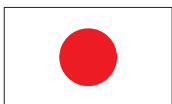




THE ACCESS AND
DELIVERY PARTNERSHIP

New Health Technologies for TB, Malaria and NTDs

Status report 2014



From the People of Japan



*Empowered lives.
Resilient nations.*



Credit: Michal Osmenda

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UNDP, TDR, PATH (2015). The Access and Delivery Partnership: Status Report 2014 (New York).

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Status report 2014







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LIST OF ABBREVIATIONS

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

ABOUT THE ACCESS AND DELIVERY PARTNERSHIP

The adverse impact of tuberculosis (TB), malaria and neglected tropic diseases (NTDs) on development outcomes has resulted in new approaches and partnerships to tackle the global deficiencies in research and development, and treatment access. One such initiative is the strategic partnership between the Government of Japan and UNDP, which promotes research and development, and expedites access to and delivery of health technologies used to address TB, malaria and NTDs. This partnership comprises two complementary components, which reflect the Government of Japan's and UNDP's strategic goals on global health¹:

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

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

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

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

The ADP is a five-year project, running from April 2013 until March 2018. This Report provides a status update on the ADP activities for Year 1 (1 April 2013 to 30 June 2014).



From the People of Japan

PARTNERS



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Resilient nations.*

United Nations Development Programme

UNDP is the UN's global development network, advocating for change and connecting countries to knowledge, experience and resources to help people build a better life. We are on the ground in 166 countries, working with them on their own solutions to global and national development challenges. As they develop local capacity, they draw on the people of UNDP and our wide range of partners.



The Special Programme for Research and Training in Tropical Diseases

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



PATH

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



THE ACCESS AND DELIVERY PARTNERSHIP

New Health Technologies for TB, Malaria and NTDs



Credit: Terrie Schweitzer/Flickr

GLOBAL CONTEXT

Effectively addressing the health impact of TB, malaria and NTDs represents a major opportunity to improve health outcomes and alleviate poverty in LMICs.

TB accounts for 1.5 million deaths every year² and an estimated 3.3 billion people are at risk of malaria globally, with more than 580,000 deaths occurring in 2013³. 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 WHO are prevalent in 149 countries and share many common features, including the disproportionate prevalence in poor and disadvantaged populations, their significant impact on child and maternal health, on global and national economic output and on progress towards global development goals.

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 fully achieved without simultaneously addressing NTDs. The post-2015 development framework process should recognize that NTD control and elimination will significantly improve the health and well-being of marginalized communities, enhance economic outcomes and contribute to broader development goals.

In addition to being diseases of poverty and inequality, TB, malaria and NTDs are relatively neglected by the research sector and share an urgent need for increased innovation for the development of health technologies that meet the needs of populations in LMICs.

Furthermore, evidence suggests that capacity in LMICs to access, introduce and deliver vaccines, diagnostics and medicines to treat TB, malaria and NTDs is weak⁴. While new health technologies coming to market for TB, malaria and NTDs may become available, positive public health outcomes will only result from the effective adoption by communities and the health systems of LMICs⁵. An enabling policy and regulatory environment, the existence of basic infrastructure, adequate human resources, and functioning primary and secondary health care delivery systems are some of the crucial factors in determining the access to and delivery of health technologies.

Bridging the gap between research and development (R&D) and access and delivery will depend on innovative partnerships between a broad range of stakeholders, including the main actors within the national health systems, the patient communities, non-governmental organizations (NGOs), product development partnerships (PDPs), the private sector and academia.

HOW THE ADP WORKS

Recognizing the capacity gaps hindering effective access to and delivery of essential new health technologies, the ADP supports LMICs in addressing major bottlenecks.



Frameworks for introduction of new health technologies by countries typically point to three essential phases: 1) Innovation or R&D of new technologies, 2) Introduction or preparation of new technologies for use by target populations and 3) Integration phase where new technologies are integrated in routine use within the health system, ensuring that they are able to reach and benefit target populations.

