-income countries; and one that can be further exacerbated by a range of factors – from geography and climate, to socioeconomic issues.

Systems for delivering new health technologies are complex and interconnected. They require diverse and simultaneous approaches. The Access and Delivery Partnership (ADP) brings together different sectors and critical capacities to address the breadth of issues that frequently hamper delivery of new health technologies within health systems. This cross-sectoral nature is among the partnership’s main strengths.

The design and scope of the ADP is ambitious, and in line with what is needed to sustainably and successfully address these persistent challenges. The 2030 Agenda for Sustainable Development, in adopting a clear target for the elimination of the epidemics of AIDS, TB, malaria and NTDs, offers a strategic opportunity for adopting innovative approaches that combine promoting progress in research and development on new health technologies, with strengthening national capacities for the delivery of these technologies.

The ADP is working with countries to tackle these challenges through capacity-building and partnership approaches. The ADP focuses on those interventions that allow for well-defined, inclusive and transparent decision-making, so that long after the partnership is gone, sustainability is built into national systems.

The leadership of the Government of Japan in supporting this initiative needs to be commended. It is visionary to not only catalyse product development and research, but to also have the foresight to invest in strengthening capacity and partnerships for access and delivery, so that essential health technologies, when available, actually get to the people who need them.

Dr. Mandeep Dhalwal
Chair of the ADP Advisory Group
Director, HIV, Health and Development Team,
Bureau of Policy and Programme Support, UNDP
A VISIONARY PLATFORM TO ADDRESS TUBERCULOSIS (TB), MALARIA AND NEGLECTED TROPICAL DISEASES (NTDS)

The Access and Delivery Partnership (ADP) is a unique alliance. Led and coordinated by the United Nations Development Programme (UNDP), the ADP is a distinctive collaboration between UNDP, TDR (the Special Programme for Research and Training in Tropical Diseases) and PATH. Working together, these ADP partners leverage the expertise of each organization, and within focus countries, to draw upon the full range of technical skills necessary to strengthen capacity to access and introduce new health technologies. The ADP emphasizes consultation, collaboration and implementation with partner country governments and stakeholders.

New health technologies are broadly defined as medicines, 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 yet to be introduced in low- and middle-income countries (LMICs). The introduction of new health technologies can place a burden on existing health systems, including new requirements for regulation, supply and distribution, as well as health personnel training. Accordingly, the ADP focuses 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.

The ADP partners collaboratively assist a focused group of countries to enhance their capacity to access, deliver and introduce new health technologies for TB, malaria and NTDs through sustainable, rational and evidence-based decision-making across multiple sectors. The ADP extends its impact beyond focus countries by developing and disseminating best practices and through the promotion of South–South collaboration.
The Government of Japan established and supports the ADP as part of an initiative comprising two complementary projects, which it implements through ongoing collaboration with UNDP:

- The Global Health Innovative Technology (GHIT) Fund stimulates innovation and research through the development of medicines, diagnostics and vaccines for TB, malaria and NTDs.
- The ADP amplifies the influence of the GHIT Fund by assisting LMICs to enhance capacities to access, deliver and introduce new health technologies.

The Global Health Innovative Technology (GHIT) Fund is a new model for global health research and development (R&D) financing. It was launched in April 2013 as an initiative between seven Japanese pharmaceutical companies, the Government of Japan, the Bill & Melinda Gates Foundation, the Wellcome Trust and UNDP. The Fund invests in and manages a portfolio of product development partnerships (PDPs) aimed at neglected diseases that afflict the world’s poorest people. A key aim of the GHIT Fund is to link existing PDPs with Japanese partners that have expertise in drug R&D. To date, GHIT has invested in over 60 global PDPs, with 23 leading to screening...
of unique compound libraries in Japan, resulting in identification 18 potential drug candidates.

The ultimate goals and business models of the ADP and GHIT Fund bear close resemblance, with both aiming to eliminate devastating infectious diseases in developing nations, and each adopting strategic intersectoral approaches that are integrated across multiple elements of complex value chains. This generates and reveals significant opportunities for synergy between the two initiatives – as well as with other PDPs.

Through the exceptionally visionary strategy of stimulating R&D for new health technologies through the GHIT Fund, while at the same time helping to safeguard their sustainable access and equitable delivery in LMICs through the ADP, the Government of Japan successfully brings together what have historically been two parallel elements of the global health response.

