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**THE ACCESS AND  
DELIVERY PARTNERSHIP**

*New Health Technologies for TB, Malaria and NTDs*



*Empowered lives.  
Resilient nations.*

# Phase **1** Final Report

Building Capacity for Access and Delivery of  
New Global Health Technologies for Tuberculosis  
(TB), Malaria, Neglected Tropical Diseases (NTDs)  
and Other Diseases in Low and Middle Income  
Countries (LMICs)

April 2013 – June 2014



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# Acronyms and abbreviations

<b>AIDS</b>	Acquired Immunodeficiency Syndrome
<b>ADP</b>	Access and Delivery Partnership
<b>AMRH</b>	African Medicines Regulatory Harmonization
<b>API</b>	Active Pharmaceutical Ingredients
<b>ARV</b>	Anti-retrovirals
<b>AU</b>	African Union
<b>AU PMPA</b>	African Union Pharmaceutical Manufacturing Plan for Africa
<b>BPJS</b>	Badan Penyelenggara Jaminan Sosial, Indonesia
<b>CEWG</b>	WHO Consultative Expert Working Group on Research and Development: Financing and Coordination
<b>COSTECH</b>	Tanzania Commission for Science and Technology
<b>CUHAS</b>	Catholic University of Health and Allied Sciences
<b>EAC</b>	East African Community
<b>FDA</b>	Food and Drug Administration
<b>GHIT Fund</b>	Global Health Innovative Technology Fund
<b>HITAP</b>	Health Intervention and Technology Assessment Program
<b>HIV</b>	Human Immunodeficiency Virus
<b>HTA</b>	Health Technology Assessment
<b>IAPHL</b>	International Association of Public Health Logisticians
<b>KCMC</b>	Kilimanjaro Christian Medical Center
<b>KCRI</b>	Kilimanjaro Medical Research Institute
<b>LMICs</b>	Low- and middle-income countries
<b>MDGs</b>	Millennium Development Goals
<b>MOH</b>	Ministry of Health
<b>MOHSW</b>	Ministry of Health and Social Welfare
<b>MOU</b>	Memorandum of Understanding

<b>MUHAS</b>	Muhimbili University of Health and Allied Sciences
<b>NADFC</b>	National Agency for Drug and Food Control
<b>NECA</b>	National Evidence-based Healthcare Collaboration Agency
<b>NEPAD</b>	New Partnership for Africa's Development
<b>NGO</b>	Non-governmental organization
<b>NICE</b>	National Institute for Health and Care Excellence
<b>NIHRD</b>	National Institute for Health Research and Development
<b>NIMR</b>	National Institute for Medical Research
<b>NTDs</b>	Neglected tropical diseases
<b>PDP</b>	Product development partnership
<b>PSS</b>	Pharmaceuticals Service Section
<b>R&amp;D</b>	Research and development
<b>RHSC</b>	Reproductive Health Supplies Coalition
<b>SDGs</b>	Sustainable Development Goals
<b>TB</b>	Tuberculosis
<b>TDR</b>	Special Programme for Research and Training in Tropical Diseases (World Health Organization)
<b>TFDA</b>	Tanzania Food and Drug Authority
<b>UN</b>	United Nations
<b>UNAIDS</b>	Joint United Nations Programme on HIV/AIDS
<b>UNDP</b>	United Nations Development Programme
<b>UNDP BDP</b>	United Nations Development Programme Bureau for Development Policy
<b>WHO</b>	World Health Organization
<b>WHO-CC</b>	World Health Organization Collaborating Centre for Advocacy and Training in Pharmacovigilance

# I. Executive summary

Tuberculosis (TB), malaria and neglected tropical diseases (NTDs) have an adverse impact on human development. TB accounts for 1.3 million deaths every year, and an estimated 3.3 billion people are at risk of malaria globally. NTDs disproportionately affect the so-called 'bottom billion' — the 1.4 billion people who live below the US\$1.25 per day poverty line. Long-term sustainable development, poverty reduction and improved health outcomes cannot be successfully achieved without simultaneously addressing NTDs.

This collaboration between the United Nations Development Programme (UNDP) and the Government of Japan marks the initial phase of a strategic partnership to promote research and development and to increase access to and delivery of health technologies used to address NTDs, TB and malaria. This innovative partnership consists of two major complementary components: the Global Health Innovative Technology (GHIT) Fund and the Access and Delivery Partnership (ADP). The ADP brings together UNDP, the World Health Organization Special Programme for Research and Training in Tropical Diseases (WHO/TDR) and PATH.<sup>1</sup> Recognizing the capacity gaps in low- and middle-income countries (LMICs) to effectively access and deliver needed new health technologies, the partnership supports countries to strengthen their capacities to address bottlenecks in this area.

The submission of this report to the Government of Japan marks the successful completion of the ADP's first phase (1 April 2013 to 30 June 2014). UNDP has been working with WHO/TDR, PATH and other technical partners on strengthening capacities in select LMICs, ensuring appropriate policy and regulatory frameworks; monitoring of safety issues; health financing; and pricing, supply and delivery systems for access to and delivery of the new health technologies for TB, malaria and NTDs. ADP has been focusing its Phase 1 efforts on strengthening the partnership as well as on establishing relationships with government stakeholders and champions, building on the comprehensive, context-specific evidence base that partners have consolidated through extensive consultations and reviews in-country. Following the selection of Ghana, Indonesia, Tanzania and Thailand as the ADP's focus countries for this phase, strategies to achieve the ADP's objectives have been established across each of the five project pathways.

The focus of **Pathway 1** is on strengthening national capacities for developing a coherent policy and legal environment for access and delivery. Over the course of Phase 1, initial country missions supported the collection of information about policy gaps and incoherence, highlighting the priorities for the ADP in Phase 1 and beyond. As this process was conducted in a participatory manner, buy-in has been secured from government stakeholders. For example, in Indonesia, UNDP has responded to requests for capacity-building for the review of the policy and legal environment in the country, to facilitate the introduction of public health considerations. The proposed establishment of an intersectoral planning committee will also be crucial to lead the ADP's efforts in Indonesia, convene relevant stakeholders and identify priority areas.

The focus of **Pathway 2** is the strengthened capacity to identify and address bottlenecks impeding effective access to and delivery of health technologies. WHO/TDR has produced a key training manual — an Implementation Research Toolkit — to support the capacity-building activities; it will be available to support implementation and operations research activities in the focus countries over the next 36 months. In Tanzania, for instance, a national consultation bringing together three national control programmes and health systems experts supported extensive analysis of the national health systems which provided the basis for the prioritization of research questions and plans of action to address the gaps and implementation bottlenecks. A framework for training and strengthening capacity for operations and implementation research was subsequently developed for a 36-month period.

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<sup>1</sup> PATH is an international non-profit organization working on global health innovation and headquartered in Seattle, Washington.

**Pathway 3** focuses on strengthening capacities of target countries to monitor the safety of new health technologies in real-life contexts (scaled-up deployment). In Indonesia, having identified the Food and Drug Authority as the partnership's main counterpart for this pathway, WHO/TDR will be working with stakeholders to assess the training needs in the area of pharmacovigilance. Resource persons from WHO's Department of Essential Medicines and Health Products will support this process.

**Pathway 4** focuses on evidence-based, sustainable decision-making for resource allocation and commercialization of new health technologies at appropriate pricing to ensure that supply meets demand. Consultations confirmed that there is a significant need to develop or strengthen Health Technology Assessment (HTA) processes to be more systematic, country-driven and evidence-based. The ADP has successfully engaged with global-level partners and established HTA agencies to leverage their expertise for capacity development. Engagements at country level in Tanzania and Indonesia are supporting the prioritization of health technologies for upcoming market assessments and local production feasibility studies.

Efforts under **Pathway 5** aim to strengthen the capacity of delivery systems, including the supply chain of new health technologies. Following the development of a Supply Chain Assessment Tool, PATH initiated activities in Indonesia and Tanzania with an in-depth Supply Chain Assessment, which served to uncover and define the key issues hindering the introduction of new products into the supply chain. In Indonesia, materials, tools and resources will be developed to strengthen the capacity of central-, provincial- and district-level personnel to effectively plan for and procure new health products and technologies. In Tanzania, the ADP will support a structured planning process for new health technologies.

To tailor the support provided by the ADP to the needs of specific countries and the pipeline of future products, the partnership has been supporting a range of efforts to develop a base of strategic information and evidence to inform capacity-building efforts, under **Pathway 6**. In Phase 1, a mapping of pipeline technologies for TB, malaria and NTDs is being finalized, with the aim of identifying those expected to be ready for market introduction by 2020. At the global level, the ADP supported a capacity-building workshop on the global debate on financing for research and development on NTDs through a partnership with the South Centre.

The ADP has made significant headway in terms of implementation of country-level activities during Phase 1. In Indonesia and Tanzania, the multi-stakeholder project planning and inception workshops resulted in the development of comprehensive country implementation work plans, outlining the country-level activities under each of the project pathways. In Ghana, country-level activities have focused on Pathways 1, 2 and 3 — in line with the findings of consultations with government stakeholders and technical partners to identify the range of national priority issues. While the current focus is on activities under Pathways 1–3, activities under Pathways 4 and 5 may be added to the country implementation work plan in the future. Ongoing implementation of activities related to Pathways 4 and 5 in Indonesia and Tanzania will also provide useful models and learning for Ghana. In Thailand, while recent political developments have not encouraged comprehensive implementation of country-level activities, the project partners have engaged in active dialogue and consultations with key stakeholders in the country, including conducting trainings with technical experts from Thailand to promote South–South learning.

The ADP's first phase has been rich in experiences and learning that will guide the implementation of global- and country-level activities in the partnership's second phase. Importantly, any actions that have been planned are informed by a consolidated, context-specific evidence base, which ties together the challenges and needs across all six pathways of the partnership. Significant efforts were made in the first phase to consult with all relevant actors across the health system to identify priority areas for access and delivery and to ensure a high level of national commitment and ownership of the partnership's activities and results.

The complexity of the access and delivery systems at the country level has presented a significant challenge during this initial phase of project implementation. The broad, overarching and multidisciplinary approach of the project requires direct engagement with a range of key stakeholders to address this challenge, which is also a unique opportunity to address it. In providing focused programme and policy guidance across the multiple sectors, the ADP seeks to extend and expand critical national capacities to access and introduce new technologies in effective, rational and evidence-based ways. The ADP has provided added value to the target countries by facilitating engagement between ministries and by forging collaborations between ministries that may not have traditionally worked together in a coordinated manner. Identifying and addressing the capacity gaps within the interacting pathways in an integrated manner will contribute towards improving access to and delivery of new health technologies in LMICs.

## II. Context

Tuberculosis (TB), malaria and neglected tropical diseases (NTDs) have an adverse impact on human development. TB accounts for 1.3 million deaths every year, and an estimated 3.3 billion people are at risk of malaria globally, with more than 600,000 deaths occurring in 2012.<sup>2</sup> NTDs disproportionately affect the so-called 'bottom billion' — the 1.4 billion people who live below the US\$1.25 per day poverty line. The 17 NTDs listed by the World Health Organization (WHO) are prevalent in 149 countries and share common features. These include their prevalence in poor and disadvantaged populations, and their significant impact on child and maternal health, on global and national economic output and on progress on the Millennium Development Goals (MDGs) and the post-2015 Sustainable Development Goals (SDGs). The impact of NTDs stretches across multiple development sectors, including water and sanitation, nutrition, maternal and child health, and education. Long-term sustainable development, poverty reduction and improved health outcomes cannot be successfully achieved without simultaneously addressing NTDs.

