Global Antibiotic Research and Development Partnership (GARDP)

From: Rohit Malpani [redacted]
Sent: Tuesday, May 31, 2022 8:56 AM
To: Consultations <consultations@worldbank.org>
Cc: Manica Balasegaram [redacted]
Subject: Feedback from GARDP regarding Financial Intermediary Fund for Pandemic Preparedness and Response

[External]
Dear Madam or Sir

Please see attached feedback from the Global Antibiotic Research and Development Partnership (GARDP) with respect to a White Paper for a proposed Financial Intermediary Fund for Pandemic Prevention, Preparedness and Response.

Best wishes
Rohit Malpani

The Global Antibiotic Research and Development Partnership (GARDP) is a not-for-profit organization accelerating the development of and access to lifesaving treatments for drug-resistant infections that pose the greatest threat to health. GARDP was created by the World Health Organization (WHO) and the Drugs for Neglected Diseases *initiative* (DNDi) in 2016 to ensure that everyone who needs antibiotics receives effective and affordable treatment, no matter where they live. We aim to develop five new treatments by 2025 to fight drug-resistant infections, focusing on sexually transmitted infections, sepsis in newborns and infections in hospitalized adults and children.

GARDP welcomes the establishment of a proposed Financial Intermediary Fund for Pandemic Prevention, Preparedness and Response (FIF). Such a fund could play a critical role in strengthening the collective capacity of all countries to ensure that the economic and human consequences of COVID-19 are not repeated.

It is critical that the FIF includes investments to strengthen the response to antimicrobial resistance (AMR), a pandemic of drug-resistant infections. AMR already is having significant short- and long-term consequences for global public health and the global economy. According to recently released data published in the Lancet, at least 1.27 million people died of drug-resistant infections in 2019. AMR also threatens the viability of surgical and curative medical interventions, such as chemotherapy.
Thus, AMR is no longer just a threat with future consequences, but a complex existential emergency of infections, with most attributable deaths caused by just 6 pathogens. A FIF could immediately benefit the current and long-term response to AMR as many countries lack adequate surveillance and diagnostic capacity, infection prevention and control, and access to

existing antibiotics, while in other countries rising rates of resistance require new treatments not yet developed.

Research and development for new antibiotics to address AMR, now and in the future, remains significantly under-resourced and inadequate. Overall R&D investment for AMR – US$ 1.5 billion in 2020 – is insufficient to sustain the pipeline of new treatments for bacterial infections. Funding for clinical development from Phase 2 onwards is inadequate to address current pipeline demands and to ensure access and appropriate use.

Even if new funding is applied to the current pipeline, it will not overcome rising rates of drug resistance. According to the latest review by the World Health Organization (WHO) of the antibiotic pipeline, and despite some increases in public investment in recent years, current antibiotic research and development (R&D) is inadequate to counter rising rates of drug-resistant infections. Of the 76 anti-bacterials in clinical development, only four have new modes of action not previously exploited by marketed antibacterial drugs, and few address the current problems of drug resistance. Furthermore, most new antibiotics approved in recent years offer limited benefit over existing treatments, with 82% of recently approved antibiotics derivatives of existing classes with well-established drug resistance.

Furthermore, clinical development does not stop at approval of an antibiotic by a regulatory authority. In the case of new antibiotics that are being developed using streamlined development pathways, the sparse data in populations with the highest levels of resistance necessitate a substantial package of studies to demonstrate effectiveness. Overall, only 22% of R&D funding is expended on these late stages of product development and is concentrated with a few funders. Finally, there are significant investments required to enable the timely and accurate diagnosis of drug-resistant infections, and to assure that an appropriate treatment is provided. This requires specific investments to facilitate timely registration, estimate demand, strengthen procurement, and introduce measures to ensure sustainable access.