The Government of Japan plays a long-established spearhead role in global health, including through prioritization of global health in its foreign policy. The Kyushu-Okinawa Summit Meeting in 2000 elevated infectious diseases onto the G8 agenda for the first time; since then, the Government of Japan has maintained a leadership role, up to the recent G7 Ise-shima Summit Meeting (2016) which included the call for concrete measures against infectious diseases, public health emergency responses, universal health coverage (UHC), and prioritized R&D and innovation. The Government of Japan promotes R&D of new health technologies to address TB, malaria and NTDs, as well as facilitating access to and delivery of such health technologies in LMICs. Related priorities of the Government of Japan build on synergies between its 2013 Strategy on Global Health Diplomacy, 2011–2015 Global Health Policy, Basic Design for Peace and Health 2015 and 2016 Development Strategy for Gender Equality and Women’s Empowerment.
INTERSECTORAL APPROACHES TO PROMOTING ACCESS AND DELIVERY OF HEALTH TECHNOLOGIES

TB is one of the world’s deadliest communicable diseases: in 2014, 1.5 million people died from the disease.\(^1\) Malaria accounted for 438,000 deaths in 2015, with most occurring among children under five years of age in sub-Saharan Africa.\(^2\) NTDs affect 1.7 billion people,\(^3\) accounting for one of the highest burdens among all infectious and parasitic diseases. There is also a gender dimension to NTDs, given the higher prevalence of certain NTDs among women and increasing evidence of gender-based inequities in access to treatment and other related health services.

In short, TB, malaria and NTDs are diseases of poverty and inequality, with the greatest impact on the poorest and most vulnerable people and communities.

Acknowledging the impact of these diseases on human and social development, the United Nations adopted the 2030 Agenda for Sustainable Development, which comprises 17 Sustainable Development Goals (SDGs). SDG 3, which focuses on health and well-being, has set an ambitious target to end the epidemics of acquired immunodeficiency syndrome (AIDS), TB, malaria and NTDs by 2030. Towards this end, the SDGs underline the need for R&D on new medicines and vaccines, as well as for health systems strengthening and UHC to enable access to essential health technologies.

The partnership between the Government of Japan and UNDP embodies the SDG approach through two complementary aspects:

First, the synergistic relationship between the GHIT Fund and the ADP promotes collaborative innovation for R&D of new medicines, diagnostics and vaccines for TB, malaria and NTDs and strengthens capacities of LMICs to access and deliver these new health technologies.

Second, the intersectoral approach shared by the GHIT Fund and the ADP – where relevant partners come together to jointly tackle issues that cut across a range of established operational silos and

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technical disciplines – is increasingly recognized as reflective of the kind of integrated partnership needed to deliver the SDGs, particularly with regard to SDG 3 on good health and well-being, and the G7 Ise-Shima Vision for Global Health.

Achieving these ambitious goals must also be cognizant of the extensive and rapid changes taking place in national and geopolitical landscapes, against which the ADP and other initiatives also operate. In particular, the number of low-income countries has roughly halved in the past 15 years due to the economic transition of previously poorer nations. This switch has allowed many ‘new’ middle-income countries to graduate from prior dependence on development assistance, and to assume greater ownership and responsibility for national health system design, management and domestic resourcing. However, this has often occurred before national health systems have had the opportunity to undergo a similar graduation, making the need for targeted capacity building all the more urgent.

The ADP approach enhances country capacities for rational and evidence-based decision-making across multiple sectors, supporting access to and delivery of health technologies beyond the scope of the GHIT Fund outputs. As a result, this boosts sustainability and resilience within multiple national policy and programme mechanisms and institutions, as well as inspiring improved domestic investment in critical health priorities. The partnership also emphasizes the uniqueness of respective national and subnational contexts, stressing the distinct priorities for health systems to promote access and delivery in each setting.

In this context, innovation is crucial but insufficient for health systems to deliver essential health technologies to the communities and populations that need them most. In the wake of the failure of market-driven models for health technology development to finance R&D for diseases primarily affecting LMICs, enduring innovation gaps are being closed by a new generation of PDPs, such as the GHIT Fund. The power and benefit of pooling unique capabilities and skills in efforts to discover, develop and deliver new health technologies more quickly and effectively are increasingly recognized.
Structured through six strategic, inter-related ‘pathways’, ADP activities address the range of essential capacities related to alignment of legal, policy and regulatory frameworks, new product safety monitoring, pricing, supply and delivery systems.