ADP observes that there is an interim phase, the country's decision-making process, which is critical for the successful delivery of new

health technologies. Therefore, the ADP approach is predicated upon the assumption that strengthening a country's decision-making process will improve the uptake of innovative technologies, resulting in increased health impact.

Two key bottlenecks associated with the decision-making phase in LMICs are: (1) capacity gaps in the identification and introduction of new technologies that are appropriate to their country context, and (2) lack of appropriate tools and information (knowledge products) to support countries in strengthening their

related technical and institutional capacities.

The ADP has identified four key competencies that define a country's capacity to address these bottlenecks – information, technical expertise and capacity, leadership and decision-making and management structures and processes.

Information on health technologies that is pertinent to decision-making may include efficacy and resource requirements, procurement data, clinical guidelines, safety and quality,

intelligence about comparable products, global endorsement and regulatory or intellectual property status.

Access to information regarding the target population, such as demographic and disease burden/epidemiological data, and manufacturing and health system capacity (e.g. supply chain performance) are also vital to the decision-making process. After introduction, continued access to information relating to the safety and quality of the health technology is critical for governments to make decisions on sustained use of the technology.

To support decision-making and management of new health technologies, relevant stakeholders need sufficient **technical expertise and capacity** to understand and interpret information relevant to these technologies. Necessary technical expertise includes epidemiology, health technology assessment, cost analysis, legal and policy analysis, market analysis and procurement/forecasting, among others.

Technical expertise also entails the capacity of governments to assess whether particular technologies (such as drugs/vaccines) should be locally manufactured, packaged or imported, as well as determine the best strategies for cost-effective delivery.

Leadership competency, such as the presence of thought leaders or champions and political commitment to public health protection, or on specific health issues, is essential in facilitating and driving the in-country decision-making and management processes.

Another key requirement is the presence of a well-defined and

transparent **decision-making process** and management infrastructure. Generating intelligence as the basis for specific health technology decisions often requires the presence of a scientific body(ies) to review research data and literature, clarity of roles and responsibilities, existence of supporting tools such as standard operating procedures for procurement and distribution and a well-functioning post-introduction monitoring of technologies. In addition, such processes must be supported by coherent policy guidance and political will. Typically, decision-making on new health technologies involves multiple stakeholders within each country, such as the ministry of health, the ministry of commerce and/or industry, the ministry of finance, research institutions, international agencies and other stakeholders. Therefore, the presence of a coordinating body is also important to facilitate decision-making.

Among these four key competencies, the ADP strategic approach aims, in particular, to strengthen the decision-making component in focus countries; ADP regards this aspect as being most amenable to durable improvement and to capturing of learning that is of greatest potential benefit to other countries. It should be emphasised that the ADP approach does not target specific technologies and products.

The ADP strategic approach addresses the determinants that influence how well LMICs are equipped to absorb and adopt new health technologies, including ensuring the appropriate linkages between innovation and access, promoting an enabling environment for innovation, ensuring sustainable and affordable access to health technologies and enabling strategic

South-South collaboration and learning. Knowledge products generated by ADP will provide invaluable synthesis of best practices and lessons learned that contribute to decision-making capacity in other LMICs.

In support of this approach, six key 'pathways' are employed for capacity-building along the value chain of access and delivery:

Pathway 1 aims at strengthening national capacities for the development of a coherent and enabling policy and legal environment for access and delivery of new health technologies. Laws and policies need to appropriately balance and integrate public health, trade, fiscal priorities, as well as overall development objectives. Where domestic R&D and local pharmaceutical production capacities are increasingly recognized as important elements of sustainable health systems, the right balance should be struck between meeting current needs and developing future capacities.

The shift from controlled clinical trial settings to real-life health systems often highlights impediments to effective access to and delivery of health technologies. Scaled-up delivery and use of new technologies in any population invariably reveals previously unanticipated events and considerations, including those associated with contexts and/or sub-populations not covered during preceding trials. Studies suggest that governments pay considerable amounts from health budgets towards covering associated costs.