In addition to being diseases of poverty and inequality, TB, malaria and NTDs are disproportionately neglected by research-based pharmaceutical companies and share an urgent need for increased innovation for health technologies. Of the 1556 new medicines approved between 1975 and 2004, only 1.3 percent were specifically developed for tropical diseases and TB.<sup>3</sup> Furthermore, evidence suggests that capacity in low- and middle-income countries (LMICs) to absorb, deliver and provide access to vaccines, diagnostics and medicines to treat TB, malaria and NTDs is weak.<sup>4</sup> While the number of new health technologies coming to market for TB, malaria and NTDs is increasing, a public health impact will come only after they are adopted into the health systems of LMICs.<sup>5</sup> LMICs require capacity development in the areas of legal and policy frameworks, optimizing technologies and monitoring safety, and pricing, supply and delivery systems. Bridging this gap between research and development (R&D) and access and delivery requires innovative new partnerships between key stakeholders, including the main actors within the national health systems, United Nations (UN) agencies, product development partnerships (PDPs), non-governmental organizations (NGOs), the private sector and academia.

<sup>2</sup> TDR, 'Global Report for Research on Infectious Diseases and Poverty', TDR, Geneva, 2012.

<sup>3</sup> Wells, W. and Brooks, A., 'PDP Support of Country Decision Making: A Discussion Paper', TB Alliance, New York, and PATH, Seattle, 2012.

<sup>4</sup> Oxfam, 'Ending the R&D crisis in Public Health: Promoting pro-poor medical innovation', Oxfam Briefing Paper, Oxfam, Oxford, 2008; Wells, W. and Brooks, A., 'PDP Support of Country Decision Making: A Discussion Paper', TB Alliance, New York, and PATH, Seattle, 2012.

<sup>5</sup> Wells, W. and Brooks, A., 'PDP Support of Country Decision Making: A Discussion Paper', TB Alliance, New York, and PATH, Seattle, 2012.

The Government of Japan's leadership and commitment to addressing the challenges related to innovation and access to and delivery of new health technologies for NTDs are highly appreciated by the United Nations Development Programme (UNDP) and other partners. The collaboration between the Government of Japan and UNDP focuses on the promotion of R&D and on increasing access to and delivery of health technologies used to address TB, malaria and NTDs. These efforts build on the synergies between the Government of Japan's 2011–2015 Global Health Policy, which calls for new partnerships to stimulate research in NTDs, and UNDP's Strategic Plan 2014–2017, which aims to eradicate poverty, reduce inequality and improve human security, by strengthening countries' institutions to progressively deliver universal access to basic services. Sustainable capacity is critical to achieve the MDGs and future sustainable development goals, such as MDG8.E ("in cooperation with pharmaceutical companies, provide access to affordable essential drugs in developing countries"). To indicate success of MDG8.E countries must show "a proportion of population with access to affordable essential drugs on a sustainable basis". This indicator of sustainability indicates that countries must have, or develop, the capacity for access to and delivery of new health technologies. Ongoing discussions of the health goal of the post-2015 SDGs continue to reflect the importance of NTDs and the commitment to addressing the related needs as a critical part of sustainable development efforts.

The Government of Japan is leading efforts through an innovative partnership with UNDP, consisting of the Global Health Innovative Technology (GHIT) Fund and the Access and Delivery Partnership (ADP). The Government of Japan launched the GHIT Fund, a non-profit organization with "the purpose to engage exclusively in activities for the promotion and support of scientific research in the public interest and specifically for the research and development and delivery of medical products and technology for developing countries, and through these activities, to deliver Japanese technologies to the patients and citizens of developing countries...". GHIT, with its mandate reflecting MDG8.E, supports partnerships between Japanese research organizations and global PDPs or academia to provide affordable essential health to LMICs on a sustainable basis.

The complementary ADP is a unique partnership bringing together the UNDP, the World Health Organization Special Programme for Research and Training in Tropical Diseases (WHO/TDR) and PATH. Recognizing the capacity gaps in LMICs to effectively access and deliver needed new health technologies, the partnership supports countries to strengthen their capacities to address bottlenecks in this area. The ADP complements the work of the GHIT Fund by bridging the chasm between R&D and access and delivery in LMICs. UNDP, working with WHO/TDR, PATH and other technical partners, will strengthen capacity in select LMICs, ensuring appropriate policy and regulatory frameworks; monitoring of safety issues; health financing; and pricing, supply and delivery systems for access to and delivery of these new health technologies for TB, malaria and NTDs. The Government of Japan's engagement is particularly timely, given the maturation of the R&D sector producing new drugs for global diseases and the critical need for capacity-building for their access and delivery in LMICs.

The submission of this report to the Government of Japan marks the successful completion of the ADP's first phase.<sup>6</sup> The report outlines implementation results to date and discusses the challenges the partnership has faced and the lessons it has learned to this point. Progress to date is presented in the context of the agreed country-level work plans, which illustrate the rationale for the approaches guiding activities in each country. Other sections present the plans for strategic monitoring and evaluation of the partnership and joint efforts to ensure visibility and communication to enable the ADP's experiences and successes to shape efforts in other countries.

<sup>6</sup> The ADP project's Phase 1 covers the period from 1 April 2013 to 31 July 2014. Phase 2 will begin on 1 August 2014 and end with the project termination date on 31 March 2016.





## Implementation results

The ADP's focus and approach require primarily effective working relationships between the partners — UNDP, PATH and WHO/TDR — as well as strong partnerships with and leadership from government stakeholders in the project's focus countries. Engagement on policy and strengthening of capacities and systems will generate sustainable results with buy-in and ownership from the governments in question. In this context, ADP has been focusing its Phase 1 efforts on strengthening the partnership as well as on establishing relationships with government stakeholders and champions, building on the comprehensive, context-specific evidence base that partners have consolidated through extensive consultations and reviews in-country. The achievements of Phase 1 provide a strong basis and position partners well for the activities planned for Phase 2 in the four focus countries and beyond.

### i. Project inception

To ensure a strategic approach to the partnership and the global- and country-level activities, the project partners undertook a series of preparatory work from April 2013 to March 2014 and implementing activities from November 2013 to June 2014. Partners collated relevant evidence to inform the partnership's priorities, selected focus countries for national-level capacity-building efforts and established partnership agreements between the three main organizations. A systematic review of the global landscape of TB, malaria and NTDs examined approaches and strategies adopted to promote access to and delivery of health technologies. This review served to identify valuable lessons to inform the development of the ADP's strategic plan and future implementation described below.

Project partners agreed on a strategic approach for the project that focuses on the **three key determinants** that affect how well LMICs are equipped to absorb new health technologies, namely:

- promoting innovation that can develop and adapt suitable health technologies to meet the specific needs of the populations in developing countries;
- promoting affordability, by addressing factors that determine the cost of health technologies; and
- strengthening national capacity so that the health care infrastructure and the policy/regulatory environment are adequately equipped to make health technologies available.

In line with the strategic approach, the project partners agreed on six key pathways for capacity-building at national level that informed the **partnership's objectives** and which in turn will support countries to achieve MDG8.E.

Project partners agreed to focus on countries in Africa and Asia, where the burden of TB, malaria and NTDs is high and where the project is likely to contribute significantly to improving health outcomes. In August 2013, project partners undertook an extensive assessment of countries against agreed criteria, comprising four categories of indicators: political will and commitment; existing in-country or domestic capacity; availability of information; and the potential for high impact and South–South cooperation. **Ghana, Indonesia, Tanzania and Thailand** were selected as the initial set of focus countries.

In October and December 2013, through a cross-cutting and multidisciplinary approach, extensive efforts were made to consult with important national stakeholders (including the Ministries of Health, Trade and Industry, Science and Technology, National Agencies of Drug and Food Control and local phar-

maceutical industries) in Ghana, Indonesia and Tanzania to establish partnerships and ownership across the board. The country visit to Thailand was postponed due to the political situation in Bangkok. Instead, the project partners conducted informal consultations with some key stakeholders in Thailand, including the Ministry of Public Health, the Health Intervention Technology Assessment Program (HITAP), the International Health Policy Program (IHPP) and WHO Thailand.

The positive and supportive reactions from government stakeholders set the basis for country visits to Ghana, Indonesia and Tanzania with a view to engaging key government officials, policymakers and technical partners at the national level to assess the country situation with regard to the implementation of project activities and to identify potential synergies and linkages with national priorities and needs.

In February and March 2014, multi-stakeholder project planning and inception workshops were organized in Indonesia and Tanzania, with the aim of consulting with national policymakers on the proposed ADP activities. The workshops provided valuable opportunities for project partners and national policymakers to jointly develop comprehensive country implementation work plans. The integrated package of capacity-building activities as defined in the country implementation work plans were warmly welcomed in Indonesia and Tanzania, where ongoing technical and financial support from the Government of Japan has already made significant progress in public health.

To ensure the optimal level of engagement and of resource allocation for in-country activities, the partners agreed to initiate a comprehensive range of activities in Indonesia and Tanzania, while a more limited range of activities will be implemented in Ghana. Consultations have been conducted with the UNDP Country Office, government stakeholders and technical partners in Ghana on the range of priority issues. Based on the findings of these consultations and factoring in the level of financial and human resources required, the partners have agreed to develop a draft work plan for Ghana, which will focus on Pathways 1, 2 and 3, which are related to capacity-strengthening for coherent legal and policy frameworks and for disease control programmes and drug regulatory frameworks. The partners further agreed that this decision may be revisited on a yearly basis, and that activities in Pathways 4 and 5 may be added to the Ghana country implementation work plan, as needed. It was also noted that the implementation of activities related to Pathways 4 and 5 in Indonesia and Tanzania will provide useful models and learning for Ghana. In Thailand, while recent political developments have not encouraged comprehensive implementation of country-level activities, the project partners have engaged in active dialogue and consultations with key stakeholders in the country, including conducting trainings with technical experts from Thailand to promote South–South learning.

As assessment of the progress made in Phase 1 across the partnership's six pathways of the project implementation stage is presented in the narrative below and in a summary table in Annex 1.

## ii. **Pathway 1: Support strengthening of legal and policy frameworks to expedite access to and delivery of new health technologies for TB, malaria and NTDs**

The lack of policy coherence can hinder the creation of an enabling environment for development, procurement and distribution of new technologies in many LMICs. Laws and policies need to address the various intersections between public health and industrial and fiscal policies and technological innovation, to ensure sustainable access to and delivery of affordable medicines and treatments. Many LMICs now also increasingly regard the development of local pharmaceutical production capacity, and domestic R&D capacity in the public and private sectors, as important strategic elements in the development of a sustainable public health system. In this context, guided by the particular domestic needs and priorities, an appropriate balance is required between policies to meet current needs and policies to develop capacities in the future.

