European Parliament
2014-2019

Committee on Petitions

31.1.2018

NOTICE TO MEMBERS

Subject: Petition No 0513/2017 by R. N. S. (German) on multidrug-resistant pathogens and the lack of responsibility of the European pharmaceutical sector

1. Summary of petition

The petition addresses the problem of antimicrobial resistance (AMR). The petitioner states that in Germany alone, despite a well-developed public health care system, a large number of AMR-infections are registered annually. As an example, he states that 11,000 infections were recently attributed to MRSA (Methicillin-resistant Staphylococcus aureus) and 8,000 to multi-resistant Escheria coli. The petitioner is of the view that the medical profession is no longer able to respond to this problem. He believes that the current legislative framework is ineffective and outdated. In particular, the issue of inadequate pharmaceutical production processes and non-treatment of waste water continues to contribute to a rapid worsening of the problem. The petitioner also highlights the link between AMR in humans and the over-use of antibiotics in the meat industry, and points to the failure of EU agricultural policy to take account of AMR risk when distributing agricultural subsidies. In view of the seriousness of the situation and the worsening prognosis for the future, the petitioner is urging the European Commission and the European Parliament to take action. In particular, the petitioner calls upon the EU institutions to adequately enforce the rights to physical integrity, animal welfare, and environmental protection, as well as taking action in influencing the production processes of the pharmaceutical industry.

2. Admissibility

Declared admissible on 4 October 2017. Information requested from Commission under Rule 216(6).

3. **Commission reply**, received on 31 January 2018

The Commission is very well aware that antimicrobial resistance (AMR) is a major global

challenge and has serious implications on human and animal health and the economy. Each year, drug resistant infections result in an estimated 25,000 patient deaths and cause EUR 1.5 billion worth of healthcare and productivity losses in the EU. The evidence suggests that these costs will increase exponentially in the absence of decisive corrective actions. Unless tough action is taken to address it, AMR will, in addition, continue to have a significant negative impact on jobs, growth and investments.

The Commission therefore decided to prepare a new European One Health Action Plan against AMR[1] which builds on the previous 2011 AMR action plan, its evaluation and the feedback received following an extensive open public consultation. This new plan was published on 29 June 2017 and contains concrete actions with EU added value that the Commission will develop and strengthen as appropriate in the coming years for a more integrated, comprehensive and effective approach to combating AMR. All these actions are important in themselves, but they are also interdependent and need to be implemented in parallel in order to achieve the best outcome. The Commission has chosen to concentrate its efforts on key areas with the highest added value for Member States, while respecting the limits of EU competence and bearing in mind that Member States remain primarily responsible for the definition of their health policies.

The new action plan includes specific actions to improve knowledge about the contribution of the environment to AMR, and to explore possibilities for taking appropriate measures. It includes in particular the development of 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 2017)[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 next step will be to further investigate the options, conducting a full impact assessment as appropriate. It has to be noted that the existing GMP[3] for active substances already 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. Although not specifically mentioned in those guidelines, manufacturing facilities have to comply with local regulations to minimise the risk of contaminating the environment. 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 new action plan also proposes a series of actions to better control and prevent AMR, and promotes the prudent use of antimicrobials in order to limit the emergence of AMR in human healthcare and in animal husbandry. In particular, the Commission adopted EU guidelines on the prudent use of antimicrobials in human health[4] in September 2017 and EU guidelines for

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/health/human-use/environment-medicines_en
to participate contact: ENV-PHARMA-CONSULTATION@ec.europa.eu
3 https://ec.europa.eu/health/documents/eudralex/vol-4_en
4 https://ec.europa.eu/health/amr/sites/amr/files/amr_guidelines_prudent_use_en.pdf

the prudent use of antimicrobials in veterinary medicine[1] were already adopted in September 2015. Moreover, in relation to animals, the Commission will work towards relevant EU acts under the forthcoming Regulations on veterinary medicinal products and on medicated feed (once adopted by the European Parliament and the Council) providing a set of new requirements aiming at responsible use, including restrictions on preventive use. The Commission will also assist Member States in the implementation of the EU guidelines for the prudent use of antimicrobials in veterinary medicine and will continue, through the relevant EU policies including Common Agricultural Policy, to promote animal husbandry and feeding regimes which support good animal health and welfare as they reduce the need for antimicrobials.

Concerning the development of new antimicrobials, the new action plan supports research in a vast number of areas including on measures on effective infection prevention and control, development of new antimicrobials, alternative treatments and vaccines both in human and animal sectors.

Conclusion

The Commission's awareness of environmental concerns regarding AMR has triggered several initiatives, such as a public consultation on pharmaceuticals in the environment (open until 21.02.2018) and a targeted stakeholder consultation (deadline 21.01.2018).

Furthermore, the petitioner is invited to consult the Commission's new European One Health Action Plan against AMR adopted in June 2017 whose aim is in particular to strengthen infection prevention and control measures against AMR, to promote the prudent use of antimicrobials in humans and animals and to boost research towards development of new antimicrobials and alternative treatments. The Commission will regularly monitor the progress and implementation of the new action plan.

1 https://ec.europa.eu/health//sites/health/files/antimicrobial_resistance/docs/2015_prudent_use_guidelines_en.pdf