

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

### SESSION 2 - DRAFT DISCUSSION PAPER AND RECOMMENDATIONS

10 NOVEMBER 2023

#### 1. OVERVIEW

The world faces a serious antibacterial research and development (R&D) pipeline and access crisis with too few new antibiotics in development that target priority pathogens. Following discussions on this issue at the sixth meeting of the Global Leaders Group (GLG) on AMR in Barbados in February 2023, the GLG established a Financing Task Force and held information sessions to discuss issues and propose solutions related to financing of R&D in the leadup to the UNGA high-level meeting on AMR in 2024.

This second session provided an opportunity for GLG members to review and comment on a draft discussion paper including recommendations under six themes developed by Ms Shanelle Hall of The Yellow House consulting firm. The paper was based on a series of in-depth interviews held with GLG members and external key informants. The session was co-chaired by GLG Vice Chair Dr Chris Fearne and GLG Member Mr Yasuhisa Shiozaki.

#### 2. CO-CHAIRS' REMARKS

Dr Fearne emphasized the importance of increased financing for the AMR response, including for R&D and implementation of national AMR action plans. He thanked GLG members for their inputs into the consultation process and noted the need for the GLG to provide practical and actionable recommendations on funding for R&D and access. Mr Shiozaki noted that while the G7 and G20 - together with international organizations - have a major role to play in financing R&D and ensuring equitable access to antimicrobials, the GLG should be a leading advocate on this issue.

#### 3. PRESENTATION

Ms Hall presented an overview of the consultation process which involved a literature search and interviews with 14 GLG members and 12 external key informants. She noted that most participants discussed the issue in the context of human health, but there were some inputs on animal health. She emphasized that the goal is for the GLG to develop recommendations that are disruptive, innovative and catalytic.

The interviews touched upon a wide range of themes including the need to establish R&D targets and priorities, global access strategies, push and pull incentives and other potential revenue sources, and clinical trial and regulatory issues. Ms Hall proposed a draft overarching solution that "access to effective antimicrobials is a global public good that should not be left to market forces, and that stimulating R&D and safeguarding access requires collective action across a range of financial, non-financial and mutually reinforcing interventions to maneuver through the challenges and build resilient, equitable systems".

Such a solution would involve three elements: 1) Long-term, predictable financing to achieve robust R&D and global access; 2) Financing accompanied by a set of complementary interventions that cover the end-to-end value chain; and 3) Coordination bringing together the capacities of the public and private sectors.

The six draft recommendations emerging from the consultation were:

1. WHO should lead the establishment of shared, global R&D targets for antibiotics and complementary diagnostics with implementation roadmaps and target product profiles (TPPs);
2. Public and private funders should increase funding for push incentives that support antibiotics and complementary diagnostics (with access strategies);
3. The G7 and G20 should take the lead in establishing pull incentives for R&D and complementary diagnostics (aligned with R&D targets and implementation roadmaps and with greater coordination);
4. National and regional regulatory bodies should achieve a regulatory system maturity commensurate with a stable, well-functioning and integrated regulatory systems for medicines (WHO maturity level 3);
5. National governments, WHO, partners and donors should significantly expand efforts to increase access to essential antibiotics while ensuring their appropriate use; and
6. Efforts should be made to reduce fragmentation and achieve results through coordinated action (potentially through a “network of networks” approach).

Ms Hall described several details under each of the proposed recommendations. She noted that animal health was not covered in detail in the discussion paper or recommendations, perhaps because of a perception that there is not the same pipeline and access crisis as in human health. However, she noted that R&D and access priorities in animal health include the need for new vaccines and more precise and rapid diagnostic methods, and the potential need for an AWaRe-type framework for antibiotics used in animals.

#### 4. DISCUSSION

The following points were made by GLG members in the discussion:

- The focus on access in the paper is welcome and important because there is a need for more vision on access to antimicrobials in the AMR response;
- The suggested addition of a paragraph in the paper on why diagnostics are so important for reducing antimicrobial use in humans and animals;
- The need for push incentives to target small and medium enterprises;
- The need to decolonize pharmaceutical manufacturing by strengthening capacity in LMICs;
- The importance of access in LMICs, which require external and domestic funding, and implementation support;
- The need for new formulations of existing classes of animal drugs to facilitate optimal use;
- Some support was expressed for an animal antibiotic AWaRe-type system, as well as access targets for animal drugs. There were several requests for more attention to animal health in the paper.
- The need to increase awareness of these issues in government;
- The importance of coordinating market incentives, especially pull mechanisms;
- The need for recognition of the work of the AMR Action Fund and the AMR R&D Hub;
- The need for pull mechanisms to incentivize companies to reinvest their own money;
- The need for improved coordination among regulatory agencies;
- The need to differentiate between access to existing and future products;

- Whether the paper should also discuss key issues in the agri-food sector, e.g. alternatives to antimicrobial use in crops;
- The potential to address some environmental issues in the paper;
- The potential role of existing financing mechanisms;
- The need to incentivize scientists and researchers to remain in this field; and
- The importance of continuing to emphasize prevention e.g. IPC, waste management, biosecurity.

Several GLG members indicated that they would send written comments on the paper.

## 5. CONCLUSION

Dr Fearne noted that there was broad consensus on the content of the document, but that there could be some revisions based on the comments made during the session and further written input. It was also suggested that the paper include framing related to prevention and animal health. The Secretariat requested that written inputs be provided by 15 November.

## 6. ADDITIONAL ITEM ON THE WHO PANDEMIC INSTRUMENT

Dr Getahun drew the attention of GLG members to the ongoing negotiations on the WHO pandemic instrument and his concerns that its current text significantly narrows the relevance of AMR in the instrument compared to previous drafts. He sought and received agreement from GLG members present on a draft GLG statement urging the INB to further consider the inclusion of AMR in articles in the draft instrument relating to pandemic prevention and public health surveillance, preparedness, readiness, and research and development.