The focus of this pathway is on strengthening national capacities for developing a coherent policy and legal environment for access and delivery. Over the course of Phase 1, the partnership, under the leadership of UNDP, has established strong linkages in the focus countries to support the achievement of this first objective. Initial country missions supported the collection of information about policy gaps and incoherence, highlighting the priorities for the partnership in Phase 1 and beyond. As this process was conducted in a participatory manner, buy-in has been secured from government stakeholders, who have not only expressed support for the partnership and its policy-focused objective but have proactively requested the ADP's engagement in specific, ongoing efforts related to access and delivery.

## Indonesia

A number of ongoing developments in Indonesia provide opportunities for collaboration, with the potential of beneficial synergies between existing national programmes and the proposed ADP activities under Pathway 1. Indonesia is currently establishing a new national social security system, covering five benefit programmes, including a national health insurance system that seeks to provide universal health coverage by 2019. It can be expected that ensuring long-term sustainability, particularly in terms of regulating and managing the cost of medicines and other health technologies, will be an important focus. The Indonesian government has also been supporting a broader policy goal of promoting domestic pharmaceutical production and has taken certain measures to increase the availability and affordability of essential medicines. Given the government's policy goal in relation to domestic pharmaceutical production, there is a need for greater focus on identifying the specific needs for capacity-building and technological advancement in the domestic pharmaceutical sector.

A difficulty lies in the current capacity of the local industry to produce the medicines at an affordable cost, which will require further examination of the need for other related policies and strategies — for instance, to address cost-effectiveness and economies of scale, as well as the effective transfer of technology, manufacturing know-how and R&D capacity. In addition, the Ministry of Law and Human Rights is currently undertaking a process of reviewing the relevant policy and legal frameworks, with a view towards clarifying the implications of its provisions for access and delivery. The ADP identified and has been implementing a set of activities to support the development of a coherent legal and policy framework and the implementation of policy approaches appropriate to national priorities and needs.

### *Training workshop on public-health-sensitive policy and law*

Given the current focus on the policy and legal review in the context of public health, the Ministry of Law and Human Rights requested the ADP's support to build capacity among its staff. The ADP subsequently organized a training workshop in Bali on 20–21 May 2014, with the objective of building the capacity of relevant Ministry staff on the effective integration of public health considerations within existing national policy and legal frameworks, to enable and promote domestic innovation and access to affordable health technologies.

This training represents the ADP's first capacity-building effort in Indonesia and an important entry point to identifying and meeting other capacity needs in access and delivery. Working with national stakeholders, a range of capacity-building needs will be identified to strengthen capacities for the implementation of policy approaches, including the development and implementation of appropriate innovation models in Indonesia.

### *Intersectoral planning meeting*

To consolidate the implementation phase in Indonesia, the ADP organized an intersectoral meeting on 19 June 2014 to consult with all stakeholders and ensure a coordinated approach in the design and undertaking of the activities. The objectives of the meeting were to: identify the focal points within the

different government agencies for the various interventions in the implementation work plan; clarify the management and funding arrangements for the ADP in Indonesia; and agree on a mechanism for the coordination and management of its activities. The intersectoral planning meeting was chaired and facilitated by Professor Agus Purwadianto, Senior Advisor to the Minister of Health on Health Technology and Globalization. Participants agreed on the need for mechanisms to formally elucidate the partners' commitment and ensure coherent implementation of the ADP, including the establishment of an intersectoral planning committee, convened and chaired by the Ministry of Health, comprising of representatives from a range of relevant government agencies and ministries.

It is envisaged that the intersectoral planning committee will play a key role in providing policy guidance on the prioritization of support in this area and approaches to reconcile differing policy objectives and goals. The committee would also be well placed to convene stakeholders from across the different fields and sectors of public health, pharmaceutical R&D and production, science and technology, and financing and investment, with the aim of identifying the areas of support needed along the value chain of development and delivery of and access to new health technologies.

## Tanzania

Within the public health and innovation policy framework in Tanzania, the key policy and implementation issues relate to: the strengthening of sustainable local pharmaceutical production to meet public health needs; and the development of an enabling environment to support domestic pharmaceutical R&D and innovation.

### *Study on the pharmaceutical market and industry structure in Tanzania and Ghana*

Domestic pharmaceutical production is increasingly seen as a viable option to ensure access to medicines in much of Africa, which is reflected in the prominence of domestic production in regional frameworks such as the African Union Pharmaceutical Manufacturing Plan (AU PMPA) and the Regional Pharmaceutical Manufacturing Plan of Action of the East African Community (EAC). Currently, Tanzania's pharmaceutical industry is facing a range of challenges, including weak regulatory capacity, uneven distribution to the consumer market, human resource gaps and legal barriers. Tanzania has expressed commitment to achieving self-sufficiency and is giving local producers a 15 percent preferential treatment during the consideration of tender processes to supply the local health system. While Tanzania has taken some steps towards addressing legislative and policy incoherence, much work remains to be done.

The policy and legal framework governing the regulation of medicines, protection of intellectual property rights and procurement requires a coherent approach to enable the objective of access to affordable medicines to be met. There is a need for the integration of public health and industrial policies in Tanzania to meet challenges related to domestic production, as well as the development and strengthening of technological competencies for domestic pharmaceutical production, which can be facilitated through an appropriate policy framework for training, technological learning and upgrading. In this context, the ADP identified a number of activities for Phase 1.

To increase understanding of the pharmaceutical market and industry structure in Africa and to analyse the implications for innovation and the production of essential medicines, the ADP has commissioned a study with special reference to Ghana and Tanzania. The findings will support efforts to strengthen the policy and legal framework, the various intersections between public health and related health policies and those of industrial and fiscal policies, as well as medicines regulation.

Based on the review's findings and the input from national stakeholders, a range of national capacity development training activities will be identified to enable the development of appropriate innovation models in Tanzania. Specific areas of focus could include the implementation of national legislation, as

well as relevant workshops on the implementation of an integrated industrial, public health and innovation policy framework.

Initial discussions with the Commission of Science and Technology have led to plans for a multi-stakeholder meeting to consider questions around the integration of R&D, innovation and local pharmaceutical production. The Commission's considerations of local R&D needs provide an opportunity to broaden the discussion and address the larger policy and legal environment to ensure access and delivery.

## Ghana

Ghana has shown strong political commitment to addressing access and delivery issues. In regional- and country-level efforts to implement the AU PMPA, Ghana has emerged as a leader in implementing the plan's accompanying business plan and in strengthening the country's ability to produce affordable, high-quality medicines. With these ongoing efforts and investments by a range of domestic and international stakeholders, the ADP is identifying opportunities to build on synergies and to leverage the existing political momentum. This has required a tailored approach to initiate engagement of the ADP in Ghana to identify synergies and expand existing partnerships and coalitions to include the ADP.

Following an initial scoping mission in October 2013, the ADP initiated activities in Ghana in June 2014, with further in-country consultations facilitated by UNDP with key stakeholders, including the Ministry of Health and the Ministry of Justice. Following initial discussions with the ministries and securing their strong support for the project, the Ministry of Justice has requested UNDP's support to engage parliamentarians during the process of legislative review. This provides an important entry point for a longer-term engagement strategy with various ministries and stakeholders on policy coherence. To support this engagement, UNDP has commissioned an assessment of the current legal framework in Ghana from the perspectives of innovation, public health and access to medicines. The assessment will inform recommendations for legislative reform, in particular in the context of the objective and aim of the AU PMPA.

### iii. Pathway 2: Enhanced capacity to identify and address country-specific health system needs for effective access to and delivery of new health technologies

Health technologies that have proved efficacious in the strictly controlled scientific settings of clinical trials may not be as effective when used within the contexts of routine systems or real-life settings. This is often due to issues of the physical environment, socio-economic or cultural issues, as well as health systems and user characteristics. These issues can constitute impediments to effective access to and delivery of health technologies in LMICs.

The focus of this pathway is the strengthened capacity to identify and address bottlenecks impeding effective access to and delivery of health technologies. Specifically the work will focus on the development of relevant skills within health systems to: estimate burden of disease and assess needs and identify barriers/bottlenecks to the scale-up and effective use of health technologies; plan, study, analyse and implement appropriate activities for addressing and mitigating identified bottlenecks; and identify and train women health professionals to sustain capacity beyond the lifetime of the project. The WHO TDR leads the implementation of activities for this pathway. It has produced a key training manual — an Implementation Research Toolkit — to support the capacity-building activities; this will be available to support implementation and operations research activities in the focus countries over the next 36 months.

## Indonesia

Health services are decentralized, and challenges remain at the local level, affecting service delivery. There is also a need to strengthen capacity for operations/implementation research towards improved service delivery of interventions and robust, sustainable health services in general. The need for a vital statistics registry was also identified during the national consultations. In this context, the ADP will be supporting an in-depth analysis of national capacity for operations/implementation research. Since there are well-established health research institutions and systems in Indonesia, this output will primarily support and build on the work of the Ministry of Health, the National Institute of Health Research and the National Training Agency. The analysis will articulate the efforts of the Ministry of Health, research and academic institutions in operations/implementation research. It will form the basis of a stakeholder consultation, led by the National Institute for Health Research and Development (NIHRD), with involvement from TB, NTD and malaria control programmes, the Global Fund's Country Coordinating Mechanism and the WHO, which will result in the development of a framework for strengthening operations and implementation research capacity in Indonesia over a 36-month period.

Following the stakeholder consultation and the preparation of the framework for capacity-strengthening, an action plan for conducting studies aimed at improving access to and delivery of interventions at the district level will be developed. A series of training activities will be embedded within the malaria, TB and/or NTD programmes to implement the plan. TDR will make available a training tool (<http://who.int/tdr/publications/topics/ir-toolkit/en/>) to facilitate the training. It is anticipated that the National Training Agency will lead this activity, with support from key universities.

## Tanzania

Tanzania has a progressive approach to self-reliance in national health research, with several national institutions taking the lead and presenting opportunities to strengthen the capacity for operations/implementation research towards improved access and delivery. These institutions include the National Institute for Medical Research (NIMR), the Ifakara Health Institute, the Muhimbili College of Health and Allied Services (MUHAS) and the Council for Science and Technology. The capacity of implementers to identify challenges and work with appropriate collaborators to design and undertake research to address bottlenecks linked to physical, socio-economic and cultural factors, health systems and stakeholders is key to successful programme implementation. In this context, the ADP identified and has been implementing a number of activities for Phase 1.

### *Analysis of national health system capacity for operations and implementation research*

Led by the NIMR, the ADP is supporting an analysis of national capacity for operations and implementation research with the involvement of the Ministry of Health (disease control programmes). The analysis will articulate the gaps and implementation bottlenecks limiting effective implementation of efforts to effectively control malaria, TB and NTDs.

To initiate this analysis, the NIMR, with support from WHO/TDR, facilitated a national consultation bringing together three national control programmes (the National TB and Leprosy Programme, the National Malaria Control Programme and the NTD Control Programme) as well as health systems experts and NIMR scientists on 27–28 May 2014. The workshop's objectives were to: identify gaps and bottlenecks limiting effective implementation of efforts to control malaria, TB and NTDs; identify causes of health system failure; propose strategies to address gaps and bottlenecks that weaken the health system; and propose strategies for effective integration and strengthening of health systems. Each control programme provided an in-depth gap analysis which highlighted some consistent challenges across the various programmes, including human resource constraints such as remuneration, demand, supply and shortages, recruitment, retention, competencies and education. Others included the organization of and relation-

ships between different levels of government and infrastructure and logistics-related issues that lead to poor laboratory services and supply chain challenges. Coordination and the accuracy and completeness of strategic information also present challenges for planning and monitoring. Health financing concerns related to a general lack of adequate resources and an over-reliance on external sources.

