

Proposal for the 2023 G7 Summit

Building a global architecture to ensure access to health technologies for Neglected Tropical Diseases (NTDs)

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Asia Africa Medical Innovation Consortium (AMIC)

Neglected Tropical Diseases Subcommittee¹

With the establishment of the GHIT Fund (Global Health Innovative Technology Fund) in Japan, the first funding agency of its kind in the world, the development of new technologies for NTDs is being actively conducted in Japan. In contrast, however, there is no global system in place to bring these new technologies to the patients in need in developing countries. Our hope is that the Japanese government will lead the discussion on access to health technologies for NTDs at the 2023 G7 summit to further ensure that innovation is used to improve the health of patients globally.

NTDs refers to a group of 20 diseases defined by WHO, including lymphatic filariasis, onchocerciasis, schistosomiasis, mycetoma, rabies, leprosy and other wide-ranging diseases. While many of these diseases are believed to be able to be eliminated or controlled, 1.7 billion people worldwide are still being affected. This is a challenge shared by all humankind for creating a vicious cycle of health disparities and poverty on a global scale, and is clearly stated in Target 3.3 of SDGs Goal 3; "By 2030, end the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases [...]".

In 2013, the GHIT Fund, a public-private fund, was established in Japan to support research and development, investing approximately 26.9 billion yen to date in the development of drugs for malaria, tuberculosis, and NTDs. Thanks to these efforts, several drugs are currently under development in the field of NTDs and are expected to be launched in the near future.

However, due to the lagging development of health care systems and basic infrastructure in the regions where NTDs are endemic, alongside the lack of an internationally established mechanism to deliver NTDs medicines to patients in developing countries, it is unclear whether these medicines could actually improve the health of the endemic regions. Without further global efforts, it is difficult to foresee whether the products that are created with the investment of Japanese funds, technology, and their expertise will actually be implemented in the field.

¹ This subcommittee is a group of dedicated stakeholders who aim to contribute to the global effort to control NTDs by deepening collaboration among industry, government, academia, and the private sector in Japan. The Japan Alliance of Globally Neglected Tropical Diseases (JAGntd) at the Institute of Tropical Medicine, Nagasaki University serves as the secretariat.

Japan has a long history of having a strong presence among the international community in the field of infectious diseases. During the G8 Kyushu-Okinawa Summit in 2000, the establishment of the Global Fund for AIDS, Tuberculosis, and Malaria was triggered when Japan, as the chairing country, addressed the fight against infectious diseases as a major issue. In June 2022, the Japanese government along with stakeholders from around the world signed the Declaration of Global Partnership for NTDs (commonly known as the Kigali Declaration).

We hope that the upcoming G7 Summit in 2023 will address the support for the development of access to medicines for NTDs as one of the agenda items, and discuss how end-to-end support should be provided. The prevalence of NTDs is an indicator of the lagging development of health systems, and issues on this topic can be positioned as a concrete example in building universal health coverage and resilient health systems, which are the pillars of the Japanese government's global health strategy.

The major problems in the field of access to medicines for NTDs are that the supply of medicines is largely unsustainable due to an over-reliance on donation by a couple of pharmaceutical companies, and the absence of a global framework to bring medicines to patients in endemic areas. Compared to HIV/AIDS, malaria, TB, and AMR (antimicrobial resistance), the field of NTDs lacks organizations, partnerships, and mechanisms to provide a sustainable supply of health technologies and to support the control activities in developing countries.

It is necessary to develop a global framework by creating new organizations that support NTDs, expanding the scope of existing organizations, or strengthening new partnerships among existing organizations. Furthermore, it is desirable for this framework to have the following functions:

AT THE GLOBAL LEVEL

- ◆ **SUSTAINABLE PROCUREMENT OF MEDICINE** — While the basic premise is that patients should be able to obtain medicines at affordable prices, it is necessary to avoid excessive reliance on donation of medicines by pharmaceutical companies and to develop a procurement system that takes advantage of market principles. To achieve this, a new system, such as a pooled procurement mechanism, should be established as well as pooled funding in which governments of developed and developing countries and international funds participate. It should guarantee the ability to negotiate prices using bulk purchasing of medicines and “Advanced Market Commitment (i.e. advance purchase guarantee)”, and provide pharmaceutical companies with incentives for drug development to enable sustainable procurement of high-quality NTD medicines.
- ◆ **ACCELERATION OF REGULATORY APPROVAL AND GUIDELINE DEVELOPMENT** — Coordination and support should be provided to shorten the time required to obtain Prequalification (PQ) by WHO and to be adopted into WHO guidelines. It should also serve as a liaison with regulatory agencies in developed countries and countries where NTDs are endemic.

AT THE REGIONAL & COUNTRY LEVEL

- ◆ **ACCELERATION OF CLINICAL TRIALS** — In countries where NTDs are endemic, there are often delays in clinical trials due to the time required to enroll patients in clinical trials. Collaboration with African Medicines Agency, for example, should be sought to speed up and streamline clinical trials in NTD-endemic countries.
- ◆ **TRANSFER OF DRUG MANUFACTURING TECHNOLOGIES** — R&D companies with manufacturing sites in developed countries may not be able to sustainably manufacture and supply NTDs drugs by themselves due to financial reasons. For this reason, support should be provided for the transfer of manufacturing technology from the organization responsible for R&D to the organization responsible for manufacturing.
- ◆ **STRENGTHENING OF HEALTH SYSTEMS AND NTD PROGRAMS** — To ensure that medicines reach patients, it is essential to 1) strengthen primary health care and health insurance systems for diagnosis and treatment, 2) enhance the capacity of laboratory networks, 3) strengthen the supply chain of medicines and health information systems including pharmacovigilance, 4) improve recognition of the medicine among patients and health care providers to create demand and raise awareness, 5) educate patients and healthcare professionals about prevention, early diagnosis and treatment, and 6) establish a system that enables the proactive participation of residents in the target areas. However, NTDs-endemic countries have significant shortcomings in medical infrastructure, human resources, and capacity to adequately implement these measures, so assistance should be provided to compensate for these shortcomings.

Supporting Organization

- Agenes Inc.
- Astellas Pharma Inc.
- The Japanese Society of Tropical Medicine
- Japanese Society of Metabolic Medicine
- Keishinkai Medical Corporation
- Eiken Chemical Co., Ltd.
- Eisai Co., Ltd.
- Department of Microbiology, Oita University School of Medicine
- Glocal Research Center for Infectious Diseases, Oita University
- Kao Corporation
- Department of Infectious Diseases, School of Medicine, Keio University
- Saraya Co., Ltd
- Shionogi & Co., Ltd
- Sysmex Corporation
- Koichi Suzuki Laboratory, Department of Clinical Laboratory Medicine, Teikyo University Faculty of Medical Technology
- Clover Health International (NPO)
- DNDi Japan (NPO)
- SDGs Promise Japan (NPO)
- Nagasaki University
- Japanese Society for Parasitology
- Japan Pharmaceutical Manufacturers Association
- Japan Society for One Health Science