Acknowledging that multiple work areas within the health system are critical for achieving access to, introduction and delivery of health technologies, the ADP approach aims to integrate these major work areas through the following pathways:

- **An enabling policy and legal framework** is a pre-condition for an effectively functioning health system. Implementation research capacity supplements policymaking by systematically identifying bottlenecks impeding scaled-up use of health technologies, while capacities for safety monitoring permit the detection and management of adverse effects.
- **Resource allocation through evidence-based decision making** – such as that achieved through health technology assessments (HTA), which include economic evaluation of health technologies – help to ensure predictability and sustainability of financing within health systems. Health delivery systems define each country’s ability to provide access to health care, which in turn relies on good supply chain management: comprising the efficient planning, procurement and distribution of essential health technologies. Finally, there is need for strategic information and evidence that helps ADP tailor its support for optimal impact. The ADP has thus identified these essential pathways towards access and delivery, and works to support countries in ensuring that the functioning and interaction between these elements.
The ADP theory of change is founded on the observation that the quality and focus of specific national decision-making processes are critical to ensuring access to, and delivery of, innovative health technologies. Accordingly, ADP actions are based on a two-fold operational rationale: a focus on building and strengthening structures for effective decision-making ensures both positive impact and sustainable change; and capturing knowledge and best practices from the implementation of ADP activities in focus countries facilitates strategic South–South exchange of benefit to other LMICs.

In the three years since the project’s inception, ADP partners have worked closely with key stakeholders in the focus countries to: sensitize policymakers and national stakeholders to the critical elements of innovation, access and delivery; support the integration of policy guidance and institutionalization of best practice mechanisms; build cohorts of national experts capable of leading the development and implementation of health systems; and develop and use guidelines, tools and strategic evidence to inform decisions.

Integrated implementation across all ADP pathways is facilitated by strong intersectoral partnerships with government and other stakeholders in Ghana, Indonesia and Tanzania. Relevant institutions and policymakers in Thailand have continued to share key technical experience and know-how regarding the establishment of the UHC system and health governance, as a means of knowledge exchange between Thailand and focus countries. These activities built on the foundation of earlier ADP work to establish a comprehensive, context-specific evidence base and the prior intentional focus on strengthening integrated in-country networks and partnerships.

Beyond country-level activities, the ADP facilitated South-South learning and exchange among LMICs in Asia and Africa through strengthening regional platforms and convening several regional workshops and consultations.
Within each country, the ADP approach is trying to bring different institutions and different issues together. So in Ghana, we are building capacities on pharmacovigilance, and on access and delivery of medicines, which are all critical areas that need to be addressed.

Dr. Margaret Gyapong
Director of Dodowa Health Research Centre,
Ghana Health Service
January 2016
With its robust economic growth and strong democratic institutions, Ghana transitioned to lower middle-income status in 2010. Despite facing significant challenges from malaria, HIV and tuberculosis, the country is steadily moving towards achieving the health system goals of improving health outcomes and increasing system responsiveness to meet citizens’ needs. The UHC vision is comprehensive, and includes robust commitments to increase domestic investments in health.

In Ghana, the ADP has promoted policy coherence and alignment between the various national sectors relevant to health, medicines regulation, industry and innovation. Efforts are focused on ongoing policy review processes, including review of the National Medicines Policy (NMP) by the Ministry of Health (MOH). Encompassing a range of issues, including medicines selection, access and pricing, sustainable supply issues and development of pharmacovigilance capacity, the NMP seeks to promote an integrated approach to governance of the pharmaceutical sector in Ghana. The NMP ensures that efficacious and quality medicines are available, affordable and safe, which is critical in ensuring equitable access to health care under UHC. The ADP provides technical assistance to the technical working group established to revise the NMP, particularly in the development of key implementation tools comprising costed plans for NMP implementation, related monitoring and evaluation, and advocacy. The ADP also facilitated engagement of a cross-section of national stakeholders to ensure broad inputs, and promote country ownership of the NMP. The results of the ADP’s support include the development of a comprehensive implementation plan with cost estimates, a monitoring and evaluation plan to measure implementation progress, and an advocacy and communications plan to create greater awareness of related policy goals and objectives.

In addition, the ADP has an ongoing engagement with the Ministry of Justice and the Attorney-General’s Department to enhance coherence of policies relating to innovation, public health and access to health technologies, which is expected to culminate in a technical briefing for parliamentarians on integrating public health considerations in the legal framework in 2017.