#### *Development of a training and capacity-strengthening framework*

The findings of the analysis provided the basis for the prioritization of research questions and plans of action to address the gaps and implementation bottlenecks. To this end, a consultation involving staff from the major national disease control programmes (malaria, TB and NTDs), researchers and academia (COSTECH, Ifakara Health Institute, MUHAS, Kilimanjaro Christian Medical Centre (KCMC), Kilimanjaro Medical Research Institute (KCRI), Catholic University of Health and Allied Sciences (CUHAS)) was organized by NIMR in the first week of July 2014. The group prepared a framework for training and strengthening capacity for operations and implementation research within the NIMR network and disease control programmes on the mainland and Zanzibar over a 36-month period. Tools developed by TDR will be made available and support the implementation of training activities (<http://who.int/tdr/publications/topics/ir-toolkit/en/>).

### **Ghana**

Ghana has a well-established network of regional health research centres. Located in the south, middle and north of the country, these centres provide an important resource for strengthening capacity to optimize access and delivery close to the communities that will absorb and use the new technologies when they become available. The ADP initiated activities in Ghana in June 2014 with consultations with the key stakeholder for this pathway, the Health Research and Development Directorate of the Ghana Health Service. Following the consultations, an action plan for step-by-step capacity strengthening at the regional research centres will be developed.

## **iv. Pathway 3: Strengthened capacity to monitor and respond to safety issues associated with new health technologies**

Scaled-up deployment and use of new technologies in any population will invariably result in the manifestation of previously unanticipated events and adverse reactions, including those associated with the inadvertent use of these technologies by subpopulations not covered during trials associated with development. Studies suggest that governments pay considerable amounts from health budgets towards covering costs associated with adverse reactions.<sup>7</sup> Furthermore, there is evidence of a relationship between the safety profile of medicines and socio-political, economic and cultural factors, which in turn affect access, utilization patterns and public perceptions of medicines.<sup>8,9</sup>

This underscores the importance of a system for detecting, assessing, understanding and managing or preventing adverse effects or any possible drug-related problem within national health systems. Drug safety monitoring involves a wide range of partners and requires sound and comprehensive systems that make collaboration possible, as well as training, resources, political support and scientific infrastructure. This pathway focuses on strengthening capacities of target countries to monitor the safety of new health technologies in real-life contexts (scaled-up deployment).

7 White, T.J., Arakelian, A. and Rho, J.P., 'Counting the costs of drug-related adverse events', *Pharmacoeconomics*, 1999, 15(5): 445–58.

8 Avorn, J. and Solomon, D.H., 'Cultural and economic factors that (mis)shape antibiotic use: The nonpharmacologic basis of therapeutics', *Annals of Internal Medicine*, 2000, 133: 128–135.

9 Ball, L.K., Evans, G. and Bostrom, A., 'Risky business: Challenges in vaccine risk communication', *Paediatrics*, 1998, 101: 453–458.

## Indonesia

In Indonesia, consultations with stakeholders in December 2013 revealed that the Government of Indonesia is collaborating with USP and that opportunities exist to strengthen the focus of this collaboration in the area of pharmacovigilance and safety. Having identified the Indonesian Food and Drug Authority as the partnership's main counterpart for this pathway, TDR will be working with stakeholders to assess training needs in the area of pharmacovigilance.

### *Review of legal frameworks for adverse reaction reporting requirements*

One of the issues identified is the absence of a legal requirement for health professionals to report adverse drug reactions. To learn from experiences of other LMICs, a review of the laws and policies in selected countries is being conducted. The review will analyse the policy and legal frameworks, with the aim of identifying options that can facilitate the introduction of mandatory reporting of adverse drug reactions in Indonesia.

### *Establishment of a national taskforce to develop a road map for capacity-strengthening*

The limited human resources available to focus on pharmacovigilance at the national and regional levels were identified as a major limitation in capacity. Resource persons from WHO's Department of Essential Medicines and Health Products will provide technical support in the development of a road map for strengthening capacity for pharmacovigilance in the country. The Directorate of Distribution Control of Therapeutic and Household Healthcare Products under the National Agency of Drug and Food Control (NADFC) was identified as the lead on this activity. Plans are in place to coordinate these activities with health systems strengthening efforts supported by the Global Fund to Fight AIDS, TB and Malaria, which could provide resources to support the implementation of strategies aimed at improving pharmaceutical and supply chain management, drug safety and pharmacovigilance.

The need to engage with the pharmaceutical industry, health care professionals in the regions and the national regulatory authority was identified as key to develop capacity for pharmacovigilance and to evaluate and provide recommendations on adverse drug effects within the regulatory authority. This activity will focus on tailored training for the different categories of stakeholders. A team established by the Ministry of Health will coordinate the engagement of the various stakeholders for this pathway.

## Tanzania

Adverse drug reactions have a considerable impact on government health spending, which is largely unmonitored and difficult to assess in LMICs. In Tanzania, consultations with relevant policymakers and stakeholders in October 2013 revealed that the Ministry of Health and the Tanzania Food and Drug Authority (TFDA) have a system in place for reporting adverse drug reactions. The ADP has identified the opportunity to strengthen the existing mechanism by increasing the awareness and competence of health workers in reporting adverse drug reactions. As an initial step the ADP supported the training of two TFDA staff at the WHO Collaborating Centre for Advocacy and Training in Pharmacovigilance (WHO-CC) in November 2013. The WHO-CC is a regional resource with the core objective of developing and supporting pharmacovigilance expertise in Africa. The training covered targeted spontaneous reporting, electronic patient records for drug safety and strategic planning in pharmacovigilance. The overall work plan to guide implementation of these efforts is being developed in collaboration with the TFDA and is awaiting final approval. The work plan contains the following main components:

- **Situation analysis and stakeholder consultation:** A situation analysis and assessment of pharmacovigilance capacity among health care workers and within public health programmes will be conducted. The results will be presented and discussed at a stakeholder consultation. It will provide baseline information to guide the choice of training strategy. This activity will be led by TFDA.



- **Training of trainers:** To enhance the strengthening and sustainability of pharmacovigilance capacity in Tanzania, a training of trainers programme will be initiated. The objective will be to develop a cadre of health care professionals able to conduct training courses on reporting adverse drug reactions, pharmacovigilance methods, regulatory aspects of pharmacovigilance and adverse drug reaction mechanisms, and causality assessment. The training will be coordinated by the TFDA with support from the WHO-CC in Accra.
- **Data management:** The activity will focus on strengthening capacity for data management within the TFDA.
- **Strengthening pharmacovigilance modules in the curriculum of health training institutions:** One of the activities under this output is the development of modules to train undergraduate and qualified health care professionals in pharmacovigilance and the importance of reporting adverse drug reactions. Although aspects of pharmacovigilance are taught within graduate programmes and courses on clinical trials, the exposure of health professionals to pharmacovigilance during basic training is limited. The result is a limited appreciation of the importance of and channels for reporting adverse drug reactions. This activity is considered a long-term objective and will involve the Ministries of Health and Education. The chief pharmacist will lead this activity.

## Ghana

The ADP initiated activities in Ghana in June 2014 with a first country mission conducted by the partners, during which consultations were held with key stakeholders. Efforts since the initiation of the activities in Ghana have focused on building relationships with the relevant government partners, including the National Food and Drug Authority and the WHO-CC.

With a strong commitment to addressing issues of safety and pharmacovigilance observed in Ghana, there is now an agreement with the management of both institutions to collaborate with the ADP on activities to strengthen capacity to monitor and respond to safety issues associated with new health technologies. The country is clearly a leader in this area, with the National Food and Drug Authority (National Centre for Pharmacovigilance) and the WHO-CC partnering in a NEPAD/African Union/African Medicines Regulatory Harmonization (AMRH)-designated Regional Centre of Regulatory Excellence in Pharmacovigilance and Pharmacoepidemiology.

## v. Pathway 4: Strengthening capacities in LMICs to ensure evidence-based, sustainable decision-making for resource allocation for new health technologies and commercialization of new health technologies at appropriate pricing to ensure that supply meets demand

In recent years there has been recognition for fostering innovation, research and product development of health technologies that address the needs of LMICs and their significant disease burdens. Several global and regional efforts are focused on political and financial commitment for local production. The number of new health technologies coming to market for TB, malaria and NTDs is also increasing, thanks to the significant investments by a range of partners. However, the public health impact of new health technologies will come only after their large-scale adoption into LMIC health systems,<sup>10</sup> which highlights the urgent need to strengthen the capacity of access and delivery mechanisms. Regulatory policy, financing and open sources of information (partnerships) are key success factors for strengthening innovation and access.<sup>11</sup>

<sup>10</sup> Wells, W. and Brooks, A., 'PDP Support of Country Decision Making: A Discussion Paper', TB Alliance, New York, and PATH, Seattle, 2012.

<sup>11</sup> African Union, NEPAD and COHRED, 'Strengthening Pharmaceutical Innovation in Africa', African Union, NEPAD and COHRED, 2010.

While institutions have invested in strengthening health systems for increased access to products such as ARVs or vaccines, many of these mechanisms provide time-limited support, and governments are faced with challenging resource allocation decisions in periods of transition. There is a need to build capacity within the national system to develop a financially sustainable scheme that provides access to high-quality and priority services and benefits as governments move toward such reforms.

#### *Increasing understanding of key challenges related to the adoption of new health technologies*

Phase 1 of the ADP was primarily focused on understanding the key challenges faced by LMICs for the sustainable and rational adoption of health technologies as well as jointly developing key capacity-building measures to address these challenges. Desk research was conducted to understand the global landscape, lessons learned and best practices that countries are undertaking to build innovative financing mechanisms to ensure sustainability and efficient resource allocation. Consultations were held with key in-country stakeholders in Ghana, Indonesia and Tanzania to understand country-specific challenges and support the development of country-driven capacity-strengthening plans.

The discussions identified that the current decision-making processes for the identification and selection of new health technologies for national programmes have inherent challenges that impact rational and efficient resource allocation and sustainable financing of the technologies. Specifically, current health technology selection processes have limited assessment to link the evidence base of clinical efficacy and effectiveness and implementation research with analyses of economic and health system impact to determine the priority, feasibility and cost-effectiveness of the introduction of new products or interventions in local settings. Technology adoption processes are often donor-driven, with limited transition planning for when donor funding ends, and countries are often left struggling to justify and absorb the cost of financing donor-introduced interventions within their already constrained health budgets.

Therefore, consultations with in-country stakeholders confirmed that there is a significant need to strengthen capacities in LMICs to develop or strengthen a Health Technology Assessment (HTA) process to be more systematic, country-driven and evidence-based. HTA — defined as “a multidisciplinary process to evaluate the social, economic, organizational and ethical issues of a health intervention or health technology” — allows for the systematic evaluation of health technologies based on countries’ needs, develop policies and clinical guidelines, and ensure cost-effective allocation of resources.<sup>12</sup> This same information, combined with data from market and industry assessments, can inform the commercialization and management of health technologies, including pricing and supply strategies.