Pathway 2 focuses on strengthening the capacity to identify and address such bottlenecks and events.

Pathway 3 aims to strengthen national capabilities for monitoring the safety of new health technologies



Credit: Arturo Sanabria/Photoshare



Credit: RHC/Photoshare

in real-life contexts. Systems for detecting, assessing, understanding and managing or preventing adverse effects or any possible drug-related problems are also essential. Drug safety monitoring involves a wide range of stakeholders and requires robust systems as well as training, resources and scientific infrastructure.

Many governments face challenging resource allocation decisions, particularly during transition from dependence on international development assistance to reliance on domestic health budgets. **Pathway 4** promotes evidence-based, sustainable decision-making, particularly in relation to national

resource allocation and commercialization of new health technologies, including appropriate pricing. Initial consultations have confirmed that significant need exists for developing and strengthening health technology assessment (HTA) processes to be more systematic and country-driven.

Efforts under **Pathway 5** aim to strengthen the capacity of delivery systems, including supply chains for new health technologies. As the number of new health technologies coming to market for TB, malaria and NTDs increases, more choices are created and additional decisions need to be made across supply chain disciplines. The key

steps required within a functional supply chain fall under the areas of planning, procurement and distribution. The ADP works closely with governments in understanding the challenges presented when introducing new health technologies into supply systems and to work alongside planning, procurement and distribution stakeholders to address challenges and identify potential solutions.

To help tailor the support provided by the ADP, **Pathway 6** focuses on building a base of strategic information and evidence.





ACHIEVEMENTS AND RESULTS

The ADP approach to strengthening capacities and systems for sustainable policy change require strong collaboration with, leadership from and ownership by government stakeholders. In this context, the ADP has focused its efforts during Year 1 on strengthening the partnership as well as on establishing relationships with government stakeholders and champions, building on the comprehensive, context-specific evidence base that the ADP partners have consolidated through extensive consultations and in-country reviews.

The ADP has made significant headway in terms of implementation of country-level activities during Year 1. From the outset, project partners agreed to focus on countries in Africa and Asia, where the burden of TB, malaria and NTDs is highest and where the project is likely to contribute significantly to improving health outcomes. Following an assessment of political will and commitment, existing in-country/ domestic capacity, availability of information, and the potential for cooperation, Ghana, Indonesia, Tanzania and Thailand were selected as initial focus countries.

In early 2014, multi-stakeholder project planning and inception

workshops took place in Indonesia and Tanzania, which generated comprehensive implementation work plans that outlined country-level capacity-building activities under each of the ADP pathways. In Ghana, initial country-level activities have focused on Pathways 1–3.

Within these focus countries, the ADP and national stakeholders have worked extensively to strengthen mutual engagement in a cross-cutting and multidisciplinary manner, generating country ownership across the board. The ADP supported country-led multi-stakeholder consultations in defining priorities related to the challenges and opportunities for strengthening access to and delivery of health technologies.

In Thailand, project partners have engaged in active dialogue and consultations with stakeholders to identify technical partners that can help facilitate information exchange and South-South learnings between the focus countries, given Thailand's leadership and experience on issues related to the development of enabling policy and legal environment for access and delivery.



Indonesia

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

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

Select country data for Indonesia

Indicator	Data
Human Development Index Ranking	108
Population total (millions)	249.87
Life expectancy at birth (years)	70.83
Under-5 mortality rate (per 1000)	31
Gross national income per capita (USD)	8,970.35
Population living below \$1.25 a day (%)	16.2
Health expenditure (%GDP)	2.72
International Trade (% of GDP)	50.07
Incidence of TB (per 100 000 population per year) ^a	183
Deaths due to non-HIV related TB (per 100,000 population) ^a	25
Deaths due to malaria (per 100,000 population) ^a	3.8
No. of school age children treated for Soil Transmitted Helminths / treatment coverage (%) ^b	614,510 / 1.3%
No. of people treated for Lymphatic filariasis / treatment coverage (%) ^b	24,425,649 / 24.5%
No. of people treated for Schistosomiasis / treatment coverage (%) ^b	10,392 / 55.8%

