

Dutch contribution to targeted consultation on pharmaceuticals in the environment

21 January 2018

We welcome the consultation and roadmap on pharmaceuticals in the environment by the European Commission. Our contribution mainly aims to emphasize the importance of robust collaboration and understanding between all actors, between the healthcare, environment, agriculture, and water sectors. In the work on this topic in the Netherlands, it became very clear that parties in the 'chain' only can contribute positively and effectively if they are involved at the stage of problem definition, which means early in the process. To achieve this, efforts should be made to establish a dialogue between these actors, both at national and local levels. It is therefore emphasized that this contribution presents the common view of the Dutch ministry of Health, ministry of Environment, and ministry of Agriculture.

For the Netherlands, one important condition when taking any measure, is the availability of medicines for patients. Currently, fewer new medicines reach the market, the development time and costs of medicines are high. However, still many diseases do not have a cure, there are still many unmet medical needs. Therefore, because of the importance of medicines for patients who need them, we cannot prohibit them. We also do not believe that 'green design' of pharmaceuticals will solve the problems. We prefer to take measures which are concrete and feasible. For example, we do support the green and responsible production of pharmaceuticals. Also, we are looking into reduction of the release contrast agents in the waste water.

Antibiotic resistance is another priority of the Dutch government. We therefore welcome that the consultation and roadmap also proposed measures in this area. In the Netherlands, we have started monitoring the presence of antibiotics and AMR in the environment. We also conduct research on the effects of the environment on human health. Because antibiotic resistance is a global threat, we encourage measures to combat AMR in all EU member states. For example, in the Netherlands, antibiotics are not sold over the counter in pharmacies and a doctor's prescription is needed. This contributes greatly to the low usage of antibiotics. To combat the rise of AMR worldwide, we believe that GMP measures are good instruments to prevent excess antibiotic levels in waste water from factories producing antibiotics.

Finally, please find below more detailed comments on several proposed measures in question 10.

Q3: Better degradable pharmaceuticals will also break down in the human and animal body and this is not desirable from a therapeutic point of view. Thus, this has a low priority. However, designing better delivery methods and personalized medication is supported.

Q5: Transparent publication of environment data is necessary. For VMPs the EMA already publishes the environmentally relevant thresholds in the EPARs.

Q6: For VMPs the risk should be considered that industries are not willing to invest in studies; this could jeopardize availability.

Q11: the release of antibiotics and residues from manufacturing sites into the environment, poses a great risk for public health and increased AMR levels. Even though most of these production sites are not located in the EU, GMP guidelines are an important step to counter these risks. Also in the public consultation on the AMR Action Plan by DG Sante, we recommended this action to counteract the rise of AMR because of residues in wastewater.

Q14: we consider this as an effective measure especially to reduce over-the-counter sales of antibiotics. In the Netherlands, a prescription is needed for all antibiotics. This contributes to less use of antibiotics and AMR. We strongly recommend similar measures in all EU member states.

Q16: A routine dialogue between health, veterinary and environmental competent authorities is essential. This is one of the key factors in our Dutch 'chain approach'. Only with all the different

parties involved there can be mutual understanding on the problem(s), possible measures and issues involved for those measures for the different parties.

Q17: We are aware that the term eco-pharmacovigilance has been introduced and used. However, it is not clear what is exactly meant by this, how it is defined, what the scope is and who is responsible for implementing eco-pharmacovigilance. Thus, we suggest to have a more thorough discussion about this topic, and work together with the regulatory agencies that are responsible for pharmacovigilance. For human pharmaceuticals, in practice legal pharmacovigilance only regards the side effects of a specific medicine on patients, although the Regulation (1235/2010) also stresses in a recital the need for environmental monitoring. In relation to the environment, we do support monitoring the occurrence of pharmaceuticals in certain 'hot spots'. We support the principle that when a risk to the environment is identified in the ERA, adequate monitoring should be put in place for these compounds. Sharing use data or sales data with the water sector in a transparent and systematic way is also supported, for the compounds with an identified risk as well as for antibiotics. In that case, when usage of certain antibiotics is increased in an area, the water management sector can take additional measures timely.

Q21 the background document is only focused on smaller packaging for HMP's. However, we believe that this option would be more effective in the veterinary sector, especially related to antibiotics. In the Netherlands we already aim to use smaller packaging for veterinary antibiotics. Currently, because of the large packaging volumes (even 5-10 kg), antibiotics which are not used and thus discarded and wasted, with the risk that they will end up in the environment.

Finally, we would like to point you to the English version of the Dutch chain approach (not yet public available), which we can send you separately as it is not possible to upload more than one attachments.