#### *Development of strategic partnerships*

Following the inception meetings in Indonesia and Tanzania, the ADP successfully engaged with established HTA agencies such as NICE, HITAP in Thailand and PRICELESS in South Africa to leverage their expertise for capacity development in those two countries. The ADP has also engaged with global initiatives that are spearheading capacity-strengthening for HTA and evidence-based priority-setting mechanisms such as the Bill and Melinda Gates Foundation, UKAID and the Rockefeller Foundation-funded International Decision Support Initiative (iDSI) to develop a harmonized approach. Concurrently, engagement with government stakeholders, private-sector associations and local producers is supporting prioritization of health technologies for market assessments and local production feasibility studies, which will be conducted in both countries in the upcoming months.

<sup>12</sup> See: World Health Organization, ‘Medical devices: Health technology assessment,’ WHO website, 9 October 2014; [http://www.who.int/medical\\_devices/assessment/en/](http://www.who.int/medical_devices/assessment/en/)

## Indonesia

Indonesia has set goals for the accelerated scale-up of the universal health coverage scheme, for cost containment through local production and distribution of pharmaceuticals, and for utilization of generics and strengthening measures to improve the quality of health care. However, the ADP's consultation with stakeholders<sup>13</sup> in Indonesia also revealed a number of challenges related to the introduction of new health technologies, including an unstructured introduction process and limited capacity to assess the need for and effectiveness of new technologies.

### *Identification of capacity-building needs*

Indonesia already has an HTA unit embedded in the Directorate of Pharmaceuticals and Medical Devices within the Ministry of Health. However, the capacity of this unit is currently fairly limited, and stakeholders identified the need to strengthen this unit for technology selection such that it is linked to appropriate evidence/country needs and enables sustainable, cost-effective resource allocation. Stakeholders considered the ADP well placed to support Indonesia's efforts in this regard.

Discussions with stakeholders also identified that many medicines sold in Indonesia are sold at prices above the international pricing index. They attributed this higher pricing to the high cost of active pharmaceutical ingredients (APIs), raw materials and finished pharmaceuticals that must be imported into the country. Recognizing stakeholders' keen interest in establishing and increasing local production of essential medicines, the ADP identified the need for an assessment of the current pricing structure on the basis of a selected number of primary health technologies. A protocol for this study will be developed in partnership with key stakeholders.

### *Training on Health Technology Assessments*

Following input from stakeholders consulted in Indonesia and Thailand, the ADP decided to hold an HTA training workshop with key stakeholders as the first step towards strengthening HTA capacity. The main objectives of this workshop were: to raise awareness about the purpose, objectives and roles of HTA programmes in the world; to gain first-hand knowledge from experts about the challenges and experiences associated with establishing a structured HTA programme and the critical factors involved in overcoming any challenges; to share knowledge and experience on assessing applied public health technology; to discuss and identify the vision for HTA in Indonesia and the critical factors that will enable the establishment of a structured HTA programme appropriate for the country; and to outline short-, medium- and long-term major action plans.

A workshop on 23–24 June 2014 brought together 47 participants from the Ministry of Health and other ministries and agencies, with the involvement of regional experts representing HITAP, Thailand, and NECA, South Korea. The workshop confirmed the need for further strengthening of the existing HTA unit, and the completion of HTA guidelines was identified as the immediate next step. In addition, the ADP and HITAP confirmed arrangements for continued collaboration to strengthen HTA capacity in Indonesia.

The project will also support the ongoing health financing reform and scale-up of the universal health coverage scheme. Many stakeholders raised the need for developing a phased plan for inclusion of services for 'parallel' and donor-funded disease programmes such as NTDs, TB and malaria in the scheme. Specifically, needs around costing of programmes to inform resource allocation planning were highlighted. Given the existence of other ongoing initiatives, the ADP will conduct further due diligence and develop a deeper understanding of the current needs of the ongoing reform process and assess the key gaps.

<sup>13</sup> The stakeholders include several directorates of the Ministry of Health, including the Directorate of Pharmaceuticals and Medical Devices, Directorate of Communicable Diseases, National Agency for Food and Drug Control (NAFDC/BPOM), National Institute of Health Research and Development (NIHRD) and the Centre for Health Financing at the Ministry of Health, the WHO Country Office, JSI, USAID and the Global Fund Country Coordinating Mechanism.

Discussions with stakeholders also highlighted the need for further strengthening of existing processes such as the National Health Accounts and the evaluation of other innovative tools for resource tracking. In its second phase, the ADP will conduct desk research and jointly evaluate other tools and approaches for resource tracking currently being utilized, to further inform the discussions and planning of capacity-building activities with key stakeholders.

## Tanzania

Tanzania has been steadily investing in health innovation and research and is planning to scale up national insurance to achieve universal coverage. With funding from various partners, the government is investing in several initiatives to support local R&D and production capacity. Tanzania is also the leader in the EAC's initiative for regulatory harmonization for medicines in the region, with the TFDA leading the regional effort. The government has also initiated activities to better understand its potential for local production of pharmaceuticals (particularly ARVs) and has expanded private-sector investment to enhance innovation and sustainability.

ADP's consultation with stakeholders in Tanzania revealed a number of challenges. These related to the existing system to assess country needs and evidence on existing and new technologies, and the process for the selection and introduction of new health technologies. High pricing of technologies and weak sustainability of donor-funded programmes also impede continued access to technologies, while the potential for local production is still largely unevaluated.

### *Development of HTA capacity of the Ministry of Health and Social Welfare*

In this context, the ADP, under the leadership of PATH, identified a set of activities through a series of consultations with the Ministry of Health and Social Welfare (MOHSW) and other key in-country stakeholders.<sup>14</sup> One of the key activities identified is to inform sustainable resource allocation and financing through the development of HTA capacity within Tanzania. Tanzania currently does not have an HTA unit; however, the Pharmaceuticals Service Section (PSS) of the MOHSW has prioritized developing HTA capacity and included it in its national strategic plan. The Chief Pharmacist heading the PSS is a strong champion for this work, and his keen interest in establishing an HTA unit provides an entry point for creating a road map for capacity-building. Additionally, the Directorate of Policy and Planning and the Deputy Director leading the development of the health financing strategy have also emerged as key supporters for the initiative.

Consultations with key stakeholders also identified a need to assess Tanzania's pharmaceutical manufacturing industry and market and to understand areas for strengthening regional competitiveness. This could include assessing pricing structure, identifying major cost drivers, assessing economic feasibility of local production for selected medicines, and estimating existing demand for priority medicines and incremental gains if local production capacity were to be enhanced. Strengthening an industry requires supportive policies; therefore, collaboration with Strategic Pathway 1 is anticipated in implementing this activity. COSTEC was identified as a key partner for this activity, since enhancing the capacity of local industry is its prime interest.

## Ghana

The ADP had joint consultation meetings with key stakeholders in Ghana in October 2013. However, the ADP subsequently decided to concentrate its efforts under Strategic Pathway 4 on Indonesia and Tanzania in the immediate future, to achieve the best possible outcome in these two countries. The ADP,

<sup>14</sup> These include the Tanzania Commission for Science and Technology (COSTEC), Ifakara Health Institute, NIMR, MUHAS, TFDA, National Health Insurance Fund (NHIF), local pharmaceutical manufacturers such as Keko, Shelys, Zenufa and Mansoor Daya, donors and the NGO community such as the World Bank, Global Fund Country Coordinating Mechanism, JSI and USAID.

however, will continue to assess whether there is a need that could be addressed in Ghana. The Rockefeller Foundation has recently given funding to NICE International for 2012–2014 to support a series of initiatives with the Ministry of Health and associated agencies in Ghana to raise awareness among stakeholders on the role and value of using evidence-based approaches in health care decision-making and priority setting, including performance monitoring. As Ghana is implementing a universal health coverage scheme, the ADP's effort in enhancing HTA capacity in Indonesia and Tanzania could be linked with NICE's effort in Ghana in the future. In addition, the AU PMPA is working in Ghana to develop local production capacity in the country, which provides further opportunities for future collaboration.

## vi. Pathway 5: Strengthened capacity of delivery systems including supply chain of new health technologies for TB, malaria and NTDs

The number of new health technologies coming to market for TB, malaria and NTDs is increasing, creating more choices and additional decisions that need to be made across the supply chain disciplines. The key steps required within a functional supply chain fall under the areas of planning, procurement and distribution. Bottlenecks occur at any point in the supply chain, but there is often more risk for disruption and delays when introducing a new health technology, presenting 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.

The ADP's goal is to work closely with government in understanding the challenges presented when introducing new health technologies into supply systems and to work alongside stakeholders across planning, procurement and distribution to address challenges and identify potential solutions.

### Indonesia

The initial scoping visit and consultations with relevant stakeholders in Indonesia identified a range of supply chain challenges that the country is facing. Multiple agencies at the national and subnational levels are involved in the planning, procurement and distribution of health commodities, which creates particular challenges and gaps. The multiplicity of supply chain levels and players creates challenges across the chain, resulting in stock-outs of medicines and shortages of laboratory and diagnostic equipment consumables. The skills of procurement staff vary across the supply chain, and the professionalization of supply chain management is part of national efforts through the establishment of a 'Unit Layanan Pengadaan' in each government agency conducting procurement at both central and provincial/district levels. TB technologies remain underutilized, as there are challenges with forecasting, distribution and high costs. Conflicts between the national procurement policy and practice and the Global Fund's requirements present particular challenges for Global Fund-financed programmes. The supply of laboratory-related commodities appears to be facing a particular capacity gap, and they are often introduced in an uncoordinated manner.

#### *Development and implementation of the in-depth Supply Chain Assessment*

To help identify and develop tools that will strengthen the ability of key supply chain stakeholders to effectively plan for, procure and distribute new health technologies, PATH initiated activities in Indonesia with an in-depth Supply Chain Assessment in May 2014 to shape the ADP's detailed activity plan. The assessment served to uncover and define the key issues hindering the introduction of new products into the supply chain and solidify working relationships with key government agencies. The assessment also helped build political buy-in from government counterparts for the ADP's efforts to strengthen the supply chain.

The Supply Chain Assessment tool was developed from an extensive review of existing tools and adapted for its application to the assessment of supply chains for the introduction of new health technologies. The implementation of the tool in both Indonesia and Tanzania served also to pilot and re-

fine the tool and will support the development of a standard tool that can be used in other countries. The assessment tool will be one of the components of a broader toolkit that will provide additional information resources for addressing the challenges encountered when introducing new health technologies, such as planning for the possible obsolescence of existing products as new health technologies are introduced and factoring in the infrastructure needs to support the introduction of new medical equipment. The findings of the in-depth assessments in Indonesia and Tanzania have informed the project's efforts to identify and define the different modalities of product introduction and the impact different modalities have on the supply chain. As part of the supply chain toolkit, information from the assessment will support the introduction of and adequate planning for new products at each stage of the supply chain.

Several stakeholders in Indonesia identified a need to look at the planning and procurement process for TB commodities and equipment to see where improvements can be made to support the introduction of new TB products. It was also noted that planning and procurement of new laboratory equipment presented problems to government agencies. In preparation for a detailed assessment in this area in 2015, a review of the planning for and introduction of GeneXpert equipment will be conducted to identify where any bottlenecks occurred during the introduction process and what lessons might be learned that could benefit the introduction of new TB products and new laboratory equipment. The HTA unit was also identified as an important stakeholder whose decisions in selecting new products and technologies can have a significant impact on the downstream supply chain, depending on the product's storage, use and maintenance requirements. The ADP will work with the HTA unit to review its procedures for notifying supply chain agencies of new product requirements so that the necessary planning and preparations for accepting the product into the supply chain can be made in a timely manner.

