Summary Note

GLOBAL LEADERS GROUP ON ANTIMICROBIAL RESISTANCE

GLOBAL LEADERS GROUP ON AMR INFORMATION SESSION ON THE ANTIBACTERIAL PIPELINE AND ACCESS CRISIS

SESSION 1 - THE SCOPE OF THE CHALLENGE

17 MAY 2023

1. OVERVIEW

The world faces a serious antibacterial R&D pipeline and access crisis with too few new antibiotics targeting priority pathogens in development. Following discussions on this issue at the sixth meeting of the Global Leaders Group (GLG) on AMR in Barbados in February 2023, the GLG is establishing a Financing Task Force and holding a series of information sessions to discuss issues and propose solutions related to financing of R&D and national AMR action plans in the leadup to the UNGA high-level meeting on AMR in 2024. This first information session was intended to review the scope of the challenge and was co-chaired by GLG Vice Chair Dr Chris Fearne and GLG Member Mr Yasuhisa Shiozaki. Three further sessions will focus on potential solutions to the pipeline and access crisis, financing of national action plans, and development of a GLG position paper on these issues.

2. PRESENTATIONS

Ms Malin Grape, AMR Ambassador of the Ministry of Health and Social Affairs of Sweden, provided an overview of the antibiotic R&D and access "circular chain", noting that there is a wide range of factors influencing development of and access to new antibiotics in addition to the well-known market failures. These factors include public health needs prioritization; numerous pre-clinical discovery and clinical development challenges; lack of human resources; challenges associated with country registration (especially in LMICs); the need to ensure prudent stewardship and use; multiple production, procurement and supply chain challenges; and lack of sustainable financing. She noted that many of these issues were discussed at a high-level meeting on AMR hosted by the Swedish presidency of the EU Council in March 2023.

Dr Alexandra Cameron, Senior Expert and acting Unit Head, Impact Initiatives and Research Coordination in the AMR Division at WHO, presented a summary of the 2023 WHO antibacterial R&D pipeline review, encompassing antibacterial agents in both pre-clinical and clinical development. Overall, she described the pipeline as stagnant, with only two of the 12 products authorized since 2017 considered innovative and only 27 products currently in the clinical pipeline targeting priority pathogens, of which only six meet WHO innovation criteria. Most products are being developed by small companies with less than 50 employees and around a third of products in development are discontinued every year. There are major gaps in targeting highly drug-resistant pathogens and there is a lack of appropriate oral and pediatric formulations.

Dr Kevin Outterson, Executive Director of the CARB-X initiative, acknowledged the very fragile state of the clinical pipeline, but noted that there is significant innovation underway in the pre-clinical pipeline funded largely by governments. However, there is a lack of incentives and financing to move products from pre-clinical to clinical stages. He noted that private R&D investors have lost nearly $US 4 billion on antibiotics due to fragility of the market.

Preliminary analysis based on data from the Global R&D Hub, BIO and expert views suggest that total investment needs for pre-clinical development in antibacterial R&D amounts to $US 5.6 billion over the next 10 years. Expected investment at current levels is around US$ 1.9 billion, leaving a funding gap of around US$ 3.7 billion. He noted that both push and pull incentives need to increase. He also proposed that the GLG consider suggesting both innovation and financial targets for R&D for the 2024 high-level meeting on AMR.

Dr Jennifer Cohn, Director of Global Access with the GARDP initiative, described major barriers in access to antibiotics, including often high prices that vary significantly between countries, the disproportionate risk of antibiotic shortages compared to other drugs and multiple manufacturing and supply chain challenges, including poor demand forecasting and market intelligence and long regulatory approval timelines.

3. DISCUSSION

GLG members welcomed the presentations and discussed a range of issues. Several members urged GLG advocacy in favour of classifying antibiotics as global public goods that are treated differently from other drugs in terms of R&D and access, with an increased focus on public financing and agreements with the private sector on issues such as research coordination and prioritization, and drug pricing and access. This would need to be accompanied by more concerted efforts to address the lack of capacity in the R&D field, raise awareness about AMR and build a stronger global consensus around the constraints that are needed on antimicrobial use. Other issues raised by members included the need for more countries to pilot incentive mechanisms (a potential advocacy issue with the G20), the importance of harmonizing regulatory approval of new products between countries and regions, and the need for R&D/access targets in the 2024 political declaration to better define and measure progress.