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Pharmaceuticals in the Environment – Make ideas work

Key measures to reduce pharmaceuticals' emissions

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Introduction

Pharmaceutical substances are biologically highly active chemicals which can unintentionally but regularly be released into the environment. The global occurrence of pharmaceuticals was investigated in a research project funded by the German Environment Agency (UBA). Results show that more than 600 different pharmaceuticals can be found worldwide in soils, sediments, surface waters and some of them even in groundwater and – depending on treatment trains – also in drinking water[1]. At the same time detrimental effects of pharmaceutically active substances on non-target organisms - such as fish or amphibians - are reported to occur at the concentrations detected in the environment.

In order to reduce the emissions of pharmaceuticals and to protect the environment, UBA highly welcomes the development of a strategic approach to pollution of water by pharmaceutical substances by the European Commission, as laid down in the 2013 amendment (2013/39/EC) of the EU directive 2008/105/EC. According to Article 8c of directive 2013/39/EC, the European Commission is also obliged to propose measures to be taken at Union and/or Member States level to address the environmental impacts of pharmaceuticals, with a view to reduce discharges, emissions and losses into the aquatic environment. At the end of 2015, the Commission contracted a consultant to discuss and prioritise measures on the basis of the study on the risks posed by medicinal products in the environment (BIO IS, 2013)[2] and other relevant studies and reports. Results are expected by the end of 2016.

In the EU several stakeholders, such as national or federal ministries, authorities, water boards, pharmaceutical industry, scientists and interested groups already examined, defined and prioritised measures in the life-cycle of pharmaceuticals which would be helpful to reduce the pollution of water. However, a superordinate strategy on EU level is still lacking.
In view of the above and considering that the proposed measures should be taken at Union and/or Member States level UBA would like to invite the European Institutions to prioritize the following measures to reduce emissions and discharges of medicinal products in a holistic way, i.e. during their production, distribution, use and disposal.

1. Implementation of a harmonised substance based environmental risk assessment master file system (monograph system)

On one hand information on fate and effects in the environment is still missing for the majority of medicines on the market. On the other hand the current requirements for environmental risk assessments (ERAs) for pharmaceuticals submitted in the authorisation process for human and veterinary medicinal products lead to repetitive assessments. The environmental risk assessment of medicinal products should therefore be based on harmonised environmental information for each pharmaceutically active substance. This information could be compiled in ERA master files or so called monographs. Applicants could refer to this existing environmental information instead of generating data and information on their own.

With this approach, the environmental risk assessments for different products with the same active substances would be harmonised and harmonised risk mitigation measures could be achieved.

Other positive effects by sharing those information would be reducing animal testing, lowering costs for authorisation of medicinal products and reducing administrative burden. And finally, this approach would promote a fair level playing field for every applicant, either applying for a marketing authorisation for a new product or a generic one.

In this context, it is desirable to establish a joint process involving all marketing authorisation holders of a product that contains a specific substance in order to obtain information on its properties and environmental data. Therefore, a process for sharing of studies as already practiced in other European legislations, e.g. REACH should be implemented.

These measures were already part of the proposals by the BIO IS study (2013) commissioned by the European Commission:

- “Developing a monograph system based on experience from REACH, biocides and plant protection products legislation” (1.1)
- “Testing the framework on pilot substances” (1.2)
- “Establishing a catching-up procedure to assess active substances (which would be more feasible if the MA procedure becomes active substance

based): Prioritization of substances to assess; Results of assessment to feed the monograph system (e.g. short summaries of study reports and their assessments like for plant protection products)" (2.2)

2. Increase of data transparency

Discharge of pharmaceuticals into the environment makes risk management necessary, in particular for water. But risk management can be done with sufficient information only. Besides, also the public has a justified and increasing interest on such information. Therefore, a shared database on EU level would be useful if not indispensable. Such a database should contain valid data on the fate and effects of pharmaceutically active substances. This would facilitate access to the relevant environmental data for all those responsible, in particular water authorities and providers.

The BIO IS report (2013) recommends:

- "Requiring medicinal agencies to communicate ERA results and data to water authorities and other interested parties" (5.4)
- "Increasing availability of ERA data and results. Improving information provided in EPARs and national PARs [(European) Public Assessment Report]: Publication of ERA results and endpoints as a minimum standard;" (6.1)
- "Creating a dedicated centralized Internet database, which could stem from or constitute the monograph system" (6.2)
- "Improving the communication of information that could be relevant to environmental authorities, including granting access to confidential data gained during authorisation of substances, and providing summaries and key endpoints in open access" (23)

However, these recommendations are not addressed in the current legislation. This should be changed to allow relevant stakeholders and the interested public to access environmental data. In this way, the increased demand for exchange of environmental information between national competent authorities would be taken into account, especially within the sectorial framework directives such as the water and ground water directives. Furthermore, it would help to implement the public right of access to environmental information as laid down in the Aarhus convention.

3. Inclusion of environmental risks in the benefit-risk balance for human medicinal products

At present and in contrast to veterinary medicinal products the environmental risk assessment is not part of the benefit-risk balance for human medicinal products. In consequence, environmental risks are not crucial for the question whether human medicinal products will be authorised or not. However, with due regard to human health and a healthy environment it is indispensable to take environmental risks of human medicinal products into account.

