Science-Policy Event "Pharmaceuticals in the Environment: Current scientific developments and policy responses".
November 21, 2013 - 14:00 - 17:30, CDMA building, Brussels

Stakeholder position statements

Four event participants kindly accepted to present brief position statements on the topic of Pharmaceuticals in the Environment, in reaction to the project presentations at the Science-Policy Event. (Please refer to www.pharmas-eu.org for a list of the presentations and the powerpoint slides.)

These participants were (in order of statements):

1. Jason Snape – Principal Environmental Scientist, AstraZeneca UK.
2. Helen Clayton – Policy Officer, EU Commission, DG Environment, Unit ENV.C.1-Water.
3. Almut Bonhage – Executive Secretary, EUREAU (European Federation of National Associations of Water Services)
4. Susan Haffmans – Project Coordinator, PAN-Germany (Pesticide Action Network – Germany)

1. Jason Snape – AstraZeneca UK

To date AstraZeneca's experience with the 2006 EMA guidance for environmental risk assessment (ERA) has resulted in no Risk Quotient (RQ) values greater than 1. In many cases the RQ values were less than 0.001 and were based on worst case Predicted Environmental Concentration (PEC) assumptions. The challenge society faces going ahead is to identify the 1-2% of legacy drugs that do pose a risk to environmental health in an intelligent manner.

Recognising the community challenges raised over legacy data gaps and the need for greener drugs, industry has responded to the concerns through a joint public-private initiative with the European Commission, with an IMI project entitled EcoRiskPrediction. This is a ca. €7.9M project where ten European Pharmaceutical Industries will cofund a programme of work to develop tools to assess the environmental properties of drugs earlier within the drug discovery and development process.

Regarding transformation products (TPs), Jason Snape held that the total residue approach in the current ERA guidance is fit for purpose. Most RQ values are in the 0.01-0.0001 range for Active Pharmaceutical Ingredients (APIs), therefore if one assumes 100% molar conversion to a single TP it would have to be 100 - 10,000 times more toxic than the parent to pose a risk. Consequently, it is Mr Snape's opinion that there were higher priorities for environmental assessment and management than TPs. For TPs produced in drinking water treatment processes these assumptions may not hold true and further assessments might be needed.

Jason Snape also challenged the fact that the NoPills presentation concluded that the ecological value of Sewage Treatment Plants upgrades was vague and that more needed to be done to ensure that the costs and benefits were clearly defined so society could make informed choices. The AstraZeneca experiences with ecopharmacovigilance to date indicate that most risks (when MECs exceed PNECs) occur in only a few cases and these tend to be site specific. Therefore any upgrades might not need to be EU-wide but targeted to particular areas/sites of concern.

2. Helen Clayton – DG Environment, Unit ENV.C.1-Water.

The results of projects such as PHARMAS and the other projects described are important to the Commission in its development of policy, including in the review of the priority substances list under the Water Framework Directive and the planning of measures to protect the environment from emerging pollutants. The Commission is keen to ensure that databases of environmental monitoring data arising from such projects are maintained in an accessible form, and is establishing a new Information Platform for Chemical Monitoring (IPCheM) which will aim to host such databases or provide links to them, covering chemical substances in water and other environmental compartments, food and feed, products and indoor air, and biomonitoring. It would be helpful if relevant data from PHARMAS etc. could be incorporated. At least two new research projects on emerging pollutants, including pharmaceuticals, are beginning – SOLUTIONS under FP7, and at least one project under a Joint Programming Initiative call. These could usefully take into account the outputs from PHARMAS and its sister projects. The Commission is required to develop a strategic approach to pollution of water by pharmaceutical substances by 2015; DG ENV and DG SANCO will work closely together on this, taking account of all relevant available data.

3. Almut Bonhage – EUREAU

EUREAU welcomes the current research activities carried out by the PHARMAS project in the context of the EU's 7th Framework Programme for Research, and looks at its results with great interest.

EUREAU understands that is difficult for scientists to define what harm is done by the presence of pharmaceutical products in the environment. However, the lack of scientific evidence should not restrain policy makers from assessing the risks and taking political decisions now. Even partial or incomplete data show clear trends that can and should be taken into consideration in decision making.

EUREAU favours the combination of approaches at different levels as outlined in the presentation of the project noPills.

EUREAU is promoting a strategy that will limit the emissions, discharges and losses of pharmaceuticals to the aquatic environment with the different partners (pharmaceutical companies, doctors and patients associations, consumers associations, etc.). End-of-pipe-treatments do not constitute a sustainable solution since they are never complete, they entail additional use of chemicals, as well as additional energy consumption.

4. Susan Haffmans – PAN-Germany

Pharmaceuticals are increasingly found in the environment, including surface and groundwater, and many of them at ecological relevant concentrations. The status of environmental risks posed by pharmaceuticals looks worse than a decade ago. Low biodegradability of pharmaceuticals and their persistence in surface water, sediments and soils poses a threat to the environment. Standard long-term tests conducted with fish, daphnia, and algae as test organisms revealed effects at concentrations of less than 1 µg/l, some even at much lower concentrations. Mixture toxicity can be substantially higher than the sum of the toxicity of each individual substance. Aquatic organisms are threatened by the effects of multiple pharmaceutical pollutants. Soil organisms like bacteria and fungi and e.g. dung fauna, which play an important role in the ecosystem, are – in some cases heavily – affected by pharmaceuticals.

To improve the situation PAN Germany makes the following recommendations:

- To minimize pharmaceutical pollution of the environment integrated concepts are needed. This includes a high degree of coherence between various areas of legislation (legislation on human and veterinary pharmaceuticals, water, animal husbandry, etc.).
- To close the existing data gap a systematic environmental monitoring (occurrence and effects of pharmaceuticals) with transparent publishing of data has to be established.
- Special attention should be paid to substances which specifically effect the environment, e.g. PBT substances, and to substances which are released in large quantities.
- A feedback mechanism from monitoring data to authorisation and use of pharmaceuticals should be established. E.g. monitoring data should be taken into account in the pharmacovigilance system of veterinary pharmaceuticals.
- Regular environmental review programmes for authorised veterinary pharmaceuticals should be introduced. A start should be made with those veterinary medicinal products that have never been tested for their environmental impact.
- Threshold values for pharmaceutical residues in water bodies should be set.

Specific goals for reducing the amount of antibiotics used in livestock farming should be set and controlled.

But compiling better data and setting threshold values is not enough. Prevention has to come first. Healthy animals don't need pharmaceuticals. Therefore husbandry practices that foster animal health should be promoted and subsidies that hinder such efforts should be stopped.

For more Information:
http://www.pan-germany.org/gbr/project_work/veterinary_pharmaceuticals.html