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

a WHO (2015). Indonesia: WHO statistical profile. Retrieved from <http://www.who.int/gho/countries/idn.pdf>

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



A number of ongoing developments in Indonesia provide opportunities for synergies between existing national programmes and the ADP. For example, Indonesia is currently establishing a new national social security system, which includes a national health insurance scheme that seeks to provide universal health coverage (UHC) by 2019. The ADP is working closely with the Government of Indonesia on efforts to ensure the long-term sustainability of UHC.



Credit: CIFOR

In this context, the focus for the ADP has been the technical support and capacity strengthening on issues related to the affordability and availability of new health technologies. Stakeholder consultations have identified a need for capacity strengthening of the Health Technology Assessment (HTA) Unit in the Ministry of Health to enable health technology selection based on appropriate evidence and country needs, as a means of sustainable, cost-effective resource allocation in support of the UHC initiative.

In Year 1, the ADP convened a consultation, which provided first-hand knowledge from experts on the challenges commonly encountered in establishing a structured HTA programme. The consultation also identified the vision for HTA in Indonesia and the critical factors

and action steps that will facilitate the establishment of a nationally appropriate programme.

In collaboration with the Ministry of Law and Human Rights, the ADP has provided technical support on the development of a coherent legal and policy framework, and the implementation of policy approaches, appropriate to national priorities and needs. This included a training workshop to strengthen the capacity of relevant ministry staff on the effective integration of public health considerations within existing national policy and legal frameworks. Ongoing work includes the provision of technical advice and recommendations for the review process of legal instruments to integrate national priorities for promoting domestic research,

development and technological capacity.

In the context of the Government's policy goal of promoting domestic pharmaceutical production, ADP, in partnership with key stakeholders, is developing a protocol for assessing the cost and pricing structure of imported active pharmaceutical ingredients (APIs), raw materials and finished pharmaceuticals.

Consultations have also underlined the need for examination of 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.

The need for a national registry for key epidemiological and clinical data, and for strengthened capacity

for implementation research aimed at improving service delivery, were also identified during national consultations. In this context, the ADP is supporting an in-depth analysis of national implementation research capacity. This will build on the work of the Ministry of Health, the National Institute of Health Research and the National Training Agency.

Limited human resources was identified as a major capacity limitation for pharmacovigilance at the national and regional levels. In partnership with the Department of Essential Medicines and Health Products at WHO, ADP will provide technical support for the development of a road map for strengthening pharmacovigilance capacity in the country. The Directorate of Distribution Control of Therapeutic and Household Healthcare Products under the National Agency of Drug and Food Control (NADFC) is identified as the lead partner organization 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, to implement strategies aimed at improving pharmaceutical and supply chain management, drug safety and pharmacovigilance.

Multiple agencies at the national and sub-national levels are involved in the planning, procurement and distribution of health commodities, creating a range of supply chain challenges, resulting in stock-outs of medicines and shortages of laboratory and diagnostic consumables. The skills of procurement staff vary

across the supply chain, and the professionalization of supply chain management is part of ongoing national efforts.

In May 2014, the ADP conducted an in-depth supply chain assessment that revealed key issues hindering the introduction of new products into the supply chain. The findings will help augment the capacity of central-, provincial- and district-level personnel to effectively plan for and procure new health products and technologies. One challenge identified by several stakeholders is the planning and procurement process for TB commodities and equipment to see where improvements can be made to support the introduction of new TB technologies.

In partnership with the Ministry of Health, the ADP also organized an inter-sectoral consultation with government stakeholders to discuss the coordination of ADP activities, given their broad range. It was agreed that an inter-sectoral planning committee, comprising representatives from a range of government agencies, should be established, convened and chaired by the Ministry of Health, to facilitate a coordinated and coherent approach. It is envisaged that the committee will play a key role in providing guidance on the prioritization of support and reconciling differing policy objectives and goals.