In Ghana, the ADP has adopted a health system strengthening approach to equip stakeholders with the necessary skills to develop and sustain the health system and ensure efficient and effective access to new health technologies. One aim is to build a cohort of researchers who are able to effectively plan and conduct priority implementation research. The Research and Development Division of the Ghana Health Service (GHS) and the network of Health Research Centres across the country serves as the lead country partner for this area of the ADP’s work. To this end, the ADP supported sensitization and training of policymakers and staff members from GHS, regional training centres...
and national disease control programmes on the importance of implementation research in the effective introduction of new health technologies. These trainings focused on the process of prioritizing implementation challenges and setting the national health research agenda. Seven managers and senior researchers from one regional health research facility were successfully trained in developing implementation research proposals, resulting in the development of four research study protocols. Through ADP support, national researchers have so far been able to raise almost US$80,000 in research funding. One of these studies has been funded by the Global Fund and is being implemented by the National TB Control Programme. Another study, addressing the persistent transmission of lymphatic filariasis, has also secured funding from the UK Department for International Development and will commence in June 2016. A review of the National Health Research Agenda was undertaken with one of the key outputs being a list of priority research areas to improve effectiveness of disease control. The process of national agenda-setting for implementation research has been documented and will be published, along with a compendium of priority research areas. Overall, the robust stakeholder analyses and engagement has strengthened dialogue and relationships between control programmes and researchers, and equipped disease control programme teams to explore why certain challenges persist despite massive programme efforts. Programmes have also been empowered to develop action plans and activities to systematically address common challenges, and there is increased awareness among top research managers and policymakers on the critical importance of implementation research.

The ADP is working with the country’s pharmacovigilance programme in providing technical and capacity-building support to the Ghana Food and Drugs Authority in the development and implementation of a management system for individual case safety reports. The ADP will support the incorporation of a consumer reporting section, validation of the various sections of the system, and large-scale training of health care providers and regional pharmacovigilance officers, as well as media campaigns for patients for customer reporting. A common database for this purpose will help in the effective management of pre- and post-approval safety information.
Given the increasing communicable and non-communicable disease burden in Indonesia, we anticipate many new health technologies to be introduced to address these diseases. There is a need to monitor the safety of these new technologies, and we have learned from the ADP on how to set up active pharmacovigilance and improve our capacity to manage [adverse drug reactions] in the future.

Dr. Siti Abdoellah
Head, Sub-Directorate of Surveillance and Risk Analysis of Therapeutic Products, National Agency of Drug and Food Control, Ministry of Health, Indonesia

January 2016

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Country profile

Human Development Index Ranking
110

Population total (millions)
253

Gross national income per capita (USD)
9,788

Population living below $1.25 a day (%)
16.2

Public health expenditure (% of GDP)
3.1

Life expectancy at birth (years)
69.9

Under-5 mortality rate (per 1000 live births)
29.3

TB epidemiology

TB prevalence (per 100,000) 647

TB incidence (per 100,000) 399

Deaths due to TB (per 100,000) 49.5

TB case detection (%) 32

MDR-TB in new/re-treatment cases (%) 1.9 / 12

Malaria epidemiology

Estimated cases of malaria (per 100,000) 1621

Total deaths due to malaria (per 100,000) 2.6

Children aged <5 years with fever who received treatment with any antimalarial (%) (2013) 1

NTDs epidemiology

SAC population requiring PC for STH / coverage 39,041,065 / 11.0%

Population requiring PC for LF / coverage 92,591,397 / 23.4%

Population requiring PC for SCH / coverage 192,000 / 0.1%

Estimated incidence of dengue fever (per 100,000)  40

All data from 2014 unless where stated. SAC: school-aged children, PC: preventive chemotherapy; STH: soil-transmitted helminths; LF: lymphatic filariasis; SCH: schistosomiosis.

Indonesia is currently rolling out a national health insurance system, which includes the goal of making basic care available to all by 2019. Key related issues for the ADP have focused around development and implementation of policy approaches that are appropriate to national priorities and needs. The ADP has worked with the MOH, the Ministry of Law and Human Rights and the national competition authority (KPPU) on delivering an integrated approach towards multisectoral policy and decision-making, as related to improving the availability, affordability and accessibility of medicines and other health technologies, as well as the efficient delivery of these technologies.

The ongoing collaboration with these agencies supports the effective integration of public health perspectives into the national policy and legal frameworks, helping to animate a cadre of technical personnel within the various ministries with relevant capacities in policy review and analysis. The ADP has recently broadened its cooperation to a cross-section of government actors, whose varied areas of responsibility influence access and delivery, with the aim of enabling national stakeholders to identify and analyse priority issues for policy review. This intersectoral group provides an important forum to facilitate and promote regular exchanges and coordination between national stakeholders on relevant policy review processes.

National policymakers from various sectors have articulated their support for the ADP approach on promoting policy coherence. The ADP will continue to respond to requests from stakeholders and provide the relevant technical and policy support to enable intersectoral policy coherence.

The decentralized health services in Indonesia face persistent challenges at the local level, affecting service delivery. A recognized need exists to strengthen capacity for implementation research towards improved service delivery and robust, sustainable health services in general. Following prior support to strengthening of implementation research capacity at the Universitas Gadjah Mada (UGM), helping to establish it as a related resource centre in the region, the ADP has been working with UGM in supporting the MOH to conduct in-depth analysis of national capacity for implementation research.