Based on findings from the above assessment of the planning and procurement processes for new products and technologies, materials, tools and resources will be developed to strengthen the capacity of central-, provincial- and district-level personnel to effectively plan for and procure new health products and technologies. This activity, as currently proposed, would include conducting a training workshop in which the developed capacity-strengthening tools and materials would be introduced to a select group of trainers whose role would be to then provide downstream training to planning and procurement personnel at the provincial and district levels.

## **Tanzania**

According to the Supply Chain Assessment performed by USAID in 2013, significant gains have been made in improving the public-sector supply chain — in particular, the availability of ARVs. Other medical stocks, however, remain uneven due to various factors including inadequate financing, limited efficiencies within the national supply chain, poor infrastructure, outdated or manual management information systems, human resource-related challenges and poor stakeholder coordination. Allocation of responsibilities related to procurement and distribution to different agencies working at central and local levels presents challenges related to coordination. Technical assistance around laboratory equipment and supplies seems to be lacking.

### *Development and implementation of the in-depth Supply Chain Assessment*

As in Indonesia, PATH piloted and implemented the Supply Chain Assessment tool in Tanzania in May 2014. This assessment focused on central-level planning and coordination between different units under the MOHSW, including the National TB and Leprosy Programme, National Malaria Control Programme, NTD Programme, Pharmaceutical Services Section, Diagnostics Service Section, Directorate of Policy and Planning, Procurement Management Unit and Medical Stores Department. The work plan, based on the main gaps, has been developed with buy-in from national stakeholders.

### *Capacity-building to strengthen the supply chain for new health technologies*

Based on results from the May 2014 assessment, the ADP will support a structured planning process for new health technologies. In-country stakeholders agreed that it would be beneficial to begin this process by holding a supply chain linkages workshop that brings all supply chain players together to identify communication gaps between units/key players of the supply chain, specifically in relation to new health technologies. The workshop will be the beginning of discussions for strategic planning for new health technologies along with ascertaining each unit's role and accountability. Supply chain communication needs to improve, especially for new health technologies. The workshop will be held during the first quarter of 2015.

The ADP will also work with the NTD programme to build capacity for regional and district pharmacists and health centre staff in regards to the NTD supply chain. This work will begin with ADP working with other key stakeholders to develop an NTD supply chain brochure and providing or supporting training in the next phase. The NTD supply chain is different from essential medicines due to the mass distribution campaigns and manufacturer requirements of long forecasting plans (at times, five-year forecasts are required).

A Logistics Management Unit has been formed within the Pharmaceutical Services Section (PSS) and has been tasked with oversight and coordination of supply chain in Tanzania. As part of this initiative, an action plan was developed in 2014 and was shared with the ADP. The ADP will work closely with PSS to build capacity in some of the identified areas such as building skills to develop algorithms and developing basic quantification tools.

Additionally, Pathway 5 will coordinate with HTA activities conducted under Output 4 to ensure that procurement and supply chain constraints are taken into consideration.

### **vii. Pathway 6: To provide and consolidate strategic information and evidence to inform capacity-building efforts that will improve access to and delivery of new health technologies for NTDs**

To tailor the support provided by the ADP to the needs of specific countries and the pipeline of future products, the partnership is supporting a range of efforts to develop a base of strategic information and evidence to inform capacity-building efforts. In Phase 1, a mapping of pipeline technologies for TB, malaria and NTDs is being finalized with the aim of identifying those expected to be ready for market introduction by 2020. The analysis will identify the major innovative elements in new health technologies that may place additional requirements or burdens on existing health systems, including financing for procurement; drug regulations; the establishment of patient registries and pharmacovigilance systems; supply, distribution and storage; and health personnel training. This mapping work will include an analysis of the challenges and opportunities for facilitating an enabling policy and legal environment in LMICs for the introduction of new health technologies.

In support of Pathway 1, UNDP is supporting the development of a number of technical guidance notes and briefing papers to strengthen engagement with policy and legal issues related to access and delivery. This includes a technical paper on strategic interventions for enhancing access and delivery, along with a briefing note analysing the common bottlenecks and opportunities for changing the enabling policy environment for pharmaceutical innovation that delivers affordable health technologies, which will provide useful overarching policy guidance for the implementation of the ADP.

To support specifically Pathways 4 and 5, PATH has also commissioned a qualitative study to understand the challenges and best practices from the introduction of new technology, the GeneXpert diagnostic

for multidrug-resistant TB in Uganda and Zambia. This study will inform the strategic planning for the project and will be completed in Phase 2. PATH hopes to publish the findings to inform the global dialogue on the adoption of new technology in the subsequent years of the project.

At the global level, the ADP supported a capacity-building workshop on the global debate on financing for R&D on NTDs through a partnership with the South Centre. In a workshop on mechanisms to promote research and development for TB, malaria and other NTDs, organized in Geneva on 31 March – 2 April 2014, the South Centre facilitated discussions among policymakers in ministries and departments dealing with health, science, technology, education and trade from 14 developing countries. The aims of the workshop were to increase the understanding and awareness of issues relating to the availability of and access to new medical products for TB, malaria and NTDs, and to promote engagement in global discussions on policies and mechanisms to increase financing and coordination for NTDs and options for strengthening R&D capacity in developing countries. The participants agreed on the need for a global framework to support R&D for NTDs to coordinate efforts among the various initiatives and parties involved, but also saw the need for greater commitment from and the involvement of governments, including those of endemic countries. The workshop was an opportunity to introduce the ADP to policymakers and provided a useful forum in which to identify appropriate follow-up in the target countries.

### viii. Financial management

UNDP has maintained financial oversight to ensure that funds are used in the most cost-effective manner and that expected deliverables and outputs are achieved. In April 2013, UNDP received the total contribution amount of US\$3,639,389 from the Government of Japan (Japan–UNDP Partnership Fund), including US\$2,946,105 for the advisory and capacity-building activities, US\$238,360 for staff costs and US\$454,924 for UNDP cost recovery (see Annex 2). As of 7 October 2014, the total estimated expenditures amount to US\$3,607,579.28, including US\$2,907,487.61 for the advisory and capacity-building activities, US\$383,461.99 for staff costs and US\$316,629.68 for UNDP cost recovery. The figures are tentative, and the financial closure process is being performed.

The budget reallocation was conducted after the consultations with the project partners and the Advisory Group members. During the period between April and June 2014, the partners discussed the level of expenditure and the projections for the final expenditure levels at the end of Year 1. By the first week of June 2014, the partners had projected that WHO/TDR and PATH would reach 85 to 88 percent of the delivery rate. To ensure the full delivery of the project, partners agreed on the reallocation of funds between project outputs. This allocation of resources across the project outputs was explained to the Advisory Group at its meeting on 5–6 June 2014. As a result, UNDP's staff costs were increased from US\$238,360 to US\$383,461.99, and project oversight costs from US\$276,105 to US\$418,284.35. The reallocation of the budget was made to mitigate the risk of under-expenditure, including delayed implementation of specific activities at the country level that made it necessary for UNDP to provide additional support for components of activities implemented under Outputs 2–5.

In terms of the closing balance, it is estimated that about \$31,809.72 will be unspent. It is intended that the unspent funds will be carried over to the budget of the next year's programme activities in the approved project document, 'Building Capacity for Access and Delivery of New Global Health Technologies for Tuberculosis(TB), Malaria, Neglected Tropical Diseases (NTDs), and Other Diseases in Low and Middle Income Countries(LMICs)':



## IV. Sustainability

Sustainability of the ADP's results is supported on various levels. The project's approach to strengthening skills and systems at national level ensures that there is a transfer of resources for countries to develop and implement solutions that are appropriate to their context. Policy coherence and strengthening of the legal and policy frameworks of the respective countries ensures systemic change that will sustain change beyond the provision of inputs from the ADP. Alignment of the ADP's efforts with other ongoing initiatives and national strategies is an important underlying principle which will further support sustainability of the results achieved.

Critical to these sustainable results will be country ownership and leadership by national stakeholders in identifying the main challenges, developing solutions and taking change forward. The ADP's investments to date have focused on building this foundation of national support and engagement. The national work plans agreed in the first half of 2014 with buy-in from the respective national governments represent the first outcome of these partnerships with local stakeholders.

## V. Project management

### i. Quality of monitoring and evaluation

To support effective monitoring of the ADP, partners agreed on defined targets outlined in the project work plan. These support individual partners to track their progress against the agreed activities and objectives. Partners have been establishing organization-level monitoring systems to track activities. PATH, for example, has been engaging its monitoring and evaluation (M&E) technical team to develop the organizational M&E framework for the project. Further, capacity-building workshops led by the partners have a three-part evaluation designed to pre-test, post-test and evaluate workshop trainers and expectations of the content. The capacity assessment will be revisited towards the end of the project to identify how well tools and processes assisted in closing gaps and compressing implementation timelines.

Building on ongoing efforts by each partner, the ADP has identified the need to develop a broader M&E framework to monitor and evaluate the impact of the ADP at the outcome level in each country and globally. The partnership's concerted theory of change will provide the basis for the M&E strategy that will be developed early in Phase 2 of the project and implemented from then on.

### ii. Timely delivery of outputs

Throughout Phase 1 of the ADP, partners have delivered outputs and achieved results in a timely manner. Due to the nature of the project, its focus on national ownership, participatory approaches and the importance of supportive political relationships and contexts, the investment required to establish a strong foundation for the partnership and project in-country is extensive.

The uniqueness of the partnership required UNDP to establish new mechanisms for project management and oversight. Formalizing the partnership with PATH included capacity and financial assessments to inform the partnership agreement. With the donor's agreement, these requirements were taken into account in the planning and monitoring of results for Phase 1, which was subsequently extended by three months.

### iii. Project oversight and management structure

Using UNDP's NGO implementation modality, PATH has been implementing the project, together with UNDP and WHO/TDR as the responsible parties. Under this modality, PATH, WHO/TDR and UNDP have been responsible for the implementation of their assigned components of the project. In accordance with the Project Document, UNDP has also successfully recruited two dedicated staff members to provide the management, technical and operational support to the ADP, as well as to provide the relevant support to the GHIT Fund project. In addition, the ADP has contributed support for staffing at the UNDP Country Offices in Ghana and Tanzania, and consultations are underway to provide the same to the UNDP Country Office in Indonesia.

The ADP benefits from the support of a high-level Advisory Group, which was established in August 2013 with the aim of providing strategic and substantive advice to the project partners. The Advisory Group comprises experts in the fields of public health, development and NTD R&D, as well as civil society. Its work is guided by agreed Terms of Reference to provide non-binding technical and strategic advice for the implementation of the ADP.

In Phase 1, the Advisory Group, which had convened twice via teleconference and once in person, was provided with an overview of the project and consulted on issues related to the strategic collaboration for project leverage. The most recent meetings in June 2014 served to update the Advisory Group on the implementation progress of the ADP, obtain technical advice and strategic guidance on the overarching approach of the ADP and identify and discuss the ways in which the Advisory Group can effectively carry out its role and function. Discussions identified opportunities for strategic collaborations with other ongoing initiatives to avoid duplication and maximize the impact of the ADP's resources and expertise.