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Tanzania

“The capacity building and strengthening activities [of the ADP] will prove to be important interventions that will have a positive influence on the Government’s health programming. This project fits in line with [Tanzania’s] Strategic Master Plan for the Neglected Tropical Diseases Control Programme”.

Dr. Neema Rusibamayila, Acting Director of Preventive Services of the Ministry of Health and Social Welfare, Government of Tanzania, March 2014

Select country data for Tanzania

Indicator	Data
Human Development Index Ranking	159
Population total (millions)	49.25
Life expectancy at birth (years)	61.53
Under-5 mortality rate (per 1000)	54
Gross national income per capita (USD)	1,702.12
Population living below \$1.25 a day (%)	67.87
Health expenditure (%GDP)	7.28
International Trade (% of GDP)	81.27
Incidence of TB (per 100,000 population per year) ^a	164
Deaths due to non-HIV related TB (per 100,000 population) ^a	12
Deaths due to malaria (per 100,000 population) ^a	43.7
No. of school age children treated for Soil Transmitted Helminths / treatment coverage (%) ^b	563,423 / 4.2%
No. of people treated for Lymphatic filariasis / treatment coverage (%) ^b	17,114,802 / 42.9%
No. of people treated for Schistosomiasis / treatment coverage (%) ^b	2,882,418 / 27.59%

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

a WHO (2015). United Republic of Tanzania: WHO statistical profile. Retrieved from <http://www.who.int/gho/countries/tza.pdf?ua=1>

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

Tanzania plays a key role in the East African Community (EAC) initiative for regulatory harmonization for medicines, with the Tanzania Food and Drug Authority (TFDA) leading the regional effort.

The Ministry of Health and Social Welfare (MOHSW) and the Tanzania Food and Drug Authority (TFDA) have a system for reporting adverse drug reactions. ADP has identified an opportunity to strengthen the existing mechanism by increasing the awareness and competence of health workers in reporting adverse drug reactions. The overall work plan to guide implementation of these efforts will focus on key components; including situation analysis and stakeholder consultation, training of trainers; data management and strengthening pharmacovigilance modules in the curriculum of health training institutions.

Tanzania has also been steadily investing in health innovation and research. With funding from various partners, the Government is investing in several initiatives to support local R&D and production capacity. The ADP supported a situational analysis of the local pharmaceutical sector, identifying relevant industrial policy and other policy measures, as well as gaps and opportunities to strengthen local manufacturing capacities.

Within the public health and innovation policy framework in Tanzania, key policy issues relate to the development of an enabling

environment to support domestic pharmaceutical R&D and innovation, and the strengthening of sustainable local pharmaceutical production to meet public health needs. Ongoing discussions with stakeholders such as the Commission of Science and Technology are focused on promoting the integration of policy and decision-making related to R&D, innovation and local pharmaceutical production. An appropriate policy framework for training, technological learning and upgrading would also help to facilitate development and strengthening of technological competencies for domestic pharmaceutical production.



Credit: Bremen Leak/Photoshare

There are plans to scale up the national health insurance scheme in Tanzania to achieve universal coverage. A key priority in this context relates to sustainable resource allocation and financing, and ADP is contributing to this process through support for the development of HTA capacity in the country. Although Tanzania does not have an HTA unit at present, the Pharmaceuticals Service Section (PSS) of the MOHSW has prioritized developing HTA capacity through its inclusion in the national health sector strategic plan. 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.

In partnership with the National Institute for Medical Research (NIMR), the ADP is also supporting an analysis of national capacity for operations and implementation research with the involvement of the Ministry of Health. The analysis will identify 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 the ADP, facilitated a national consultation bringing together the National TB and Leprosy Programme, the National Malaria Control Programme and the NTD Control Programme, health systems experts and NIMR scientists.

The NIMR also held a consultation involving staff from the major national disease control programmes (malaria, TB and NTDs), researchers and academia on the prioritization of research questions and plans of action to address the gaps and implementation bottlenecks. 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.