Having assessed the country’s capability for implementation research, the ADP supported the MOH in reaching a consensus on an implementation research strategy on TB, malaria and NTDs. Implementation bottlenecks faced by the disease control programmes were mapped and the major factors responsible for a relatively limited implementation research capacity were identified. As a follow up to this assessment and the resulting framework for capacity-strengthening, a series of training activities will be delivered by the ADP in partnership with UGM, focusing on identifying and training managers and senior researchers to build their capacity for developing proposals for implementation research, resource mobilization and study implementation.

With an estimated 19,000 new multidrug-resistant TB (MDR-TB)
cases annually, Indonesia has been identified as one of five pilot countries where bedaquiline is being introduced as part of combination therapy for MDR-TB in adults. In accordance with WHO interim guidance on the use of bedaquiline to treat MDR-TB, active pharmacovigilance measures must be in place to ensure early detection and proper management of adverse drug reactions. This has provided an entry point to support the development of tools, approaches and systems for active surveillance of adverse events of other new health technologies, including those that will be entering the Indonesian market in the near future.

The ADP continued to support the capacity strengthening of the National Pharmacovigilance Centre (NPC), including the participation of key staff members in a regional forum on pharmacovigilance for knowledge exchange and building of partnerships between pharmacovigilance experts in the region. The ADP has also supported capacity strengthening in active safety monitoring and pharmacovigilance within the national TB programme and the pharmacovigilance teams in hospitals, to ensure early detection and proper management of adverse drug reactions, with a specific focus on bedaquiline.

The National Agency of Drug and Food Control (BPOM) has identified ‘risk assessment’ and ‘crisis management’ as key capacity gaps in Indonesia’s pharmacovigilance system, and the ADP is currently holding discussions with the NPC on planning further trainings and technical support in this area.

With the national health insurance programme aiming to reaching full population coverage (253 million) by 2019, the government is focused on ensuring affordability and cost-effectiveness of health technologies. In this context, the ADP, in partnership with Thailand’s Health Intervention and Technology Assessment Programme (HTAP), introduced the Health Technology Assessment (HTA) approach to policymakers as a tool to inform the process of prioritization, selection and introduction of health technologies. The ADP supported the MOH in establishing the HTA committee (HTAC) within the Centre of Health Insurance to manage the HTA implementation process. Efforts by the ADP further extend to facilitating the institutionalization of HTA through the development and implementation of the national HTA roadmap and action plan, which includes strengthening the capacity of policymakers and key technical personnel to assess the need, effectiveness and safety of new health technologies.

The ADP and HITAP have also provided technical support to the HTAC in piloting the HTA approach on two new health technologies, which generated key evidence that will help reduce mortality and increase estimated savings of up to US$6 billion over the next five years. The HTA approach will be critical in generating best value for money and addressing equity considerations, and to inform the development of a health financing strategy to deliver the benefits package as Indonesia moves towards UHC.

The ADP is currently working with HTAC to finalize a series of policy briefs detailing the lessons learned and recommendations on strengthening the policy and process related to HTA.

A country assessment and consultations with stakeholders involved in the public procurement process, particularly the National Public Procurement Agency (LKPP), identified significant challenges faced by sub-national service procurement units. These challenges relate to effective decision-making around planning and procurement of new medical equipment and health technologies, and are largely due to limited product knowledge, and lack of information on quality standards and market prices. The ADP is supporting LKPP in addressing these impediments with the aim of improving the availability of new health technologies in the more geographically remote provinces, such as Papua, North Sulawesi and East Kalimantan, where expertise on new technologies and financial resources are limited. This included development of a training module on planning, procurement and distribution of medical and laboratory equipment and other new health technologies. This training module will be incorporated into the national standard procurement training programme and will be used for further training activities aimed at increasing capacities for planning and procurement in over 700 hospitals across Indonesia. The ADP has also supported the planning and procurement process for TB commodities and diagnostic equipment as part of the introduction and national scale-up of new TB medicines and diagnostics.
An integral part of a sustainable health delivery system is the ability to facilitate equitable access to, and delivery of, the needed health services and technologies... Accordingly, the government has identified the need for strategies to ensure access; strengthen control of safety; enhance harmonization and coordination of procurement, and stocking and distribution.