As the lead agency for the partnership, UNDP has the responsibility for project oversight and management, developing and facilitating the implementation of a coherent strategy across all partners. Over the course of the initial inception meetings, UNDP facilitated the development of the partnership agreements and the formulation of the project strategy, which provides, among others, a guiding approach for project implementation and an effective division of roles and responsibilities for the partners. The project work plan, which details the scope and sequencing of project activities, is placed within a coherent strategic framework that leverages the respective competencies and expertise of UNDP, WHO/TDR and PATH. Essential operational and reporting modalities for timely disbursement of funds have also been established.

## VI. Communications and visibility

Since its inception the project has supported several initiatives to increase the visibility of the donor and the ADP among relevant stakeholders at national and global levels. Materials that introduce the project and its main objectives have been developed in the form of a 'Fast Facts' publication and a 10-page booklet, produced by UNDP. The booklet illustrates Japan's Global Health Policy 2011–2015 and highlights Japan's important leadership role in the field of global health.



Booklet: Front cover (left) and back cover (right)

In addition, partners have been publicising the project's inception and initial results through blog posts and articles on their respective websites. For instance, Tenu Avafia's blog on the UNDP public website highlighted the Government of Japan's important role in promoting R&D and access to and delivery of new health technologies.<sup>15</sup> The ADP has also been branded through a joint logo (see the front cover of the booklet), which is present on all published materials, as well as acknowledgment of the support of the Government of Japan to the partnership.

To increase the strategic value and impact of the communication efforts, a consulting firm, Inis Communications, has been contracted to facilitate the development of a communications strategy for the ADP, which will be completed and agreed on early in Phase 2 of the project implementation.

In support of future communication, positioning and advocacy efforts, partners have already identified existing initiatives linked to the ADP's strategic objectives and plan to engage and share learning from the project to inform global policy related to access and delivery in LMICs. Some key regional and global initiatives include the AU/NEPAD-supported PMPA, the Bill and Melinda Gates Foundation-funded initiatives such as the International Decision Support Initiative (funded also by the UK Department for International Development) with NICE (UK) and HITAP Thailand, and ASEAN and AU regional harmonization and collaborative activities. Specifically for Pathways 4 and 5, plans include collaboration with the People that Deliver initiative, which is focused on building human resource capacity to support the public health supply chain, including engagement of professional logisticians from Indonesia and Tanzania in its 2014 conference. Learning from Pathway 5 will be shared with other global health supply chain initiatives. As project tools are developed and project findings are identified, these will be shared with others interested in commodity supply such as the International Association of Public Health Logisticians (IAPHL), StopTB, Roll Back Malaria, PSM Toolbox, People that Deliver and the Reproductive Health Supplies Chain Coalition (RHSC).

<sup>15</sup> See: Avafia, T., 'To address health challenges, we must pay attention to Neglected Tropical Diseases', UNDP website, 25 April 2014; <http://www.undp.org/content/undp/en/home/ourperspective/ourperspectivearticles/2014/04/25/to-address-health-challenges-we-must-pay-attention-to-neglected-tropical-diseases-tenu-avafia.html>.

## VII. Implementation challenges and lessons

### i. Project risks and actions

Over the course of the first phase of implementation, project partners have identified a number of operational risks that could influence the achievement of the partnership's objectives. These operational risks have included lack of in-country presence in the focus countries. The challenges associated with this situation include the time-frame required to build relationships with government partners and follow up with individual stakeholders on commitments and action plans. Collaboration between project partners at country level will help mitigate this risk, as partners provide support and can leverage each other's strengths and existing relationships across pathways. Formal recognition by the governments in focus countries will also be crucial to mitigating this risk and ensuring continuity of government engagement and support for the project.

Potential political risks may also affect implementation. For instance, Indonesia faces national elections, which could result in a change of government stakeholders and will require the re-establishment of relationships and commitment. The intersectoral planning meeting in Jakarta, in June 2014, helped to mitigate this risk by establishing a strong base of support across sectors and different levels of government. Project implementation in Thailand was postponed due to the political situation in the country, which raised some uncertainty related to the level of government engagement, as well as the possibility of changes in policy and leadership of the relevant ministries. To minimize the risk of such changes and their impact on the achievement of results in Thailand, the ADP has thus far focused its engagement in terms of building technical partnerships with relevant key actors, rather than the implementation of national-level projects, until the political situation and longer-term role of key government agencies are clarified.

The multitude of existing initiatives and projects focusing on access to medicines for NTDs also presents a risk to continued political engagement. ADP partners have also sought to manage expectations from country-level stakeholders regarding the level of financial resources that are available and the focus of the project. The ADP will also invest efforts to ensure appropriate communication and positioning of the project to facilitate the management of expectations and added value at the country level.

### ii. Project challenges and lessons learned

The complexity of the access and delivery system at country level has presented a significant challenge during this initial phase of project implementation. The multitude of ministries and government stakeholders engaged in the various aspects to ensure access and delivery requires a multi-stakeholder approach. Challenges related to effective policy implementation and the establishment of related systems can often be traced to the lack of coordination between ministries. The broad, overarching and multi-disciplinary approach of the project requires direct engagement with a range of key stakeholders to address this challenge, which is also a unique opportunity to address it. The ADP intends to provide added value by facilitating engagement between ministries and by forging collaborations between ministries which may not have traditionally worked together in a coordinated manner.

This has required the identification of strategic entry points to initiate and establish coordination and coherence across the access and delivery process, including the introduction and selection of technology and resource allocation. In Indonesia and Tanzania, the government's commitment to universal health coverage has provided a suitable opportunity to leverage political engagement. Discussions about health financing reforms were used as an opportunity for discussion with key policymakers and technocrats to develop a country-driven capacity-strengthening plan towards linking new technology selection processes with resource allocation. Stakeholders identified a strong need for capacity-strengthening and building robust HTA processes in the country that would bring together policymakers, academia, implementers, clinical experts and other key stakeholders for an evidence-based prioritization and technology adoption/introduction process. The identification of key champions in both countries will also contribute to sustaining political buy-in and support the implementation of the jointly developed work plan.

Close collaboration with government stakeholders has also guaranteed support for the collection of comprehensive information, identification of challenges and the implementation of initial activities. Integration and alignment of ADP activities with national and local strategic plans will also increase sustainability of political engagement. In Tanzania, for instance, ADP's activities are supporting the 2014–2020 strategic plan of the newly established Pharmaceutical Service Section (PSS) at the MOHSW.

Facilitating greater multisectoral engagement has also supported national stakeholders to consider challenges in the health system in a comprehensive manner. A review of the various dimensions of the health system allows for evaluation of challenges and progress across the system and to improve linkages between various initiatives supported from domestic and international sources. While the lack of a multidimensional approach presents a challenge to rapid implementation of the project, improvement in this area will ultimately lead to sustainable and comprehensive change in improving access and delivery.

## VIII. Next steps

The ADP's first phase has been rich in experiences and learning that will guide the implementation of global- and country-level activities in the partnership's second phase. Importantly, any actions that have been planned are informed by a consolidated, context-specific evidence base, which ties together the challenges and needs across all five pathways of the partnership. Significant efforts were made in the first phase to consult with all relevant actors across the health system to identify priority areas for access and delivery and to ensure a high level of national commitment and ownership of the partnership's activities and results. The strengthening of relationships with national stakeholders and increasing the momentum for implementation in Ghana, Indonesia and Tanzania will remain an important focus moving forward.

Looking ahead at the ADP's second phase, implementation of the work plans developed in Phase 1 will be underpinned by a number of strategic approaches to ensure that results are achieved in a sustainable manner. Strong collaboration and coordination between the partners will be critical to ensure systemic change and sustainability. An integrated approach to implementation will ensure that the impact of activities undertaken within each strategic pathway complement and mutually support each other to facilitate a multisectoral approach to achieve the overarching objective of health system strengthening. Efforts will thus be made to ensure coherent programming between the project partners and, where possible, to coordinate and organize joint activities. Larger, multifaceted projects (such as Global Fund-supported programmes) and multi- or intersectoral coordination at the national level present important lessons for the ADP to build on. In Indonesia, for instance, the proposed intersectoral planning committee, chaired by the Ministry of Health, will be an important mechanism to facilitate an integrated and coherent project implementation process. Phase 2 will place an emphasis on identifying and working with other ongoing forums and initiatives in the project countries, which will be supported by a mapping exercise providing an inventory of related efforts, to identify opportunities to maximize ADP's added value.

In the next phase, the partnership will also seek to initiate consultations with national stakeholders in Thailand on the potential scope of implementation there, while continuing its collaboration with technical partners, such as HITAP, the International Health Policy Program (IHPP) and WHO Thailand, on facilitating information exchange and South–South cooperation between the project countries.

The second phase will also see a strengthening of project management structures and strategies to ensure effective monitoring, evaluation and communication of the ADP's results. Increasing the visibility of the partnership and communicating its results to a broader audience will play an increasingly important role. The development of a comprehensive communications strategy and plan is, therefore, planned for the upcoming months. The central goal of the communications plan will be to craft a clear and coherent understanding of the ADP's goal and activities among key stakeholders at global and national levels. The strategy and plan will support coherent and integrated in-country implementation, support communications between and among project partners and stakeholders and promote stakeholder outreach and expanded engagement.

# Annex 1:

## Overview of Phase 1 activities and main achievements

Pathway	Country	Activities
<b>Pathway 1:</b> <b>Support strengthening of legal and policy frameworks to expedite access to and delivery of new health technologies for TB, malaria and NTDs</b>	<b>Indonesia</b>	<ul style="list-style-type: none"> <li>• Country visit (9–13 December 2014)</li> <li>• Project planning and inception meeting and finalization of country work plans (26–27 February 2014)</li> <li>• Training workshop for patent examiners in Bali (20–21 May 2014)</li> <li>• Analysis of the current policy and legal frameworks</li> <li>• Intersectoral planning meeting (19 June 2014)</li> </ul>
	<b>Tanzania</b>	<ul style="list-style-type: none"> <li>• Country visit (16–18 October 2013)</li> <li>• Project planning and inception meeting and finalization of country work plans (5–6 March 2014)</li> <li>• Study on pharmaceutical market and industry structure (Tanzania and Ghana)</li> <li>• Discussions with the Commission of Science and Technology to plan multi-stakeholder meeting on integration of R&amp;D, innovation and local pharmaceutical production</li> </ul>
	<b>Ghana</b>	<ul style="list-style-type: none"> <li>• Country visit (22–25 October 2013)</li> <li>• Study on pharmaceutical market and industry structure (Tanzania and Ghana)</li> <li>• In-country consultations with key stakeholders, including the Ministry of Health and the Ministry of Justice (9–12 June 2014)</li> <li>• Assessment of current legislative framework in respect to innovation, public health and access to medicines</li> </ul>
	<b>Thailand</b>	<ul style="list-style-type: none"> <li>• Exploratory dialogue with the Ministry of Public Health, HITAP, the International Health Policy Program (IHPP) and WHO Thailand</li> </ul>
<b>Main achievements under Pathway 1</b>	<ul style="list-style-type: none"> <li>✓ Buy-in secured from government stakeholders in Ghana, Indonesia and Tanzania expressing support for the partnership and proactively requesting ADP's engagement in specific, ongoing efforts related to access and delivery</li> <li>✓ Capacity built of 35 staff members from the Ministry of Law and Human Rights on the integration of public health considerations within policy and legal frameworks in Indonesia</li> <li>✓ Strategic partnership established with the Ministry of Law and Human Rights of Indonesia</li> <li>✓ Intersectoral planning committee established in Indonesia for national coordination and oversight of national activities, under strong leadership by national champion</li> <li>✓ Increased understanding of the pharmaceutical market and industry structure in Africa and their implications for innovation and production of essential medicines</li> <li>✓ Increased understanding of Ghana's current legislative framework from the perspectives of innovation, public health and access to medicines</li> </ul>	