In this sense also the BIO IS (2013) study suggesting:

- "ERA to be taken into account in risk/benefit analysis (thus in Marketing Authorisation MA) for human medicinal products" (5.1)
- "Ensuring that environmental issues are taken into account in the pharmacovigilance systems of medicinal products for veterinary and human uses by amending Directives 2001/82/EC and 2001/83/EC to include eco-pharmacovigilance" (7.4)

4. Improvement of communication and education of all stakeholders in the healthcare system

In order to raise awareness towards the environmental risks and hazards pharmaceuticals may pose, specific training programs should be offered to healthcare professionals such as medical practitioners and also chemists and pharmacists. Medicinal doctors should be encouraged to prescribe pharmaceuticals with less significant environmental impact when choosing between therapeutically equivalent substances.

The BIO IS study (2013) mentions:

- "Actively involving the public and professionals through information and education/ training, including better environmental information in packaging leaflets and integrating environmental considerations (e.g. regarding prescription practices, alternatives) into medical education and advanced training" (13, 15, 16, 17)

5. Implementation of direct references between EU legislation related to medicinal products and water (e.g. Water Framework Directive)

The Water Framework Directive (WFD) should be used as a tool to address the issue of pharmaceuticals in

the environment as it sets timescales for action and is binding for all Member States. The WFD contains the legal basis for setting environmental quality standards (EQS). However, at present the intention to add pharmaceuticals to the list of priority substances at EU level does not exist. Furthermore the establishment of EQS for pharmaceuticals is prevented because data from the environmental risk assessment are considered to be confidential and thus not sharable. Therefore, a respective requirement should be included into the pharmaceuticals legislation which would allow the use of these data for the establishment of EQS under the WFD for the list of priority substances or for national EQS. Furthermore, systematic post-marketing surveillance of pharmaceuticals should be implemented in order to verify the success of measures required during the authorisation process of a medicinal product.

Also the Bio IS study (2013) recommends:

- "Including a direct reference in Water Framework Directive Article 16(2)(a) to ERA carried out under the EU legislation on medicinal products (Directives 2001/82/EC and 2001/83/EC) to prompt consideration of ERA for authorised APIs in reviews of the Priority Substances list" (15.1)
- "Imposing checks on the implementation of Risk Mitigation Measures (RMM)" (7.2)
- "Data (particularly for water obtained pursuant to the Water Framework Directive (WFD) or from water authorities) is used for the evaluation of related products, and for post-market evaluation, possibly leading to non-authorisation, the revision of Risk Mitigation Measures (RMM), or MA withdrawal" (7.1; 18.1/18.3)
- "Systematically monitoring active pharmaceutical ingredients in compartments of concern, including in drinking water and sewage" (22; 16.2; 19.1; 19.2)

6. Improvement of sewage treatment systems where appropriate

Most pharmaceutical residues are removed only insufficiently in municipal sewage treatment plants using the current technologies. Numerous projects (e.g. COHIBA in the Baltic Sea region or MICROPOLL in Switzerland) clearly show that the installation of advanced treatment technologies according the best available technologies is an indispensable cost effective measure of any strategy to reduce the input of pharmaceuticals and other micro pollutants into surface waters. There are already proven technologies available which could be introduced by a stepwise approach starting with large waste water treatment plants to cost efficiently reduce the input of these substances. Therefore, the improvement of the wastewater removal technologies should be promoted in order to develop cost-efficient and sustainable methods for the removal of pollutants. Considerable research and practical implementation in this respect are undertaken by the national sewage water utilities.

Additionally, Member States should locally evaluate the amount of substances stemming from hot spots (hospitals and other healthcare institutions) in smaller agglomerations in order to assess whether it is more cost efficient to impose measures (such as improved waste water treatment) at this source or to remove these substances in a municipal sewage treatment plant.

The BIO IS study (2013) suggests:

- "Ensuring appropriate maintenance and design of sewage networks and wastewater treatment plants" (10)
- "Providing guidelines on wastewater treatment methodologies to assist wastewater treatment authorities/companies" (14.4)
- "Imposing more stringent requirements for waste water treatment at "hot spots", such as hospitals, at least for specific molecules that have a particular impact on the environment" (14.2)

Summary

One of the major goals of the EU Commission is the protection of human health and the environment. If this is taken seriously, one have to acknowledge that it is urgent to implement strong and effective measures to reduce emissions of pharmaceuticals. Respective measures have already been defined by various stakeholders, such as national and federal ministries, authorities, water boards, pharmaceutical industry, scientists and others. These measures should be merged now in order to work out an EU strategy for the reduction of the environmental impact posed by pharmaceuticals.

UBA proposes six key measures which should be taken into account in the review of legislation concerned to promote the best protection of our water from

pollution of pharmaceuticals.

1. Implementation of a harmonised substance based environmental risk assessment master file system (monograph system)
2. Increased data transparency
3. Inclusion of environmental risk in the benefit-risk balance for human medicinal products
4. Improvement of communication and education of all stakeholder in the health system
5. Implementation of direct references between EU legislation on medicinal products and water (e.g. Water Framework Directive)
6. Improvement of sewage treatment systems where appropriate

Emissions of pharmaceutical into the environment should be reduced as far as possible. Let's take action now in order to achieve and to guarantee a safer environment for us and the next generations.

Literature

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