Significant gains have been made in improving the public sector supply chain. Apart from antiretroviral (ARV) medicines, however, medical stocks remain unpredictable due to various factors including inadequate financing, limited efficiencies within the national supply chain, poor infrastructure, outdated or manual management information systems, and challenges related to human resource and stakeholder coordination.

In May 2014, the ADP conducted a supply chain assessment, focusing on central-level planning and coordination between different units under the MOHSW. The resulting work plan, based on the main gaps that were identified, has been developed with buy-in from national stakeholders. In-country stakeholders agreed that it would be beneficial to begin this process by holding a supply chain linkages workshop among all supply chain players to identify communication gaps, specifically in relation to new health technologies.



Ghana

Ghana has shown strong political commitment to addressing health-related access and delivery issues.

In regional- and country-level efforts to implement the African Union (AU) *Pharmaceutical Manufacturing Plan for Africa* (PMPA), Ghana has emerged as a key country for the roll out of the PMPA and the accompanying business plan. With ongoing efforts and investments in the country, undertaken by a range of domestic and international stakeholders, the ADP is identifying opportunities to build on synergies and leverage existing political momentum.

Following stakeholder discussions, ADP commissioned an assessment of the current legal framework in Ghana from the perspectives of innovation, public health and access to medicines. This included expert legal opinion and recommendations on the relevant policy and legal frameworks in Ghana with respect to the linkages to public health, domestic R&D and pharmaceutical production. Since then, the ADP has been working with parliamentarians to review and implement enabling legislation.

Select country data for Ghana

Indicator	Data
Human Development Index Ranking	138
Population total (millions)	25.9
Life expectancy at birth (years)	61.13
Under-5 mortality rate (per 1000)	72
Gross national income per capita (USD)	3,532.33
Population living below \$1.25 a day (%)	28.59
Health expenditure (%GDP)	4.78
International Trade (% of GDP)	102.08
Incidence of TB (per 100 000 population per year) ^a	66
Deaths due to non-HIV related TB (per 100,000 population) ^a	4.4
Deaths due to malaria (per 100,000 population) ^a	68.7
No. of school age children treated for Soil Transmitted Helminths / treatment coverage (%) ^b	2,289,325 / 100%
No. of people treated for Lymphatic filariasis / treatment coverage (%) ^b	7,859,416 / 76.8%
No. of people treated for Onchoceriassid ^b	3,495,861

All data are from 2013 and derived from UNDP (2014) Human Development Reports unless where stated
 a WHO (2015). Ghana: WHO statistical profile. Retrieved from <http://www.who.int/gho/countries/gha.pdf?ua=1>
 b WHO Global Health Observatory Data Repository. Retrieved from <http://apps.who.int/gho/data/node.country.country-GHA?lang=en>

In addition, the ADP is in consultations with the Ministry of Health to support the current process to review the national medicines policy and the development of an implementation plan for the policy. Both these initiatives will provide important entry points for a longer term engagement strategy with various ministries and stakeholders on policy coherence.

Ghana is a leader in addressing issues of safety and pharmacovigilance, with the National Food and Drug Authority (National Centre for Pharmacovigilance) and the WHO Collaborating Centre for Advocacy and Training in Pharmacovigilance (WHO-CC) partnering with The New Partnership for Africa's Development (NEPAD)/AU/African Medicines Regulatory Harmonization (AMRH)-designated Regional Centre of Regulatory

Excellence in Pharmacovigilance and Pharmacoepidemiology. A collaborative agreement has been reached between the National Food and Drug Authority, the WHO-CC and the ADP on activities to strengthen capacity to monitor and respond to safety issues associated with new health technologies.

Ghana has a well-established network of regional health research centres that provide an important resource for optimizing access and delivery close to the communities absorbing and using new technologies. Following consultations with the Health Research and Development Directorate of the Ghana Health Service, an action plan for step-by-step capacity strengthening at the regional research centres is under development.