Pathway	Country	Activities
<b>Pathway 2:</b> <b>Enhanced capacity to identify and address country-specific health system needs for effective access to and delivery of new health technologies</b>	<b>Tanzania</b>	<ul style="list-style-type: none"> <li>• Analysis of national capacity for operations and implementation research</li> <li>• National consultation with three national control programmes (the National TB and Leprosy Programme, the National Malaria Control Programme and the NTD Control Programme), health systems experts and NIMR (27–28 May 2014)</li> <li>• Consultation with national disease control programmes, researchers and academia (COSTECH, Ifakara Health Institute, MUHAS, KCMC, KCRI, CUHAS) (July 2014)</li> </ul>
	<b>Ghana</b>	Consultations with Health Research and Development Directorate of the Ghana Health Service (June 2014)
<b>Main achievements under Pathway 2</b>	<ul style="list-style-type: none"> <li>✓ Implementation research toolkit produced by WHO-TDR to support capacity-building and implementation of operational research</li> <li>✓ National capacity in Tanzania for operations and implementation research assessed</li> <li>✓ Increased understanding of health systems gaps and bottlenecks to inform future strategic interventions in Indonesia and Tanzania</li> <li>✓ Framework for training and strengthening capacity for operations and implementation research in Tanzania finalized</li> </ul>	
<b>Pathway 3:</b> <b>Strengthened capacity to monitor and respond to safety issues associated with new health technologies</b>	<b>Indonesia</b>	<ul style="list-style-type: none"> <li>• Review of the laws and policies on legal requirements for reporting of adverse drug reactions in selected countries</li> <li>• Establishment of lead and national taskforce on activities related to pharmacovigilance</li> </ul>
	<b>Tanzania</b>	• Training of TFDA staff of WHO-CC on pharmacovigilance (November 2013)
	<b>Ghana</b>	• Agreement between the National Food and Drug Authority, the WHO-CC and the ADP on capacity-strengthening focus on pharmacovigilance
<b>Main achievements under Pathway 3</b>	<ul style="list-style-type: none"> <li>✓ National taskforce established for development of road map for strengthening capacity for pharmacovigilance in Indonesia</li> <li>✓ TFDA staff at WHO-CC trained on targeted spontaneous reporting, electronic patient records for drug safety and strategic planning in pharmacovigilance in Tanzania</li> <li>✓ Partnership established in with the National Food and Drug Authority Ghana and the WHO-CC to strengthen capacity to monitor and respond to safety issues associated with new health technologies</li> </ul>	
<b>Pathway 4:</b> <b>Strengthening capacities in LMICs to ensure evidence-based, sustainable decision-making for resource allocation for new health technologies and commercialization of new health technologies at appropriate pricing to ensure that supply meets demand</b>	<b>Indonesia</b>	<ul style="list-style-type: none"> <li>• Desk research on global landscape, lessons learned and best practices on innovative financing mechanisms to ensure sustainability and efficient resource allocation</li> <li>• Partnership engagement with NICE, HITAP and PRICELESS</li> <li>• Coordination with the Bill and Melinda Gates Foundation, UKAID and the Rockefeller Foundation-funded International Decision Support Initiative</li> <li>• HTA training workshop for stakeholders from Indonesia and Thailand (23–24 June 2014)</li> </ul>
	<b>Tanzania</b>	• Consultations with the Ministry of Health and Social Welfare and other key in-country stakeholders to agree focus on HTA capacity-building (16–20 October 2013, 1–6 December 2013 and 1–6 March 2014)
<b>Main achievements under Pathway 4</b>	<ul style="list-style-type: none"> <li>✓ Increased understanding of key challenges for sustainable and rational adoption of health technologies in Indonesia and Tanzania</li> <li>✓ Developed key capacity-building measures towards addressing these bottlenecks in Indonesia and Tanzania</li> <li>✓ Strategic partnerships established to leverage expertise for implementation of Pathway 4 from HTA agencies including NICE, HITAP in Thailand, and PRICELESS in South Africa</li> <li>✓ Engagement established with global initiatives spearheading capacity-strengthening for HTA and evidence-based priority-setting mechanisms (such as the Bill and Melinda Gates Foundation, UKAID and the Rockefeller Foundation-funded International Decision Support Initiative)</li> <li>✓ Increased capacity among 47 stakeholders from Indonesia and Thailand on the use of HTA and the development of a related action plan for Indonesia</li> </ul>	



Pathway	Country	Activities
<b>Pathway 5:</b> <b>Strengthened capacity of delivery systems including supply chain of new global health technologies for TB, malaria and NTDs</b>	<b>Indonesia</b>	<ul style="list-style-type: none"> <li>• Development of Supply Chain Assessment tool</li> <li>• In-depth Supply Chain Assessment (May 2014)</li> </ul>
	<b>Tanzania</b>	<ul style="list-style-type: none"> <li>• In-depth Supply Chain Assessment (May 2014)</li> <li>• Development of structured planning process for new health technologies</li> <li>• Review of the 2014 Action Plan of the Logistics Management Unit of the Pharmaceutical Services Section</li> </ul>
<b>Main achievements under Pathway 5</b>	<ul style="list-style-type: none"> <li>✓ Supply Chain Assessment tool developed based on first implementation in Indonesia and Tanzania</li> <li>✓ Supply Chain Assessments completed in Indonesia and Tanzania, leading to increased understanding of supply chain-related constraints during the implementation of new health technologies</li> <li>✓ Strategic partnership developed with the Logistics Management Unit has been formed within the Pharmaceutical Services Section in Tanzania</li> </ul>	
<b>Pathway 6:</b> <b>To provide and consolidate strategic information and evidence to inform capacity-building efforts that will improve access to and delivery of new health technologies for NTDs</b>	<ul style="list-style-type: none"> <li>• Mapping of pipeline technologies for TB, malaria and NTDs</li> <li>• Technical guidance notes and briefing papers to strengthen engagement with policy and legal issues related to access and delivery</li> <li>• Qualitative study to understand the challenges and best practices from the introduction of new technology, the GeneXpert diagnostic for multidrug-resistant TB in Uganda and Zambia</li> <li>• Capacity-building workshop on the global debate on financing for R&amp;D on NTDs in partnership with the South Centre (Geneva, 31 March – 2 April 2014)</li> </ul>	
<b>Main achievements under Pathway 6</b>	<ul style="list-style-type: none"> <li>✓ Evidence base strengthened to link ADP's efforts to ongoing R&amp;D and existing pipeline</li> <li>✓ Increased understanding among partners on key policy and legal issues related to access and delivery</li> <li>✓ Global partnerships established and consensus among participants of global workshop on framework and action plan to improve access and delivery</li> </ul>	

# Annex 2: Interim financial report

As of 7 October 2014

**Project Title:**

Building Capacity for Access to and Delivery of New Global Health Technologies for Tuberculosis, Malaria, Neglected Tropical Diseases and Other Diseases in Low- and Middle-Income Countries/Project ID 00075333

**Project Period:**

5 April 2013 to 30 June 2014

Advisory and Capacity-Building	Planned Budget	Commitments and Expenditures	
		Amount	Utilization %
<b>Project Oversight</b>	\$276,105.00	\$418,284.35	<b>151%</b>
<b>Output 1</b>	\$665,000.00	\$724,203.26	<b>109%</b>
<b>Output 2<sup>16</sup></b>	\$350,000.00	\$300,000.00	<b>86%</b>
<b>Output 3</b>	\$300,000.00	\$260,000.00	<b>87%</b>
<b>Output 4a</b>	\$370,000.00	\$320,000.00	<b>86%</b>
<b>Output 4b</b>	\$440,000.00	\$390,000.00	<b>89%</b>
<b>Output 5</b>	\$450,000.00	\$400,000.00	<b>89%</b>
<b>Output 6</b>	\$95,000.00	\$95,000.00	<b>100%</b>
<b>Subtotal for (A)</b>	\$2,946,105.00	\$2,907,487.61	<b>99%</b>

Staff Costs	Planned Budget	Expenditures	
		Amount	Utilization %
<b>Staff costs</b>	\$238,360.00	\$383,461.99	<b>161%</b>
<b>Subtotal for staff (B)</b>	\$238,360.00	\$383,461.99	<b>161%</b>

UNDP Cost Recovery	Planned Budget	Commitments and Expenditures	
		Amount	Utilization %
<b>GMS (7% for 2013 and 8% for 2014)</b>	\$272,955.00	\$234,607.75	<b>86%</b>
<b>ISS (5%)</b>	\$181,969.00	\$82,021.93	<b>45%</b>
<b>Subtotal (C)</b>	\$454,924.00	\$316,629.68	<b>70%</b>
<b>Grand Total (A) + (B) + (C)</b>	\$3,639,389.00	\$3,607,579.28	<b>99%</b>
<b>Closing balance</b>		\$31,809.72	<b>1%</b>

Please note that the financial figures are tentative, and the financial closure process is being undertaken. Once the final financial closure is done, the final financial report will be provided to the donor.

<sup>16</sup> Outputs 2 and 3 are WHO-related outputs. Please note that WHO's expenditures are still tentative. The final figures will be available in late October 2014 when the Q3 Project Delivery Report is submitted to UNDP.

# Annex 3: Project photos

## Project Inception and Planning Meeting in Bandung, Indonesia on 26-27 February 2014



**01.** Presentation by the ADP Global Team

**02.** Participant commenting on the ADP Global Team's presentations

**03.** Discussion between the ADP Global Team members and participants during a break-up session

**04.** Participant commenting on the ADP Global Team's presentations

**05.** Prof Agus Purwadianto, Senior Advisor to the Minister of Health on Health Technology and Globalization (center)

**06.** Participants from various ministries in Indonesia and the Access and Delivery Partnership Global Team

## Project Inception and Planning Meeting in Dar es Salaam, Tanzania on 5-6 March 2014



01



02



03



04



05

01. Dr. Rusibamayila and the ADP Global Team members

02. Opening remarks by Dr. Neema Rusibamayila of the Ministry of Health and Social Welfare (right) and Mr. Titus Osundia, Deputy Country Director Operations, UNDP Tanzania (left)

03. Participants listening to the ADP Global Team's presentations

04. Dr. Rusibamayila discussing with a participant from COSTEC

05. Presentation on country work plan by a participant

## The Advisory Group meeting in New York, U.S.A on 5-6 June 2014



01. Advisory Group Members and the Access and Delivery Partnership Global Team

02. Chair of the Advisory Group (left) and Advisory Group Members