Dr Mpoki M. Ulisubisya
Permanent Secretary
Ministry of Health, Community Development, Gender, Elderly and Children, Tanzania
March 2016

### Country profile

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<tr>
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<td>Human Development Index Ranking</td>
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<tr>
<td>Population total (millions)</td>
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<td>Gross national income per capita (USD)</td>
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<td>Population living below $1.25 a day (%)</td>
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<td>Public health expenditure (% of GDP)</td>
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<td>Life expectancy at birth (years)</td>
<td>65</td>
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<tr>
<td>Under-5 mortality rate (per 1000 live births)</td>
<td>51.8</td>
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### TB epidemiology

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<tr>
<td>TB prevalence (per 100,000)</td>
<td>528</td>
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<tr>
<td>TB incidence (per 100,000)</td>
<td>327</td>
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<tr>
<td>Deaths due to TB (per 100,000)</td>
<td>112</td>
</tr>
<tr>
<td>TB case detection (%)</td>
<td>36</td>
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<tr>
<td>MDR-TB in new/re-treatment cases (%)</td>
<td>3.1</td>
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### Malaria epidemiology

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<tr>
<td>Estimated cases of malaria (per 100,000)</td>
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<tr>
<td>Total deaths due to malaria (per 100,000)</td>
<td>34.7</td>
</tr>
</tbody>
</table>

### Children aged <5 years with fever who received treatment with any antimalarial (%) (2013)

<table>
<thead>
<tr>
<th>Metric</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>54</td>
</tr>
</tbody>
</table>

### NTDs epidemiology

<table>
<thead>
<tr>
<th>Metric</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>SAC population requiring PC for STH / coverage</td>
<td>12,842,759 / 31%</td>
</tr>
<tr>
<td>Population requiring PC for LF / coverage</td>
<td>26,530,192 / 77.3%</td>
</tr>
<tr>
<td>Population requiring PC for SCH / coverage</td>
<td>10,765,946 / 27.3%</td>
</tr>
<tr>
<td>SAC population requiring PC for SCH / coverage</td>
<td>6,357,534 / 37.8%</td>
</tr>
<tr>
<td>Population requiring PC for onchocerciasis</td>
<td>3,542,959</td>
</tr>
</tbody>
</table>

All data from 2014 unless where stated. SAC: school-aged children, PC: preventive chemotherapy; STH: soil-transmitted helminths; LF: lymphatic filariasis; SCH: schistosomiasis.

With the prediction that it will graduate from its low-income status in the coming decade, Tanzania has identified a sustainable health delivery system and the goal of UHC as key national development priorities, and is steadily scaling up its national insurance schemes. However, weak systems and capacities – as well as a lack of coordination and tools to identify and address country needs – have attenuated the introduction, delivery and scale-up of health technologies, which in turn has limited the effective implementation of efforts to effectively control malaria, TB and NTDs.

The country has a progressive approach to self-reliance in national health research, however, with several national institutions taking the lead and presenting opportunities to strengthen implementation research capacity towards improved access and delivery. The ADP has worked closely with the National Institute for Medical Research (NIMR) and respective national disease control programmes to strengthen national capacity in identifying challenges and design, and undertaking research to address critical bottlenecks in the introduction and delivery of health technologies in varying settings and contexts.

In collaboration with NIMR, the ADP also helped to strengthen the capacities of a cohort of national researchers for leading and conducting implementation research. The ADP previously worked with national disease control programmes to conduct an analysis of national implementation research capacity and identify the persistent gaps and implementation bottlenecks. Based on the resulting list of priority research areas, the ADP delivered training on systematic development of research proposals to 32 senior research staff from universities, research institutes and the MOH. The active participation in, and ownership of, this process by the NIMR, as well as the involvement of a large number of senior research and programme staff across the country, will facilitate sustainability in conducting implementation research.

The NIMR has subsequently secured US$160,000 in new funding for implementation research on malaria, TB and NTDs: For projects exploring strategies for motivating community drug distributors to improve mass drug administration coverage in endemic communities; and another focusing on optimization of rapid molecular diagnostics (Xpert MTB/Rif and Genotype MTBDR plus) for early MDR-TB diagnosis and treatment.

During the past year, the ADP has also supported the Ministry of Health, Community Development, Gender, Elderly and Children (MOH-CDGEC) and the Pharmaceutical Services Unit in the institutionalization of the HTA approach and built the capacity of a core group of national experts. Lessons from the ADP’s ongoing work in Indonesia have guided the technical support and capacity-building activities in the country.

The MOH-CDGEC was subsequently able to use the HTA process to evaluate the National Essential Medicines List (NEML) in terms of cost-effective prioritization and resource allocation. The ADP engaged with key stakeholders
and sectors, including senior government officers and policymakers, through multiple consultations and workshops, to raise awareness of the need for a systematic priority-setting process to inform policy development around the selection and introduction of new health technologies. This process is critical for the ultimate economic sustainability of UHC, as the NEML defines the benefits package under the national health insurance schemes, which cover almost 10 million beneficiaries at the cost US$92 million annually.

