Issue Brief

An integrated approach to the discovery, development and delivery of new health technologies for malaria, tuberculosis and neglected tropical diseases: **Tanzania**

Summary

The collaboration between the United Nations Development Programme (UNDP) and the Government of Japan to support the Global Health Innovative Technology (GHIT) Fund and the Access and Delivery Partnership (ADP) aims to streamline the research and development (R&D) of new products, to eventually introduce them in low- and middle-income countries (LMICs). The adoption of the 2030 Agenda for Sustainable Development, which incorporates the target of ending the epidemics of AIDS, tuberculosis (TB), malaria and neglected tropical diseases (NTDs), reinforces the critical need for concrete linkages between R&D and access to and delivery of new health technologies. This Issue Brief describes the collaborative efforts of the GHIT Fund and ADP in Tanzania, highlighting the development of the booster TB vaccine (DAR-901) and paediatric praziquantel (PZQ) reformulation for schistosomiasis, and the complementary initiatives that strengthen the health system to facilitate access and delivery of these innovations in Tanzania.

THE ACCESS AND DELIVERY PARTNERSHIP
New Health Technologies for TB, Malaria and NTDs

GHIT Fund
Global Health Innovative Technology Fund

From the People of Japan

UNDP 50 YEARS
Empowered lives. Resilient nations.

About the Access and Delivery Partnership and the Global Health Innovative Technology Fund

The collaboration between UNDP and the Government of Japan is a strategic partnership to promote R&D, and to increase access to, and delivery of, new health technologies for TB, malaria and NTDs. This partnership adopts an innovative, dual-pronged approach in which the Global Health Innovative Technology Fund (the GHIT Fund) stimulates R&D, while the Access and Delivery Partnership (ADP) assists low- and middle-income countries to enhance capacities to access and deliver new health technologies.

Led and coordinated by the United Nations Development Programme (UNDP), the ADP is a distinctive collaboration between UNDP, TDR (the Special Programme for Research and Training in Tropical Diseases, co-sponsored by UNICEF, UNDP, the World Bank and WHO) and PATH. Working together, the ADP partners leverage the expertise of each organization, and draw upon the full range of technical skills necessary to strengthen capacities to access and delivery new health technologies. The ADP emphasizes consultation, collaboration and implementation with partner country governments and stakeholders.

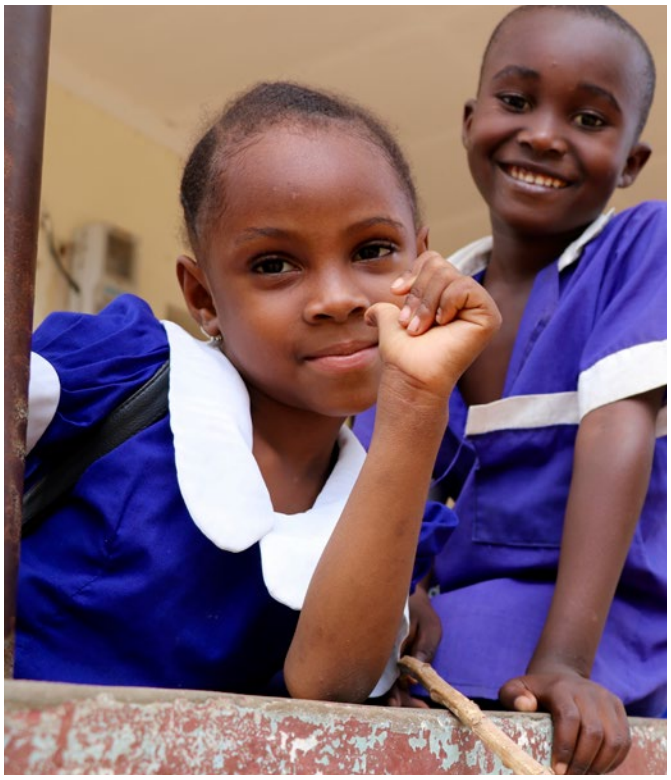
The GHIT Fund is a new model for global health R&D financing. It is an initiative between Japanese pharmaceutical companies, the Government of Japan, the Bill & Melinda Gates Foundation, the Wellcome Trust and UNDP. The Fund invests in and manages a portfolio of product development partnerships (PDPs) aimed at neglected diseases that afflict the world's poorest people. A key aim of the GHIT Fund is to link existing PDPs with Japanese partners that have expertise in drug R&D.

The ADP and the GHIT Fund are both funded by the Government of Japan.

1 Introduction

In September 2015 the United Nations (UN) General Assembly adopted the 2030 Agenda for Sustainable Development, which includes Sustainable Development Goal (SDG) 3: *"Ensure healthy lives and promote well-being for all at all ages."*[1] SDG 3.3 envisages ending by 2030 *"the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases and combat[ing] hepatitis, water-borne diseases and other communicable diseases."* SDG 3.3b urges UN Member States to *"[s]upport the research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries".*[2] Meeting the objectives laid out in SDG 3.3 is critical to assuring the well-being of present and future generations in low- and middle-income countries (LMICs). Not meeting these objectives however, will have adverse consequences for sustainable development, given the fundamental interconnections between health and development.

