## **Health Aid Promotes Human Health**



Ming Xu

Thank you for giving me the floor to talk about the commodity supply for development assistance and the role of Chinese companies.

As you know, under the Sustainable Development Goals (SDGs), international development aims at improving the lives of individuals, particularly in the low-and middle-income countries (LMICs). In the health field, it is desirable for the people there to be well equipped, to live more equitable lives, and enjoy easier access to those basic commodities, especially essential drugs, and medical services. So this is actually what is stipulated by SDGs.

When talking about the commodity supply for international development programs, I have to say, fighting major infectious diseases like AIDS, TB, malaria, and COVID-19 has become a top priority for many countries, particularly those LMICs. Let's take malaria as an example, just because of the COVID-19 pandemic, the incidence last year increased because there was less care for the vulnerable population. Most deaths happened among young children, especially in sub-Saharan Africa. So this is indeed a very challenging situation we are facing today.

When we talk about the particular market for public procurement, especially the market for development assistance, I try to give you a clear picture of diseases and donors. This is an exceptional market, and I will briefly walk you through it. The development assistance is focused primarily on major infectious diseases, maternal and reproductive health and related fields.

Major purchasers in the development assistant programs include UNICEF, the Global Fund, and other UN agencies. Some foundations, such as Bill and Melinda

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This article is based on Xu Ming's keynote speech at the PKU Global Health and Development Forum 2021.

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Gates Foundation, are also big contributors to those international development programs. Before the COVID-19 pandemic, the size of the development systems for health was just about \$35 billion to \$40 billion a year, with an average annual growth rate of roughly 1%.

But just because of COVID-19, the market expanded exponentially, particularly in the past two years. Here's the snapshot of those focused areas. Prevention, diagnosis, treatment, vaccine, nutrition, and family planning are actually the core of this market. There have been some changes in this market due to the outbreak of COVID-19.

Next, I'll talk about the Access to COVID-19 Tools Accelerator (ACT-A) Initiative. ACT-A was launched in April 2020 by WHO and other UN agencies. There are three pillars of ACT-A: vaccine, therapeutic and diagnostic partnership.

Gavi, UNICEF, and WHO are the co-conveners for the vaccine partnership. For the therapeutic partnership, UNITAID, the Global Fund are held responsible for developing deploying new therapeutics, especially in the LMICs. For the diagnostic partnership, the Global Fund is playing a crucial role, especially in deploying those badly needed In-vitro diagnostics (IVDs) for those countries at risk. FIND and WHO are providing support to this particular pillar.

The World Bank and the Global Fund are also responsible for building up the health system connector. Among other things, let's take vaccines as an example, WHO made it very clear that ensuring equitable access and a fair allocation is a priority as the vaccination campaign unfolds at scale.

When we talk about the commodity supply on the part of companies, you have to get your products registered. For ACT-A, there is a particular procedure, EUL (Emergency Use Listing), as part of the WHO approval procedure to cope with emergencies.

The EUL procedure involves a rigorous assessment of quality, safety, and efficacy data to enable early and targeted use of yet to be licensed vaccines, treatments, and diagnostics, to respond to a public health emergency of international concern. So there are three phases for EUL, preparedness phase, emergency phase, and post-listing phase.

So what is the nature, the essence of EUL, and how is the EUL procedure different from pre-qualification? Prequalification is the precondition for a particular product to be purchased by those UN and international agencies, and the procedure of EUL is intended to provide a time-limited listing for unlicensed products in an emergency context when limited data are available but products are not yet to be approved for prequalification. As part of the EUL, the expectation is that the manufacturer will complete the development of the product and submit for licensure and WHO prequalification. Here's a short description of those categories of medicines for WHO prequalification. You know that the primary types of medicines are those products related to HIV/AIDS, malaria, TB, reproductive health, influenza, acute diarrhoea, and neglected tropical diseases, etc.

In addition to that, those APIs for making formulations of these products are also required to apply for WHO prequalification.

This slide shows the prequalified China-made products. So far, there have been 33 Chinese manufacturers, which have already got the prequalification from WHO, with

55 active pharmaceutical ingredients. In terms of vaccines, there are four Chinese manufacturers with seven vaccines prequalified, including the JE vaccine, influenza vaccine, polio vaccine, and HPV vaccine. There are also some IVDs and the vector control products like bed nets. So far, there have been 10 China-made PCR tests and 2 vaccines endorsed by WHO under the EUL procedure. The Global Fund and UNICEF are the major purchases of those WHO prequalified products, including those products granted EUL status.

Before the COVID-19 pandemic, the Global Fund purchased roughly \$1.7 billion worth of health products every year. China has become a very important supplier of those essential drugs to the Global Fund. Chinese companies now rank 5th among all the suppliers of those essential products.

Lastly, I just want to bring your attention to some initiatives and arrangements launched or promoted by the UN agencies to facilitate access to those essential medicines in LMICs. Maybe you have known that Pfizer has just signed a voluntary licensing agreement with MPP, Medicine Patent Pool for its COVID-19 oral antiviral treatment candidate.

This is a special mechanism backed by UNITAID in Geneva. The MPP aims to enable affordable production of essential drugs still under patent protection by obtaining volunteering licenses from the patent holders and making these licenses available to generic companies in LMICs. However, these companies can only sell these products in designated countries.

You are not allowed to sell without permission in your own country. So this is a very special feature of this arrangement. MPP has signed agreements with 10 patent holders for 13 HIV antiretroviral, 1 HIV technology platform, 3 hepatitis C direct-acting antivirals, and 1 TB therapeutic.

Another arrangement launched by Gavi is called IPTK Bank (Intellectual Property Technology, and Knowhow Bank). This is an initiative launched by Gavi to enable the early market entry of multiple developing country vaccine manufacturers and to facilitate the rapid rollout of new vaccines in developing countries.

Another mechanism also interesting to companies is called the Product Development Partnership, such as Medicines for Malaria Venture, MMV. This is a public–private partnership to encourage pharmaceutical companies to develop innovative drugs to treat malaria.

To attract more companies to produce generic drugs, tiered pricing has been used a lot, especially in LMICs to improve the access of those essential drugs, particularly in an emergency context. So I think this is high time to think about how we may work together to galvanize more Chinese companies into providing quality-assured and affordable commodities, especially for those international development assistant programs.