Credit: Gates Foundation



Credit: Jessica Ziegler/Photoshare



Credit: waterdotorg



LOOKING FORWARD

ADP's Year 1 has been rich in experiences and learning that will guide the implementation of global- and country-level activities in subsequent years. Importantly, activities have been country-led and informed by a context-specific evidence base, which ties together the challenges and needs across all pathways of the partnership.

Significant efforts were invested during Year 1 to consult with a broad range of stakeholders to identify issues and factors influencing access and delivery, and to ensure a high level of national commitment and ownership of ADP's activities and results. Strengthening cooperation with national stakeholders while promoting country ownership and leadership

to increase the momentum for project implementation in Ghana, Indonesia and Tanzania, will remain an important focus moving forward.

To tailor the support provided to countries, ADP is supporting a range of efforts to develop a base of strategic information and evidence to inform capacity-building efforts. For example, a mapping of pipeline technologies for TB, malaria



Credit: Yaman Ibrahim

and NTDs has been undertaken to identify potential products expected to be ready for market introduction by 2020, and analyse the challenges and opportunities for facilitating an enabling policy and legal environment in LMICs for the introduction of new health technologies. A number of technical guidance notes and briefing papers on the policy and legal aspects related to access and delivery are also being developed.

The partnership has also commissioned a qualitative study to understand the challenges and

best practices from the introduction of 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 Year 2. Published findings will inform the global dialogue on the adoption of new technology in subsequent years of the project.

At the global level, the ADP supported a capacity-building workshop on the continuing global debate on financing for R&D on NTDs, organized by the South Centre. The aim was to increase understanding

and awareness of issues related to the availability of and access to new health technologies for TB, malaria and NTDs, and to promote LMICs' 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.

Looking ahead to Year 2, implementation of the work plans developed in Year 1 will be underpinned by ADP's strategic approaches to ensure that results are achieved in a sustainable

manner. Strong and organized collaboration between the partners will be critical to ensuring systemic change and sustainability. An integrated and multi-sectoral approach to implementation will have a positive impact on health system strengthening. Substantial efforts will be made to guarantee coherent programming between project partners, and to coordinate and organize joint activities.

Large, multifaceted projects (such as Global Fund supported programmes) and national inter-sectoral coordination offer important lessons for the ADP to build upon. ADP in Year 2 and beyond will place specific emphasis on identifying synergies with other ongoing initiatives in focus countries, to maximize the added value provided by the ADP.

The ADP will continue and further its collaboration with key technical partners in Thailand, including with the Health Intervention and Technology Assessment Program (HITAP), the International Health Policy Program (IHPP) and relevant government agencies, to explore effective South-South exchange and

cooperation on priority issues, such as promoting policy coherence and strengthening HTA capacities.

Sustainability of the ADP's results is supported on various levels. The project's approach to strengthening skills and systems at the 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 be sustained 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 that will further support sustainability of the results achieved.

Critical to these efforts 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 during 2014 with buy-in and tangible commitment from the respective national governments represent the first outcome of these partnerships with local stakeholders.

Year 2 will also see a strengthening of project management structures and strategies to ensure effective monitoring, evaluation and communication of the ADP's results. 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 will be important parts of initial Year 2 activities. The central goals will be to craft a clear and coherent understanding of the ADP's goals and activities among key stakeholders at all levels and to promote expanded stakeholder outreach and engagement.

Endnotes:

- 1 Government of Japan (2011). Global Health Policy 2011 – 2015. Accessed from www.mofa.go.jp/policy/oda/mdg/pdfs/hea_pol_ful_en.pdf; UNDP (2014). Changing the world: UNDP Strategic Plan 2014-2017. Accessed from www.undp.org/content/undp/en/home/librarypage/corporate/Changing_with_the_World_UNDP_Strategic_Plan_2014_17/
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- 5 Wells, W. and Brooks, A. 2012. *PDP Support of Country Decision Making: A Discussion Paper*. TB Alliance and PATH. New York and Seattle.



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