The concept underlying the collaboration between the United Nations Development Programme (UNDP) and the Government of Japan to support the Global Health Innovative Technology (GHIT) Fund and the Access and Delivery Partnership (ADP) is to address both the research and development (R&D) and access sides of the health equation in LMICs. This collaboration makes the case for an integrated approach to funding R&D along with capacity development for effective adoption of new technologies can improve public health outcomes in LMICs. This Issue Brief explores the GHIT Fund–ADP integrated approach in Tanzania. This approach is representative of the emerging strategies for improving health outcomes discussed at the 69th World Health Assembly in May 2016.[3]



Schoolchildren during a UNDP-supported mass drug administration campaign run by the government of Tanzania.
Photo: UNDP/ Natasha Scripture

Box 1: The gap between disease burden and R&D

9.6 million people developed TB in 2014

Tuberculosis (TB) is one of the world's deadliest communicable diseases. In 2014, an estimated 9.6 million people developed the disease, with 1.5 million dying from it.

An estimated 3.3 billion people around the world were at risk of malaria in 2015, with a total of 214 million cases and 438,000 deaths, mostly in sub-Saharan Africa and mostly among children under five years of age.

3.3 billion people at risk of malaria in 2015

1.7 billion people with at least one NTD in 2014

In 2014, 1.7 billion people globally required treatment for at least one neglected tropical disease (NTD).

Between 2000 and 2011, only 1 percent of the 148,445 registered clinical trials and only 4 percent of the 850 new therapeutic products registered were for neglected diseases.[7]

1% of clinical trials were for NTDs from 2000–11

It is commonly agreed by public health specialists that effectively addressing diseases that place a particular burden on LMICs requires increased attention to R&D directed to the introduction of new vaccines, diagnostics and treatments that are suitable to the environments where they will be administered.[4] It is generally recognized that diseases prevalent in developing countries, yet without substantial impact on developed countries, systemically attract inadequate R&D funding because 'market-based' demand is lacking'.[5] The urgent need to address the market's failure to fund R&D for diseases primarily affecting LMICs has focused attention on so-called 'public–private' or 'product development' partnerships (PPPs or PDPs) that use alternative non-market-based sources – both public and private – to support R&D and to make resulting treatments affordable and accessible to the people who need them.[6]

Progress on the R&D front alone will not address the major challenges facing LMICs in delivering health care adequate to achieve SDG 3. This also requires the necessary health system infrastructure and capacity, including human resources, necessary for administering or implementing both existing and new health technologies. Required also is the design and implementation of mechanisms, including funding mechanisms, that promote access for people in need.

2

Tanzania: Implementing an integrated approach

Tanzania, currently classified as a least developed country by the UN,[8] is one of several countries where the GHIT Fund and the ADP are both working hand in hand with partners on R&D and strengthening health system management. Tanzania was selected in August 2013 as one of four ADP focus countries, based on the following criteria: political will and commitment; existing in-country or domestic capacity; availability of information; and the potential for high impact and South–South cooperation.[9] In March 2014, a multi-stakeholder planning process was initiated in Tanzania with the aim of garnering support among national policymakers for an integrated package of support aimed at strengthening national capacities for developing policy and regulatory frameworks, safety monitoring, as well as supply and delivery, systems that are crucial for the introduction of new health technologies.[10]

> *"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,
> Ministry of Health and Social Welfare, March 2014.

This set the stage for the comprehensive implementation plan described below. While the initial phase of the GHIT Fund and the ADP initiatives in Tanzania began within the context of the UN Millennium Development Goals (MDGs), and especially MDG 6 (Combat HIV/AIDS, malaria and other diseases), it continues within the context of the 2030 Agenda for Sustainable Development, adopted in September 2015.

Anticipating the country's transition from its current least-developed country status, the Government of Tanzania's Health Sector Strategic Plan (HSSP IV) 2015–2020 has set ambitious goals in addressing public health needs, including "achieving a higher quality of life for the people of Tanzania at the status of a middle-income country and a health care and social welfare system at this level of development."[11] These are set within the context of the SDGs:

> ***"Sustainable Development Goals (SDGs):*** *The SDGs provide the strategic context for international development, and more specifically universal coverage of health and social welfare services. The SDGs compel this HSSP to take forward the unfinished agenda from the MDGs…"*[12]

Data from the Tanzania Ministry of Health indicate that *"[m]alaria is the leading cause of morbidity, although slowly reducing in children under-5 years old (33% of all registered diseases in 2012). Malaria meanwhile is the leading cause of death of hospital admitted patients (around 30%). The second largest cluster of diseases consists of upper respiratory tract infections and pneumonia, followed by diarrhoeal diseases and skin diseases."*[13] TB is one of the most significant diseases affecting the respiratory tract, and it is a special risk within the mining community.[14] Multidrug-resistant TB (MDR-TB) affects Tanzania, and new TB diagnostic technologies for early detection form an important part of Tanzania's health sector strategy.[15] Human schistosomiasis, an NTD prevalent throughout sub-Saharan Africa, in Tanzania is most prevalent and intense among school children under 15 years of age, with serious effects not only on morbidity and mortality but also on growth and cognitive function.[16]

