Joint AESGP – EFPIA – EGA Position Paper

on Pharmaceuticals in the Environment (PIE)

The European pharmaceutical industry, represented by the Association of the European Self-Medication Industry (AESGP), the European Federation of Pharmaceutical Industries (EFPIA), and the European Generic and Biosimilar Medicines Association (EGA), recognizes and understands the concerns raised by stakeholders as regards the presence of pharmaceuticals in the environment (PiE). For this reason, we have come together to develop the **Eco-Pharmaco-Stewardship (EPS)** concept, a proposal that strives to protect patients' access to medicines while appropriately considering environmental aspects.

Environmental concerns should not overshadow public health benefits

Medicines play a critical role in ensuring a high level of public health, and we believe that political debates on PiE should not overlook the value that medicines bring to European citizens. As pharmaceuticals can enter the environment at all stages of the product's life cycle, reducing pharmaceuticals in the environment will be the result of cooperation between the public and private sector and the consumers they serve. Therefore, all actions should strike the optimal balance between economic costs and the benefit of medicines to public health. This principle is very much part of the EPS.

How do pharmaceuticals enter the environment?

Active pharmaceutical ingredients (APIs) inadvertently enter the environment throughout the lifecycle of a medicinal product, whether via the natural excretion of medicines, improper disposal of medicines (5 to 10% of pharmaceutical substances found in the environment), and via effluents from manufacturing facilities. Whilst the impact of these effluents only accounts for 2% of pharmaceuticals found in the environment in Europe[1], many companies have already proactively improved their manufacturing processes around the world and set up on-site wastewater treatment technologies to minimize discharges of pharmaceutical substances in the environment.

EU legislation addressing potential risks of pharmaceuticals in the environment

Recognising the potential risks of pharmaceuticals in the environment, the EU has already put in place a legislative framework to address these issues. Since 2006, Marketing Authorization applications include an Environmental Risk Assessment (ERA), which examines potential risks of a medicinal substance for the environment and ensures that adequate precautions are in place where specific risks are identified. Furthermore, the Water Framework Directive (WFD) establishes a 'list of priority substances' that have proven to be harmful to the aquatic environment, as well as a new 'watch list' requiring Member States to monitor substances of potential concern. Finally, pharmaceutical manufacturing sites in the EU follow

[1] BIO Intelligence Service, Study on the environmental risks of medicinal products, 2013

strict regulatory requirements that aim to reduce emissions from industrial sites and limit potential impact on both the population and ecosystem around the sites.

The pharmaceutical industry proposes actions in areas where it has leverage

The pharmaceutical industry believes that environmental protection contributes to ensuring the health and safety of future generations. To further mitigate the risk of pharmaceuticals entering the environment, the pharmaceutical industry has proactively developed the **Eco-Pharmaco-Stewardship (EPS)** concept, a proposal that strives to protect patients' access to medicines while appropriately considering environmental aspects. Most aspects of EPS are readily implementable under current pharmaceutical legislation, thus avoiding the need for additional regulation. The proposal looks at three areas where the industry can most effectively reduce the potential environmental risks that might result from its activities and throughout the medicinal products life cycle:

- ***Pillar 1- Encouraging further research to assess the impact of PiE:*** The pharmaceutical industry is actively engaged in scientific research projects (independently and in partnership) aimed at filling the priority knowledge gaps for "legacy" APIs, medicinal products approved before 2006, in order to support informed science-based policy-making on PiE. The industry has initiated the **iPiE** project (Intelligence-led Assessment of Pharmaceuticals in the Environment) in a public-private partnership with the European Commission under the umbrella of the Innovative Medicines Initiative (IMI). This multi-stakeholder project aims at developing models for prioritising legacy products for more in-depth environmental assessment. In addition to prioritising legacy APIs, the models may also be applicable to new molecules in the early R&D stages. iPIE is expected to be completed by end of 2018.
- ***Pillar 2- Manage pharmaceutical sites' effluents effectively:*** Whilst the overall contribution of pharmaceutical manufacturing to PiE is relatively low compared with that from other sources, the pharmaceutical industry has developed and is continuously implementing initiatives which minimise API discharges from manufacturing operations through the exchange of good practices. Coupled with this, industry is proposing a 'maturity ladder' aimed at helping companies to gauge their performance and take improvement measures where needed on a risk-based approach.
- ***Pillar 3- Monitor environmental impact through extended Environmental Risk Assessment (eERA):*** In the context of EPS, the pharmaceutical industry believes that the ERA should be reviewed and, if necessary, adapted throughout the product's life cycle, for example to refine usage figures and investigate effect concerns identified post-approval. Should the ERA outcome change, environmental risk management measures could be put in place or adjusted.

In addition to these specific areas for action, the pharmaceutical industry stands ready to support European and Member States' communication activities, as well as awareness raising campaigns towards patients on the appropriate use, storage and disposal of medicines. In particular, healthcare stakeholders **jointly developed medsdisposal.eu, an online (social media) communication campaign aimed at raising public awareness on the existing collection and disposal schemes** already in place in Member States, emphasizing the fact that it is everyone's responsibility and it is easier than one may think.