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Joint Statement on Strengthening the Antibiotic R&D Pipeline by Rewarding Innovation

The emerging threat of antimicrobial resistance (AMR) for public health worldwide is not only concerning during the COVID-19 pandemic, but will become even more alarming after the current global health crisis. To combat this threat, no single actor or actor group can deliver a solution alone. A partnership approach with both the public and private sector is essential to successfully address the public health impact of AMR. There is a high unmet need for innovative antibiotics that either overcome resistances and/or offer novel treatment options to yet untargeted pathogens and to serve the needs of particularly vulnerable populations, especially children and neonates. In addition, for already approved antibiotics the access-to-market transition and their rapid availability and accessibility in high-burden countries must be much better ensured. Lastly, this goes together with an appropriate use of antibiotics to avoid the emergence of new resistances (antibiotic stewardship).

The signatories highly appreciate the efforts by the G7 health ministers under the current G7-presidency of the United Kingdom to combat AMR. However, we also see a need to intensify such activities to prevent future health crises caused by multi-resistant bacteria beyond the current efforts. As Germany will take on the G7 presidency in 2022, the G7's engagement in tackling AMR in 2022 should therefore be carried on, be intensified and continuity ensured into the Japanese presidency in 2023.

For this purpose, Germany can build on its antibiotic resistance strategy (DART 2020). The strategy describes measures to reduce AMR by adopting a 'One health' approach. However, there is a need to further define key components of a DART 2030. The objective should be to position Germany's G7 presidency effectively within the global framework of AMR-related existing and proposed measures covering all major areas of concern: research and development (R&D), successful market access supported by new incentives as well as an effective antibiotic stewardship and guidance to support use.

Since there cannot be a 'one size fits all' approach in all countries, it is important to explore a range of different options to ensure a sustainable market for antibiotics. We, therefore, urge the global leaders under the upcoming German G7 presidency to implement the following actions:

- **Strengthening the antibiotic R&D pipeline:** Current efforts in basic research for antibiotics must be sustained and strengthened to identify and develop novel chemical compound classes exhibiting innovative modes of action. Another critical phase is the translation from early-stage trials to late-stage clinical development. Funding initiatives prepared in broad collaboration, such as the AMR Action Fund, are aiming to overcome this challenge. In addition to such push incentives, sufficient pull incentives are needed to ensure that investments into new antibiotic drug R&D activities are started with the prospect of an ecosystem which rewards innovation.
- **Ensuring fast access to antibiotics:** Novel antibiotic drugs are intended to be used only if the standard treatment for an infection is not effective due to resistance. Because they are by design developed for a limited use, such reserve antibiotics face hurdles in terms of health technology assessment and reimbursement. To maintain a sustainable market, the reimbursement of reserve antibiotics for both the outpatient setting as well as for hospitals needs to be ensured by new reimbursement models.
- **Capitalizing on the opportunities offered by vaccines:** The untargeted and non-evidence-based administration of antibiotics promotes the development of AMR. While antibiotics can help treat an infection once it has occurred, vaccines offer the potential to protect against life-threatening infections and their consequences. Vaccines can therefore play multiple roles in antimicrobial stewardship strategies.
- Only if we set these recommendations into immediate action, we will be able to build an innovative and sustainable ecosystem to effectively fight AMR.