With respect to NTDs,[17] the objective of the Tanzanian HSSP is that:

> *"By 2020, transmission of Neglected Tropical Diseases (NTDs) targeted for preventive chemotherapy such as onchocerciasis, lymphatic filariasis and trachoma will be interrupted in over 90% of the endemic districts. NTDs are often associated with life-long disability and very serious chronic social and economic consequences. More than 10 NTDs affect rural poor communities and contribute to increasing poverty in the affected communities….*
> *The country will work to improve the detection and management of other NTDs including Human African trypanosomiasis, rabies, and plague. Relevant interventions and diseases diagnosis will be im proved and reporting integrated into the national and council health information systems".*[18]

Table 1: Epidemiological data for TB, malaria and NTDs in Tanzania[19]

TB [a]	
TB prevalence (per 100,000)[b]	528
Deaths due to TB (per 100,000)	112
Malaria [c]	
Estimated cases of malaria (per 100,000)	11,220
Total deaths due to malaria (per 100,000)	34.7
NTDs [d]	
Population requiring preventive chemotherapy for schistosomiasis / treatment coverage	10,765,946 (27.3%)
Population of school-aged children requiring preventive chemotherapy for schistosomiasis	6,357,534 (37.8%)

All data from 2014

The continued presence of malaria, the ongoing threat of TB, including the challenges presented by MDR-TB, and the prevalence of NTDs in Tanzania[20] provide impetus for the GHIT Fund and the ADP to focus on addressing these diseases, through investments in R&D to develop innovative medicines, diagnostics and vaccines, and health system strengthening to ensure access and delivery of these new health technologies to people in need.

In Tanzania, the GHIT Fund and the ADP are targeting these major points of unmet need.[21]

3
Accelerated research and development

The GHIT Fund is supporting a number of research projects in Tanzania. Among these are a project to develop a new TB vaccine based on an inactivated whole cell booster vaccine derived from the *Mycobacterium obuense* (a bacterium closely related to TB). During the first quarter of 2016, the GHIT Fund and its collaboration partners initiated a Phase II clinical study of the booster TB vaccine, DAR-901. This promising vaccine candidate will be tested, not only to determine if it prevents the progression to TB disease in subjects with latent TB infection but also to determine if it reduces the risk of initial TB infection. A successful outcome of this joint randomized controlled trial would position this candidate for a final confirmatory trial and possibly subsequent licensure as the first new vaccine against TB in over 100 years. The GHIT Fund's collaboration partners in this endeavour include the Muhimbili University of Health and Allied Sciences (MUHAS), Dar es Salaam, which is stationed at the clinical trial study site and is responsible for the study protocol and clinical trial implementation. The two-year study will be directed by Geisel School of Medicine at Dartmouth with Tokyo Medical and Dental University in Japan.

The GHIT Fund is also supporting the development and registration of a new praziquantel (PZQ) paediatric formulation for the treatment of schistosomiasis. Schistosomiasis is one of the most prevalent tropical diseases in the world after malaria. In Tanzania, only 27 percent of the 10.8 million people who require preventive chemotherapy for schistosomiasis received it in 2014.[22]

Table 2: The GHIT Fund portfolio in Tanzania

Project name (awarded year):
DAR-901 whole cell booster vaccine to prevent TB infection in adolescents (2015)

Disease and intervention and clinical stage:
Tuberculosis / Vaccine / Clinical Trial II

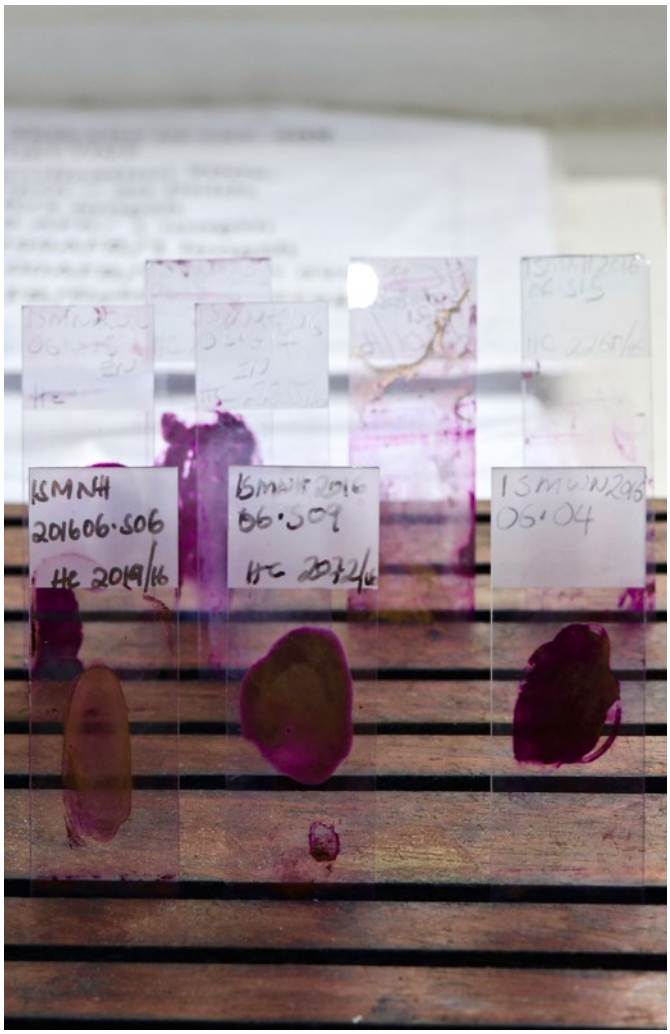
Collaboration partners:
1. Tokyo Medical and Dental University
2. Dartmouth College Geisel School of Medicine
3. Muhimbili University of Health and Allied Sciences