FOCUS OF FIF FINANCING

• Overall, GARDP supports financing and funding of AMR-related interventions for a FIF, both to address AMR as well as to support the overall response to other viral pandemics. Given the substantial overlap between AMR and zoonoses, many dual-purpose investments could be introduced to simultaneously prepare and respond to zoonotic and AMR pandemics.

• Timely access to appropriate antibiotics will be an important component of preparedness and response to future viral pandemics. Thus, evidence indicates that a diagnosed bacterial infection was associated with longer hospital stay and a greater risk of mortality among those hospitalized with Covid-19. Furthermore, future pandemics could carry a significant risk of hospitalization and secondary bacterial infections. Therefore, health systems will require timely access to effective antibiotics and diagnostics.

• With respect to AMR, we support interventions at the local, regional, and global levels in equal measure. Alongside significant need to fund existing and future R&D at all levels, there are significant funding gaps across the AMR response. This includes funding to support access

to treatments (especially in low- and middle-income countries) and funding to support and implement government National Action Plans, which remain unfunded or underfunded, thereby limiting the ability of governments to introduce measures to conduct surveillance, strengthen IPC, and ensure timely diagnosis and access. Many such investments, for example in surveillance, IPC and timely diagnosis, can also strengthen preparedness and response to other pandemic threats.

• With respect to surveillance, surveillance data of antibiotic resistance remains incomplete in many parts of the world. At present, data is lacking for 40 percent of African countries, and data generated through the WHO Global Antimicrobial Resistance and Surveillance System (GLASS) is only for a few species and infections and are likely to be underestimated. Alongside a lack of regional data, evidence and data for specific populations highly affected by AMR, such as children and newborn babies, are lacking.

GOVERNANCE OF THE FIF

• The FIF should ensure low- and middle-income countries are equal partners with respect to governance, with full and co-equal decision-making rights alongside donor countries. One lesson of the COVID-19 pandemic was that, even as low- and middle-income countries were responding successfully to the COVID-19 pandemic, despite a lack of access to medical countermeasures, these countries did not have sufficient opportunity to govern the choices and priorities of the international response.

• There are several reasons that low- and middle-income countries should play a greater role in decision-making in a FIF. First, this would ensure that strategies and solutions developed by such countries are fully accounted for and integrated into a global pandemic preparedness and response approach. Second, all countries have diverse interests with respect to priority setting and focus for pandemic preparedness and response. With respect to AMR, high-income countries are more likely to focus on stewardship and R&D, while low- and middle-income countries are more likely to be focused upon access. And while priority pathogens on the WHO Priority Pathogen List are a threat to all countries, the priorities that high-income versus low- and middle-income countries wish to focus upon may differ, and with limited resources, choices must be made between different priorities. Equitable governance can assure these choices are grounded in having the greatest public health impact, and not merely the preferences of a very small group of actors.

• The World Health Organization (WHO) played a critical role in the establishment and growth of GARDP, and continues to play a key technical, scientific, and operational role in support of the organization, as well as providing a critical link to governments and health systems around the world. The FIF should seek to work with WHO in the following ways: (a) it should provide WHO with an Observer seat on the Board; (b) it should request WHO to formulate a Strategic Technical and Advisory Group to guide the scientific and technical decisions of the FIF, while also working with other such Strategic Technical and Advisory Groups to address other disease areas; (c) it should provide resources to WHO for certain functions that enable WHO to

continue to serve as the backbone of pandemic preparedness and response, including for surveillance, communication, and regulatory support for medical countermeasures.

OPERATING MODALITIES, FUNDING ALLOCATION, FUNDS FLOW, and RESOURCE MOBILIZATION

• GARDP hopes that the FIF will also consider working directly with and through not-for-profit partnerships, including to develop and ensure access to novel tests and treatments. Such partnerships, with support from public funders, and unconstrained by commercial profitability requirements, are well positioned to work with public and private actors to viably develop and provide new antibiotics to all in need. Since 2010, nonprofit developers have developed and introduced 66 new health technologies for priority public health needs, reaching more than 2.4 billion people worldwide.