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Answer given by Mr Andriukaitis
on behalf of the European Commission
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The Commission is currently working on a strategic approach to pharmaceuticals in the environment[1], which is expected to address gaps in knowledge of the risks from pharmaceuticals in the environment and may include further actions relevant to antimicrobial resistance (AMR) at EU level.

As regards the observation from the Scientific Steering Committee[2] that the introduction of AMR genes into the environment changes microbial ecology, and its suggested areas of investigation, the Commission is focusing on how the presence of antimicrobials in the environment might increase the maintenance and spread of AMR, and what levels of antimicrobials could trigger AMR development. At the same time, it will learn more about the changes that occur in microbial ecology generally, and about whether there are indications of any other effects on the environment.

The Good Manufacturing Practice Guide for active substances[3] was adopted primarily to ensure the quality of medicines to be placed on the European market. The guide does not cover environmental protection as such, because this is generally governed by other legislation. However, the guide requires waste in and from factory buildings to be disposed of in a safe, timely and sanitary manner. The facilities have to comply with local regulations to minimise the risk of contaminating the environment. The Commission promotes dialogue and EU external action with the main pharmaceutical-producing countries to ensure environmentally sound production practices.

Information on the progress, achievements and budget for all projects of the "New Drugs 4 Bad Bugs" programme is already available on the the Innovative Medicines Initiative website[4]. Additional information is available on the Cordis website[5].

1 In accordance with Article 8c of the Priority Substances Directive (Directive 2008/105/EC as amended by Directive 2013/39/EU) https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02008L0105-20130913&qid=1539952335681&from=EN
2 https://ec.europa.eu/food/sites/food/files/safety/docs/sci-com_ssc_out50_en.pdf
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