Project name (awarded year):
Development and registration of a new praziquantel pediatric formulation for the treatment of schistosomiasis (2013 & 2014)

Disease and intervention and clinical stage:
Schistosomiasis / Drug / Clinical Phase I

Collaboration partners:
1. Astellas Pharma Inc.
2. Lygature
3. Merck KGaA
4. Swiss Tropical and Public Health Institute*
5. Farmanguinhos
6. Simcyp Limited

* in collaboration with Ifakara Health Institute



UNDP collaborates with GHIT and national partners like the Tanzanian Food and Drug Authority and the National Institute for Medical Research to strengthen pharmacovigilance efforts and empower local communities by enabling consumers to directly report adverse drug reactions. *Photo: UNDP/Natasha Scripture*

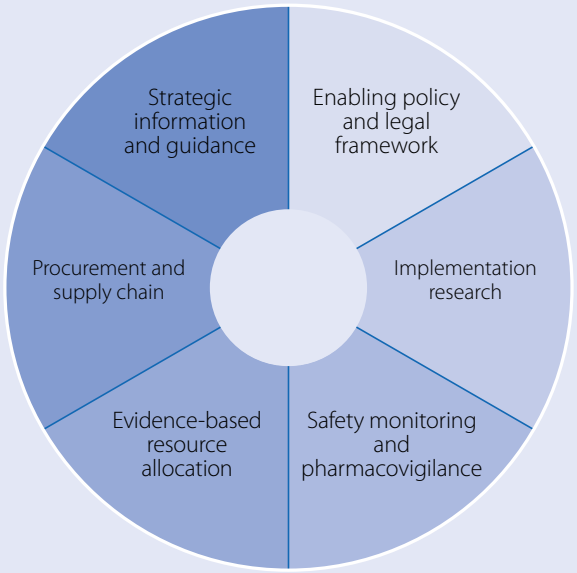
To tackle the public health problem of schistosomiasis, the non-profit Pediatric Praziquantel Consortium was formed in July 2012 to develop a paediatric formulation of PZQ. The GHIT Fund's collaboration partners in the Consortium include Lygature, Merck KGaA, Astellas Pharma Inc., Swiss Tropical and Public Health Institute, Farmanguinhos and Simcyp Limited.

The Consortium regards the development and registration of a new paediatric formulation of PZQ, with more accurate dosing and enhanced compliance in preschool children, infants and toddlers, as a cornerstone towards fulfilling the 2020 World Health Organization (WHO) commitment to address the health burden that schistosomiasis represents and the importance of controlling disease-related morbidities. A swill-and-spit taste study in African children started in Tanzania in early 2015 to assess the overall palatability of the two new candidate paediatric orally disintegrating tablet formulations. This study was conducted by the Ifakara Health Institute in partnership with Swiss Tropical and Public Health Institute. This study is being followed by a clinical trial for safety and efficacy studies in the target population of children in Côte d'Ivoire, including infants and toddlers aged between three months and two years.

4 Pathways towards access and delivery

The development of new health technologies by the GHIT Fund is a key part of the process in improving public health in Tanzania but is only one important element. The ADP identified six pathways which prioritize the key elements within the value chain of access to, and delivery of, new health technologies (see Figure 1). To meet the specific country needs for access and delivery of new health technologies, the ADP has focused capacity-building on priority elements, to facilitate a coordinated and coherent approach.

Figure 1: The ADP approach – Pathways to an integrated approach for access and delivery



New technologies must be taken through the regulatory approval mechanism, which should be functioning efficiently and effectively. Products embodying new technologies must be produced and distributed with an assurance of appropriate quality and safety. Robust health systems and capacities are thus critical to introducing new medicines, vaccines and diagnostics. The drug regulatory authority must be operating at strength to ensure that medicines, diagnostics and vaccines are safe and effective. In addition, surveillance and rapid reporting of outbreaks is essential for malaria control. Effective control of MDR-TB requires close monitoring of treatment compliance. Close attention must be paid to procurement practices and supply chain management for medicines, diagnostics and vaccines. Human resources in the health sector must be trained and deployed to make use of existing and new technologies.

> *"The ultimate results of [the ADP-supported capacity-building] effort shall be a strong and integrated health system and also increased access to and efficient delivery of new technologies for health."*
>
> **Dr. Mwelecele N Malecela,**
> Director-General, National Institute for Medical Research, March 2015.