The ADP also supported the NTD Control Programme in the country-wide campaigns for mass drug administration (MDA), by strengthening supply chain management to deliver preventive chemotherapy. The ADP developed the relevant tools, guidelines and training curricula for use in building capacities of front-line health workers, community drug distributors and district pharmacists across the country. These capacities relate to improving institutional structures and linkages, and cost-efficient and -effective practices in quantification, administration, storage and disposal of medicines. In 2014, even with 100% geographical coverage of 169 districts, the MDA campaigns were able to reach only 50% of the 49 million people at risk of NTDs. The annual spending of approximately US$183 million for NTD-related medicines alone also raises the issue of sustainability. The cohort of personnel trained by the ADP will train a further 3000 health personnel in 20 regions before the next MDA campaign in September 2016.

Adverse drug reactions are under-reported and under-addressed in Tanzania, largely as a result of low awareness and capacity among health professionals and consumers. Following on from earlier ADP initiatives that built health system capacity for monitoring and responding to safety issues of newly introduced health technologies, the ADP has continued working with the Tanzania Food and Drug Authority (TFDA) on expanding the reach of capacity-building activities on safety monitoring and pharmacovigilance at the central, regional and facility levels. So far, the ADP has supported the training of almost 300 health care providers from public and private health facilities across 20 districts. This large cohort of experts is now able to plan, implement and manage a robust, integrated and effective drug safety monitoring system. The ADP is also supporting the development and implementation of a new system that enables consumers to directly report adverse drug reactions, leading to increased reporting and the timely detection of adverse reactions.

The ADP has also facilitated cross-institutional learning and exchange by supporting the placement of TFDA staff members in New Zealand’s Medicines and Medical Devices Safety Authority and Malaysia’s National Pharmaceutical Control Bureau.
For optimal impact and results, ADP partners have taken measures to ensure a coordinated, multidisciplinary approach to project implementation. Building on the strong stakeholder commitment and ownership generated over the past three years, the ADP has focused on a number of key priorities in this regard. First, the ADP adopts an integrated approach for capacity strengthening across the sectors that impact upon access and delivery of new health technologies. Secondly, the ADP actively seeks collaboration with relevant regional and global institutions, with a view to extending the learning from ADP implementation and generating impact beyond the focus countries. Finally, the close collaboration with the GHIT Fund enables and strengthens essential linkages between drug discovery and product development, and the country-level measures required to facilitate access and delivery of new health technologies.

As initiatives to stimulate greater innovation in health technologies for TB, malaria and NTDs begin to show results, it is crucial to ensure that these new technologies can be optimally introduced into the health systems of LMICs. The ADP approach also helps capture the learning and best practices from pilot activities to benefit other LMICs and other regional or global stakeholders, thus extending the reach of the ADP.

Drawing upon the vast technical information, experience and lessons gained from focus countries, the ADP has generated knowledge for universal adaptability and applicability, contributing to an expanded global repository of information, approaches and mechanisms. A range of knowledge products have been developed and disseminated to provide policy guidance, strengthen capacity and enhance strategies on implementing best practice. For example, a comprehensive analysis was undertaken of the pipeline of medicines, vaccines and diagnostic tools for TB, malaria and selected NTDs that are anticipated for market entry by 2020, with a view to identifying promising new products and engendering a better understanding of the implications of their introduction for health systems, as well as for wider policy and regulatory frameworks.
Country ownership and intersectoral, multistakeholder collaboration

The ADP project partners have found that implementation progress is variable across the focus countries, given that such progress is very much dependent on the level of engagement, interest of national stakeholders and the prevailing political climate. To address this challenge, the strategy of the ADP has been to identify entry points for ADP activities, based on the mandate and priorities of government agencies. Integrating and aligning ADP activities with regional and national strategic plans has been important in increasing political engagement and ownership. The ADP has concentrated efforts on linking its activities with an overarching national policy goal and bringing together policy stakeholders within a multisectoral setting to raise awareness about the need for coherent decision- and policymaking.

In Indonesia, for example, the national goal of UHC has provided a strategic opportunity to leverage political engagement with ADP capacity building for the development of an enabling legal and policy environment, as well as for health technology assessment. While in Ghana and Tanzania, the synergies with regional and sub-regional action plans of the Africa Union and the East African Community has helped to promote engagement and ownership of ADP activities.

