2012/2041(INI) - 11/03/2015 - Follow-up document

This Commission staff working document concerns the progress made so far against the rising threats from Antimicrobial Resistance.

To recall, in 2011, the Commission launched a 5-year Action Plan against Antimicrobial Resistance. The progress made under the specific actions may be summarised as follows:

Action n° 1: Strengthen the promotion of the appropriate use of antimicrobials in all Member States: the European Parliament has allocated funds for a preparatory action to promote the appropriate use of antimicrobials in human medicine. The Antibiotic Resistance and Prescribing in European children (ARPEC) project funded under the Health Programme (2010-2013), aims at improving the quality of antibiotic prescribing for children in Europe and to reduce the prevalence of antimicrobial resistance in bacterial infections in children. The Commission services will publish later in 2015 data and information provided by the Member States in order to further strengthen the prudent use of antimicrobials in human medicines in the EU.

Action n° 2: Strengthen the regulatory framework on veterinary medicines and on medicated feed: the current veterinary medicines legislation does not provide sufficient tools to ensure that risks to human health arising from the use of antimicrobials in animals are adequately managed. In 2014, the Commission adopted proposals for <u>veterinary medicinal products</u> and <u>medicated feed</u>. They are currently undergoing the ordinary legislative procedure in the European Parliament and the Council.

Action n° 3: Introduce recommendations for prudent use in veterinary medicine, including follow-up reports: regardless of the efforts carried out to improve the prudent use of veterinary antimicrobials it is also necessary to update marketing authorisations to take into account of the latest scientific developments. The Commission services are finalising the drafting of Guidelines for prudent use of antimicrobials in veterinary medicine.

Action n° 4: Strengthen infection prevention and control in healthcare settings: the report showed that in the area of prevention and control of healthcare associated infections (HAI), 26 out of 28 responding countries implemented a combination of actions to prevent and control such infections. More efforts are needed to ensure adequate numbers of specialised infection control staff, receiving regular training, and with dedicated time for this task in hospitals and other healthcare settings. Tailored basic infection prevention and control structures and practices in nursing homes and other long term care facilities should be reinforced. Information on HAI to patients should be improved.

Action n° 5: Introduce of a legal tool to enhance prevention and control of infections in animals in the new Animal Health Law: the Commission proposal for a Regulation on animal health was adopted in May 2013. It is currently undergoing the ordinary legislative procedure in the European Parliament and in the Council. Its objective is to create an EU animal health legal framework for the control of major transmissible animal diseases.

Action n° 6: Promote, in a staged approach, unprecedented collaborative research and development efforts to bring new antimicrobials to patients: as rapid response, the New Drugs for Bad Bugs (ND4BB) programme was launched in May 2012. A new model for open innovation in the pharmaceutical research area has been created to spur the development of new antibiotics. This model means that research sectors and individual companies now provide unprecedented access to each others data and collaborate on solving problems of public health concern.

The Commission and the European Investment Bank are jointly developing a pilot financial facility which aims to target Infectious Diseases (ID). It is expected to be launched in 2015.

Action n° 7: Promote efforts to analyse the need for new antibiotics into veterinary medicine: the report acknowledged that there are certain gaps between the approved indications for veterinary antimicrobials and the needs of veterinarians. This area needs to be improved.

Action n° 8: Develop and/or strengthen multilateral and bilateral commitments for the prevention and control of AMR in all sectors: the Commission services are supporting and actively cooperating with the WHO in this field. Cooperation with China has started and possible cooperation with Russian is imminent. The Commission services are also contributing to the work against antimicrobial resistance in developing countries. They have also begun to develop a strategic approach to the pollution of water by pharmaceuticals. Proposals are awaited in 2017.

Action n° 9: Strengthen surveillance systems on AMR and antimicrobial consumption in human medicine: transfer of the European system for surveillance of antimicrobial consumption in human medicine to ECDC was completed in 2012. The system is now integrated as part of ECDC surveillance as the European Surveillance of Antimicrobial Consumption Network (ESAC-Net).

Action n° 10: Strengthen surveillance systems on AMR and antimicrobial consumption in animal medicine: the information collected by the three agencies: the European Food Safety Authority (EFSA), the European Medicines Agency (EMA) and the European Centre for Disease Prevention and Control (ECDC) on antimicrobial resistance and antimicrobial consumption needs to be combined and jointly analysed in order to assess the relationship between use of antimicrobials and antimicrobial resistance in animals and in humans at the European level.

Action n° 11: Reinforce and co-ordinate research efforts: after the launch of the Action Plan, research on AMR has been further supported by the Commission services with a total budget of approx. 130 million under the EUs Seventh Framework Programme for Research and Technological Development. The new EU framework programme Horizon 2020 continues to give research on infectious diseases including AMR a high priority. In 2014, the European Commission devoted 28 million to the development of new vaccines candidates against tuberculosis, and has earmarked 25 million for HIV vaccine research in 2015.

Action n° 12: Survey and comparative effectiveness research: each year, the European Antibiotic Awareness Day (EAAD) attracts strong media interest across Europe. In July 2013, ECDC provided training on the development, implementation and evaluation of prudent antibiotic use campaigns to 29 participants from 20 Member States and Norway.