The ADP has been working in Tanzania on improving capacity within the policy and regulatory infrastructure, and on developing and implementing systems to ensure the delivery of high-quality, safe and effective medicines and other health technologies.[23]

a. African Union County Model Law on Medical Products Regulation

There are multiple elements that go into delivering appropriate health technologies within any country, and the ADP pursues an integrated approach to addressing these multiple elements. One such element is the national regulatory structure that provides direction for public health authorities, including the drug regulatory authority (DRA).[24] To this end, the ADP has supported the collaborative process through which the African Union Model Law on Medical Products Regulation (AUML) was developed and ultimately adopted by the African Union Heads of State and Government.[25] The AUML provides a template that African countries, including Tanzania, can adapt to their specific circumstances, consistent with best practices for medicines regulation identified by the WHO and other collaborting partners.[26]

The ADP's work on the AUML and its collaboration with the Tanzania Food and Drug Authority (TFDA), which has played a lead role in the harmonization of medicines registration processes within the East African Community, will contribute to enhancing the capacity of the national DRA to bring new treatments into the field.

b. Safety monitoring and pharmacovigilance systems

Through the efforts of the GHIT Fund and other product development partnerships, new technologies needed to address malaria, TB and NTDs will soon be available for introduction into the Tanzanian health care system. This requires attention to the safety of patients, including monitoring of drugs innocuity and adverse reactions. And while a pharmacovigilance system exists in Tanzania, it is hampered by many challenges and the underreporting of adverse drug reactions. The ADP has helped strengthen the capacity of the TFDA to meet these challenges, as well as to address the ongoing requirements of safety and surveillance with respect to established technologies and treatments. This is consistent with the Tanzanian government's HSSP for 2009–2015:

> *"The government, through TFDA, will step up control of quality, safety and efficacy of pharmaceuticals, medical supplies, medical equipment, traditional and alternative medicines in both public and private sectors."*[27]

With the objective of strengthening health system capacity to monitor and respond to safety issues of newly introduced health technologies, the TFDA developed a four-year work plan, covering over 270 health care providers in 20 districts. In addition, four key staff from the Tanzania national pharmacovigilance centre were trained in centres of excellence for pharmacovigilance in New Zealand and Malaysia, and there are plans for similar training in the future. This large cohort of experts is now able to plan, implement and manage a robust and effective

drug safety monitoring system in Tanzania. Engagement in regional or global pharmacovigilance networks was strengthened through a range of activities, including collaboration with the WHO Collaborating Centre for Advocacy and Training in Pharmacovigilance and the WHO Essential Medicines and Health Products (EMP) Safety and Vigilance Department to convene regional workshops. The ADP is also supporting the implementation of a new system that enables consumers to directly report adverse drug reactions, leading to increased reporting and the timely detection of adverse reactions.

The HSSP 2015–2020 takes note of progress made in Tanzania towards improving the capacity of the TFDA, noting that *"the regulatory framework through the Tanzania Food and Drug Authority (TFDA) has improved over the years."*[28] The HSSP further notes that in the coming years:

> *"Enhanced regulatory capacity and resources of the Tanzanian Food and Drug Authority (TFDA) and Pharmacy Council will manage market control of medicines, diagnostics and medical devices, and oversee professional conduct in the practice of pharmacy, in the interest of public safety. Existing mechanisms at TFDA for pharmacovigilance will be reinforced, including the process for providing feedback to the source of the report on adverse drug reactions and quality problems."*[29]

The ADP work programme addresses the elements of this forward-looking strategy.

c. Supply chain and delivery systems

> *"Over the past decade, Tanzania has seen significant improvements in health outcomes, included reaching the MDG target related to child mortality, however more efforts are required to keep in pace with the growing economy. The national strategic plans, including the Tanzania Development Vision 2025 and the Health Sector Strategic Plans (HSSP), have identified the need for a sustainable health delivery system as a national development priority."*
>
> **Permanent Secretary – Health. Dr. Mpoki M. Ulisubisya,** opening of the Consultative Meeting on Policy Coherence for Health Technology Access and Delivery, Dar Es Salaam, 22 March 2016 (meeting sponsored by the ADP).

Supply chain management is a critical component of the systems through which health care goods and services are delivered, ranging from planning, procurement and pricing to transportation, storage and delivery to the patient. Not only should supply chains be efficient, but close supply chain surveillance is essential for maintaining the quality and safety of medicines and other health technologies. As more new health technologies come to market for TB, malaria and NTDs, additional decisions need to be made and linkages need to be strengthened across the supply chain to maximize cost-efficiencies and -effectiveness.

The ADP has worked extensively with the Tanzanian authorities to improve supply chain management. Much of this work has been carried out in cooperation with the Logistics Management Unit formed within the Pharmaceutical Services Unit (PSU) of the Ministry of Health, Community Development, Gender, Elderly and Children which has been tasked with the oversight and coordination of the health care supply chain in Tanzania.

The ADP collaborated with the PSU to improve supply chain performance by strengthening communication and coordination among different actors along the supply chain, as well as by increasing understanding of structured planning and procurement processes for the introduction of new health technologies. The ADP is further helping the PSU to develop an action plan on strengthening supply chain management, which will become an official component of the Tanzanian National Pharmaceutical Action Plan.