The recent focus of ADP activities on implementation of capacity-building initiatives that cut across the project pathways built upon the high degree of stakeholder engagement and country ownership of ADP interventions generated in the previous years. Continued strengthening of relationships with national stakeholders and maintaining momentum for implementation in all focus countries will remain a key focus.

South-South learning and cooperation

The ADP implementation experience in focus countries is a rich source of South–South learning and exchange. Working in the focus countries, the ADP has been able to capture the learning and best practices from in-country activities to benefit other LMICs, as well as regional or global stakeholders. To increase the impact of the project, the ADP has created forums and platforms for South–South learning and knowledge exchange on the ADP approaches, tools and interventions. Bringing together the ADP focus country stakeholders to share implementation experiences has generated proposals for collaboration between the ADP focus countries, with a focus on leveraging the experience of policymakers and technical experts in Thailand on issues such as pricing and procurement methodologies, HTA and implementation research.

Many LMICs share common challenges and health priorities, and many have implemented innovative approaches to address the bottlenecks across the value chain of innovation, access and delivery of health technologies. The ADP has enhanced regional and global learning networks on public health innovation and access to health technologies for sustained knowledge exchange and on-going capacity building on shaping governance structures and strategic interventions for coherent policymaking; and fostering South–South collaborations and coordinated support to LMICs. The ADP has successfully built partnerships with, and developed the capacity of, over 500 policymakers, technical experts, academics and other stakeholders in over 20 countries; and established strategic and technical partnerships with 13 regional and global organizations, networks, research institutions or technical entities. The ADP leverages diverse technical expertise from, for example, HITAP (Thailand) and PRICELESS (South Africa) to build capacity on implementing the HTA approach in focus countries; and established research links between universities in Ghana and Indonesia and developed them into regional centres of excellence for health research.

Engagement with regional and global initiatives

To increase awareness of ADP’s approaches, in particular those focusing on policy coherence, ADP has developed strategic and technical partnerships with regional and global organizations, including the African Union Commission and the East African Community; while in Asia, partnerships have been forged with the UN Economic and Social Commission for Asia and the Pacific (ESCAP) and the Non-Aligned Movement Centre for South–South
Technical Cooperation. The ADP has held regional consultations, focusing on the Asian and African contexts, to increase awareness of and knowledge about the linkages between health, industrial and trade policies, and their implications for innovation and access to medical technologies. Over 500 stakeholders from 10 countries in Asia and 13 countries in Africa participated in these consultations. In one example, networking and engagement of pharmacovigilance experts from Indonesia and Thailand with regional technical experts has facilitated sustained capacity building.

As part of its continuing collaboration with the African Union Commission, the ADP has partnered with the New Partnership for Africa’s Development (NEPAD) – the technical arm of the African Union – in the development of the Model Law on Medicines Regulation and Harmonization. The Model Law provides a comprehensive framework to guide African Union Member States in the provision of an enabling regulatory environment for the private sector to deliver quality, safe and efficacious medical products and technologies to the African population. The Model Law will be a vital tool in promoting an integrated and coordinated approach for health technology regulation, and in facilitating the introduction of new health technologies.
Looking ahead, ADP partners will continue to operationalize key priorities in the focus countries – Ghana, Indonesia and Tanzania. ADP will also seek to further broaden the implementation process in focus countries, so that lessons from the implementation process in each of the focus countries can be usefully applied in the others. With Thailand as a technical partner country, the ADP will seek to optimize the experience and expertise of its policy makers and technical experts in the focus countries.

The guiding approaches for the year ahead will include:

1. Implement an integrated approach towards access and delivery: The ADP will focus on implementing its integrated approach, particularly in the context of the SDGs. As its interventions take root and gain momentum, the ADP will aim to facilitate concrete linkages between the various activities and interventions, providing a continuum of capacity building that will build sustainable processes for decision-making across the value chain of access and delivery.

2. Enhance South–South exchange and learning: To create demand and generate impact beyond the focus countries, the ADP will seek to document experiences and lessons from the implementation process. Relevant knowledge generated through ADP will be disseminated through case studies, guidance and other tools, to maximize its impact.

3. Promote greater linkages between product development and national capacity strengthening:
As initiatives to stimulate greater innovation in health technologies for TB, malaria and NTDs begin to demonstrate concrete results, the ADP will initiate relevant measures to demonstrate how new technologies can be optimally introduced into the health systems of LMICs. Appropriate linkages will be made between the processes of drug discovery and product development, and the strengthening of country-level capacities for efficient prioritization and delivery of health technologies, so as to ensure positive health outcomes. To achieve this goal, ADP will strengthen its partnership with the GHIT Fund and provide specific advisory services.
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