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BPI e.V. response to the call for evidence for an initiative on antimicrobial resistance

The BPI e.V. (BPI), representing more than 270 companies, comprises the whole spectrum of the pharmaceutical industry, ranging from multinational corporations to SMEs, Mid-Caps as well as Start-ups. These companies ensure timely and safe drug supply for all patients across the EU and globally. We welcome the European Commission's initiative for a Council Recommendation which aims to set concrete objectives and activities to strengthen the action in the fight against antimicrobial resistance (AMR).

The growing resistance of bacterial pathogens to antibiotics is a significant global health threat that poses health and financial threat not only individual patients, but society as a whole. In 2019, nearly 5 million deaths worldwide were associated with AMR. Without urgent action to address AMR, its toll will only become more severe.

The envisioned Council Recommendation should include the following aspects to ensure a successful strategy to combat AMR and align actions throughout Member States.

- **Creating a sustainable and stable environment for antibiotics:** This should include a new incentive system for antibiotics. Economic incentives, such as pull incentives and reimbursement reform, provide the most promising way forward. A key feature of many pull incentives is that they either fully or partially delink the volume of antibiotics used from the magnitude of payment that is received for the product. The European Commission could assist broad implementation of these economic incentives by providing, tools, resources, and guidance for implementation. In many cases, a package of incentives will be needed to address the broken antibiotic market.
- **Harmonise global regulations for development and approval of new antibiotics:** The EMA has made strides in introducing regulations that would allow for more efficient development of new antibiotics, and their work with other stringent regulatory agencies to harmonise the regulations governing antibiotic review and approval is encouraging. Further harmonisation of clinical trial requirements across regions would be welcomed and could support faster access to new antibiotics for patients.
- **Prudent use of antibiotics, stewardship, and timely surveillance of resistance epidemiology:** Appropriate use of antibiotics by physicians is also driven by guideline and guidance documents. These documents should follow the progress that regulatory agencies are making when it comes to the evaluation of evidence by recognizing in vitro microbiological data, PK/PD data, and RWE as high-quality evidence. As new antibiotics enter the market, best practices for different types of infections could change; therefore, guidance documents should be updated on a regular basis to include newer drugs, ensuring continued use of the most appropriate products.
  With regards to the minimisation of antibiotic use in animals, we would like to stress that new EU regulation on veterinary medicines, as well as a limitation of the use of certain antibiotic groups to the humans, will lead to significant reductions in the use of antibiotics. Demands for even stricter measures would make it impossible to comply with minimum medical standards in the treatment of infectious diseases in animals, maximizing the risk that zoonotic diseases also pose for humans.
- **Establish clinical trial networks to help execute clinical studies more efficiently:** Generating comparative data in populations of interest – those individuals with resistant infections – is one of the greatest challenges in the development of new antibiotics. Creating a clinical trial network focused on antibiotic studies would also be a cost-

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effective and efficient way to bring new antibiotics to market; they can also be a tool to develop or improve upon antimicrobial stewardship programmes.

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