Tanzania's HSSP 2015–2020 reflects the in-country work programme that the ADP has undertaken with respect to supply chain management:

> ***"Health Commodities** targets focus on ensuring 100% stock availability of essential medicines in all primary health facilities in the country, through the implementation of the following six initiatives: (1) improved governance and accountability to the health commodity supply chain, (2) eliminating frequent stock outs and pilferages, (3) strengthening the management of MSD [Medical Stores Department]'s working capital and complementing MSD in the procurement and distribution of medicines through engagement with the private sector, and therefore improving accountability. The other initiatives include: (4) introducing an ICT mobile application platform, (5) expanding the SMS reporting system and (6) scaling up Total Quality Management initiatives to the primary facility level using the 5S-KAIZEN approach."*[30]

The ADP, in collaboration with central-level decision-makers at the NTD Control Programme and the PSU within the Ministry of Health, Community Development, Gender, Elderly and Children, strengthened the capacity of health professionals from the district, facility and community levels by developing comprehensive guidelines and training curricula for supply chain management for the large-scale distribution of preventive chemotherapy for NTDs during mass drug administration (MDA) campaigns.[31]

5
Conclusions

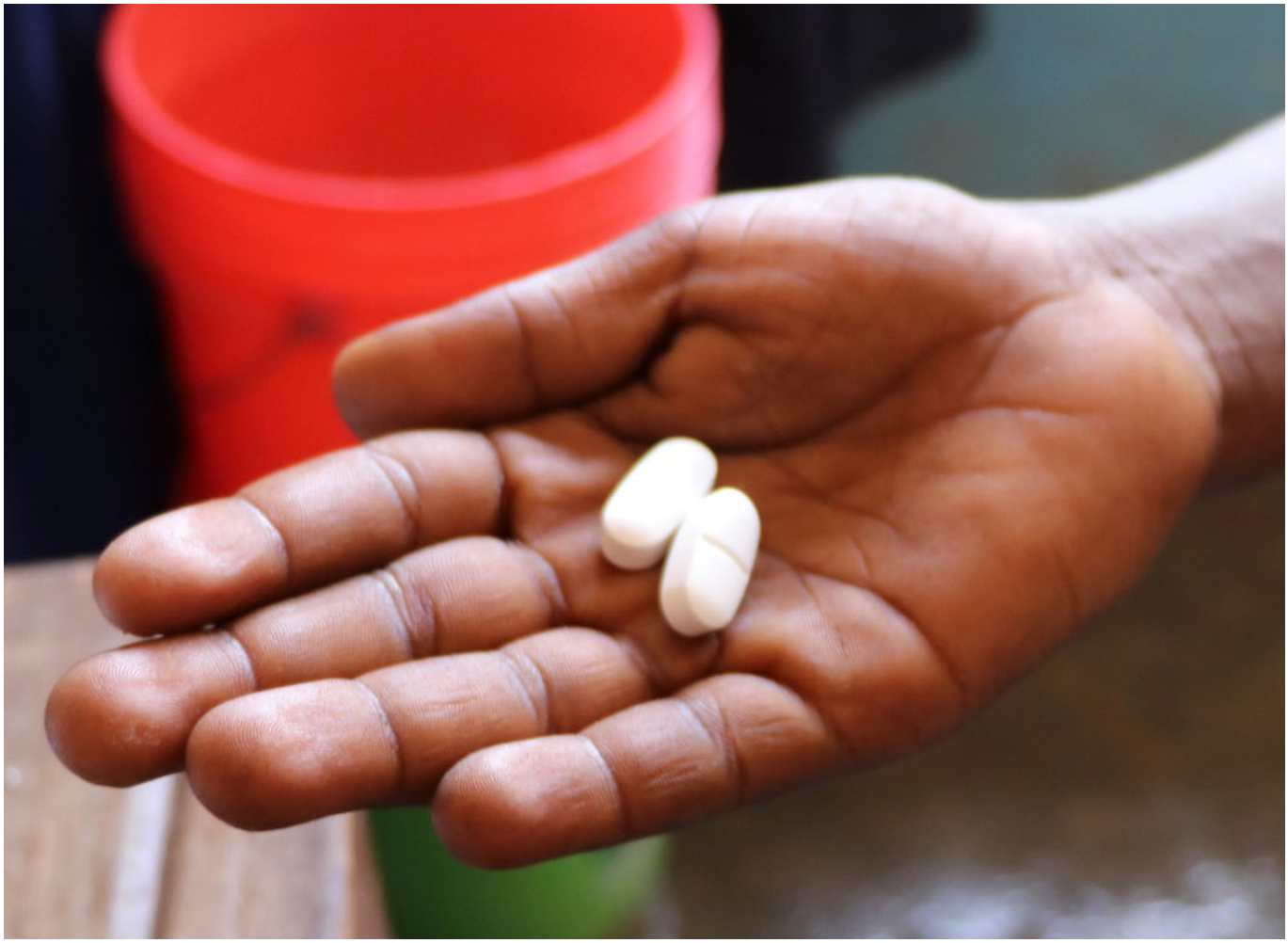
Addressing Tanzania's public health challenges requires a multipronged strategy that combines the elements of progress in R&D on new vaccines, medicines and diagnostics that directly address the threats confronting the patient community, while at the same time strengthening the country's regulatory capacity, and local capability to introduce new technologies. The GHIT Fund and the ADP together are pursuing this multipronged strategy, with accelerated R&D towards the development of vaccines and treatments that target the needs of patients in Tanzania, as well as the strengthening of systems, capacities, policies and regulatory frameworks that are necessary to effectively implement strategies to address public health challenges.

