European Parliament
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Committee on Petitions

28.2.2018

NOTICE TO MEMBERS

Subject: Petition No 0451/2017 by Martin Jürgens (German) on improving pharmaceutical production processes and environmental standards for pharmaceutical companies seeking approvals from the European Medicines Agency

1. Summary of petition

The petitioner states that antimicrobial resistance (AMR) is a growing concern for public health in the EU. His particular concern relates to the problem of antibiotic residue in wastewater and sewerage, resulting from current antibiotic production processes. He calls for the European Medicines Agency (EMA) to increase the scope of its control in the approval process for antibiotic pharmaceuticals such that it includes the consideration of environmental factors, such as wastewater run-off and the increasing acceleration of AMR contagion. The petitioner highlights the particular problem of non-EU pharmaceutical producers, whose production process may not be in line with EU environmental standards. The petitioner is concerned that such products often end up for sale in the EU pharmaceutical market.

2. Admissibility

Declared admissible on 31 August 2017. Information requested from Commission under Rule 216(6).

3. **Commission reply**, received on 28 February 2018

The Commission is aware of the growing concern about the development and spread of antimicrobial resistance (AMR) in the environment due to discharges of antimicrobials and their metabolites from various sources including pharmaceutical production plants. It has launched several initiatives to inform the best way forward based on sound evidence.

In June 2017, the Commission adopted a new European One Health Action Plan against

AMR[1] which includes specific actions to improve knowledge about the contribution of the environment to AMR, and to explore possibilities for taking appropriate measures. The new Action Plan includes developing a Strategic Approach to address the risks from pharmaceuticals in the environment. A study to support its development is underway, including a public consultation and a targeted stakeholder consultation (both launched in November)[2]. One of the options mentioned in the stakeholder consultation is the possibility of including the control of discharges to the environment explicitly in Good Manufacturing Practice (GMP) requirements.

The Strategic Approach could include policy options relevant to any part of the lifecycle of pharmaceutical substances from production through consumption to disposal. The Commission plans to adopt this approach by mid-2018. The next step will be to further investigate the options, conducting a full impact assessment as appropriate.

The new Action Plan also promotes actions and collaboration at global level. The synopsis report[3] accompanying the Action Plan mentions that some options could relate to manufacturing effluents and the collection of unused antimicrobials.

The European Medicines Agency (EMA) does not approve pharmaceutical manufacturers as this falls under the competence of national authorities. The manufacturers should comply, inter alia, with GMP requirements. For manufacturers placing products on the EU market, also in cases where the manufacturers are located outside the EU, compliance with GMP requirements is controlled by national competent authorities of the EU Member States.

The existing Guidelines on Good Manufacturing Practice[4] for active substances require that sewage, refuse, and other waste in and from factory buildings and the immediate surrounding area should be disposed of in a safe, timely and sanitary manner. Manufacturing facilities are expected to comply with local regulations to minimise the risk of contaminating the environment.

[1] https://ec.europa.eu/health/amr/sites/amr/files/amr_action_plan_2017_en.pdf
[2] - public consultation: https://ec.europa.eu/info/consultations/public-consultation-pharmaceuticals-environment_en
- stakeholder consultation: https://ec.europa.eu/eusurvey/runner/PharmaInEnvTargetedConsultation2017 (deadline 21.01.2018)
[3] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52017SC0240&from=EN
[4] https://ec.europa.eu/health/documents/eudralex/vol-4_en