The GHIT Fund and the ADP are investing in health care solutions that should dramatically improve the well-being of children in Tanzania. Diseases such as malaria, TB and human schistosomiasis have a devastating impact. Human schistosomiasis not only causes illness and death but impairs children's growth and cognitive function. The paediatric formulation of PZQ pursued by the GHIT Fund and its collaboration partners promises a significant contribution to improving children's health in Tanzania, and throughout sub-Saharan Africa where this NTD is prevalent. The elimination of NTDs is critical to achieving SDG 3.

Bearing in mind that the GHIT Fund and the ADP initiated their work programme in Tanzania in early 2014, that activity is bearing fruit in terms of the gradual strengthening of the public health and regulatory systems in the country, as reflected in its HSSP for 2015–2020, as well as in preparations to commence Phase II clinical trials of a promising TB vaccine candidate.

The work of the GHIT Fund and the ADP contributes to SDG 3, which envisages ending the epidemics of malaria, TB and NTDs by 2030 and urges UN Member States to support R&D of vaccines and medicines for communicable and non-communicable diseases that primarily affect developing countries. This work is also consistent with recent Resolution of the World Health Assembly in 2016, which call for sustainable funding of new mechanisms to promote R&D to address diseases primarily affecting LMICs.[32] Most important, the efforts of the GHIT Fund and the ADP are aimed at meeting the urgent public health needs of the people of Tanzania.

Schistosomiasis, or "snail fever", is a parasitic disease carried by fresh water snails. Tanzanian school children receive preventative medication twice a year through a UNDP-supported government programme. *Photo: UNDP/Natasha Scripture*



References

1. Despite progress over the past 15 years, *"HIV, TB and malaria continue to pose a major public health threat, killing nearly 3 million people every year. Progress has been uneven in many parts of the world, millions of people lack access to life-saving prevention measures and treatment, and growing resistance to drugs and insecticides threatens to reverse the gains. … [T]he group of diseases currently known as 'neglected tropical diseases' (NTDs), also continue to inflict a heavy burden on societies"* (World Health Organization, 'Accelerating progress on HIV, tuberculosis, malaria, hepatitis and neglected tropical diseases. A new agenda for 2016–2030', WHO, Geneva, 2015, Foreword).

2. United Nations General Assembly, 'Transforming our world: the 2030 Agenda for Sustainable Development', Resolution adopted by the General Assembly on 25 September 2015. In addition, SDG 3.d urges *"[s]trengthen[ing] the capacity of all countries, in particular developing countries, for early warning, risk reduction and management of national and global health risks".*

3. *See* World Health Assembly, 'Follow-up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination Draft resolution contained in document A69/40 as amended by a drafting group', Sixty-Ninth World Health Assembly, A69/B/CONF./6, Agenda item 16.2, 28 May 2016, reported as adopted in William New, WHO's Kieny: R&D Resolution 'An Advance That Shows Strong Recommitment', *IP-Watch,* 31 May 2016. The development and deployment of such new strategies was the subject of a number of contributions to the United Nations Secretary General's High Level Panel on Access to Medicines, the report of which should be delivered in June 2016.

4. *See, for example,* WHO-TDR, 'Health product research and development fund: a proposal for financing and operation', WHO, Geneva, 2016, pp. vii, 1; Bernard Pecoul, et al., 'Drugs for Neglected Diseases initiative (DNDi)', UN High Level Panel Contribution, 27 February 2016.

5. WHO-TDR, stating: *"These diseases are often characterized by market failure, where the commercial potential for drugs, vaccines and diagnostics is too small to spur sufficient product development activity"* (Ibid., p. 1).

6. WHO-TDR, ibid., p. 1. In May 2016 the 69th Session of the World Health Assembly approved a Resolution directing the WHO Director General "to expedite the further development of a fully functional Global Observatory on Health Research and Development that makes use of alternative funding mechanisms to promote R&D to address diseases primarily affecting developing countries". *See supra* note 3.

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

8. United Nations Conference on Trade and Development (UNCTAD), 'UN list of Least Developed Countries', UNCTAD, Geneva, 2016: http://unctad.org/en/Pages/ALDC/Least%20 Developed%20 Countries/UN-list-of-Least-Developed-Countries.aspx.

9. UNDP, 'The ADP, 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', UNDP, New York, p.9.

10. Ibid., p. 11.

11. The United Republic of Tanzania Ministry of Health and Social Welfare, 'Health Sector Strategic Plan July 2015 – June 2020 (HSSP IV), Reaching all Households with Quality Health Care', Ministry of Health and Social Welfare, Dodoma, 2015 (hereinafter 'HSSP IV'), p. 24.

12. Ibid., p. 11.

13. Ibid., p. 11–12. Prevention is improving: nearly 75 percent of vulnerable groups slept under a bed net in 2012. In Tanzania, the entire population is at high risk of malaria transmission, with 678,000 cases and 5368 deaths reported in 2014 (World Health Organization, 'World Malaria Report 2015', WHO Press, Geneva, 2015).

14. HSSP IV, p. 45. In Tanzania, over 170,000 new cases of TB were estimated in 2014, but only 36 percent were identified. A total of 58,000 TB-related deaths occurred in 2014 (Global Health Observatory website: www.who.int/gho/en/; World Health Organization, 'TB Country Profiles', WHO, Geneva, 2016: www.who.int/tb/country/data/profiles/en/).

15. HSSP IV, p. 46

16. H. Mazigo et al., Epidemiology and control of human schistosomiasis in Tanzania, *Parasites & Vectors* 2012, 5:274, 288.

17. The term 'neglected tropical diseases' refers to disease conditions found predominantly, if not exclusively, in low- or low-middle-income countries and to which minimal funding is committed to R&D because of the absence of sufficient paying market demand, including, for example, schistosomiasis and hookworm disease. *See, for example*, WHO-TDR, supra note 4, p. 9–10.

18. HSSP IV, p. 46.

19. WHO, 'Global Tuberculosis Report 2015', WHO Press, Geneva, 2015; WHO, Global Health Observatory data repository for TB (website). http://apps.who.int/gho/data/view.main.57020ALL?lang=en; WHO, Global Health Observatory data repository for malaria (website). http://apps.who.int/gho/data/node.main.A1362?lang=en; WHO, Global Health Observatory PCT databank (website). http://www.who.int/neglected_diseases/preventive_ chemotherapy/databank/en/

20. In Tanzania, 10.8 million people (including 2.9 million school-aged children) required preventive chemotherapy (PCT) for schistosomiasis in 2014. However, PCT coverage in 2014 was only 27 percent (Global Health Observatory website: www.who.int/gho/en/; and the Preventive Chemotherapy and Transmission Control (PCT) databank: www.who.int/neglected_diseases/preventive_chemotherapy/sch/db/?units=minimal&region=all&country=tza&countries=tza&year=2014).

21. While AIDS-related illnesses continue to be the leading cause of death in Tanzania, there is substantial R&D investment in treatments for HIV/AIDS, as it is also prevalent in high-income countries. Programmes such as the Global Fund and PEPFAR provide large-scale funding for Tanzania's HIV/AIDS treatment programme.

22. Global Health Observatory website: (www.who.int/gho/en/) and the Preventive Chemotherapy and Transmission Control (PCT) databank (www.who.int/tb/country/data/profiles/en/).

23. The availability of essential medicines at public health facilities is poor in Tanzania, with the availability of selected generic medicines at only 38 percent in the public sector and 50 percent in the private sector (Global Health Observatory website: www.who.int/gho/en/ ; and World Health Organization, 'MDG medicines', WHO, Geneva, 2016: www.who.int/gho/mdg/medicines/en/).

24. Submissions and presentations to the United Nations Secretary General's High Level Panel on Access to Medicines identified the lack of coordinated registration requirements for new medicines and other health technologies in LMICs as a serious obstacle to the rapid roll-out of treatments that are developed by product development partnerships, such as GHIT. *See, for example,* Bernard Pecoul et al., *supra* note 4.

25. ADP, 'New Law to Regulate Medical Supply in the African Union', ADP, New York, 15 February 2016: http://adphealth.org/blog/16/New-law-to-regulate-medical-supply-in-the-African-Union.html.

26. African Union, 'Model Law on Medical Products Regulation', African Union, Addis Ababa, January 2016.

27. The United Republic of Tanzania Ministry of Health and Social Welfare, Health Sector Strategic Plan III July 2009 – June 2015, Ministry of Health and Social Welfare, Dodoma, 2008, p. 43.

28. HSSP IV, p. 20. Further, *"TFDA was able to increase the annual number of medicine samples to be tested (from 340 to 675 between 2010 and 2012), as well as the number of samples actually processed (from 52% to 96% between 2010 and 2012) in its WHO pre-qualified quality control laboratory"* (HSSP IV, p. 20).

29. HSSP IV, p. 58.

30. HSSP IV, p. 5.

31. The ADP has strengthened institutional structures, linkages and capacities to ensure cost-effective and -efficient supply chain management for large-scale distribution of preventive chemotherapy during MDA campaigns for NTDs. In 2014, even with 100 percent geographical coverage of 169 districts, the MDA campaigns were only able to reach 23 million people (out of a population of 49 million) with 55 million treatments for soil-transmitted helminthes, schistosomiasis, onchocerciasis, lymphatic filariasis and trachoma. The cohort of personnel trained by the ADP will train a further 3000 health personnel in 20 regions before the next MDA campaign in September 2016.

32. WHA69.23, Follow-up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination, http://apps.who.int/gb/ebwha/pdf_files/WHA69/ A69_R23-en.pdf

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