

Policy Statement on Manufacturing Effluent Management

The pharmaceutical industry recognizes and understands concerns raised by stakeholders regarding the presence of pharmaceuticals in the environment (PiE). The industry is committed to playing a leading role in addressing PiE concerns and is actively engaged in managing and controlling the impact of pharmaceuticals on the environment. To this end, the Eco-Pharmaco-Stewardship framework that applies the widely accepted principles of product stewardship has been developed and is being implemented in a number of pharmaceutical companies.

While the overall contribution of pharmaceutical manufacturing to PiE is minor and less significant compared to patient use and inappropriate disposal, potential impacts may occur on a local scale when manufacturing emissions are inadequately managed. Reports of active pharmaceutical ingredients (APIs) in wastewater from pharmaceutical manufacturing indicate that concentrations can reach potentially harmful levels when wastewater discharges are not sufficiently controlled. This highlights the need for effective control of API emissions from manufacturing facilities.

The member companies of AESGP, EFPIA and Medicines for Europe agree that API emissions must be effectively controlled during both manufacturing of API and during formulation into drug products for patient use. Ensuring the use of appropriate environmental risk management measures to adequately control manufacturing effluent emissions is an important area of focus for the pharmaceutical industry and is an approach already in place in a number of companies as described by Caldwell *et al.* (2016).

The pharmaceutical industry demonstrates its engagement for sound manufacturing effluent management by developing and implementing initiatives, which address the potential risks of discharges of APIs from manufacturing operations. Antimicrobial Resistance (AMR) Alliance's work on its commitment to effectively control antibiotic releases from their operations and supply chain networks is a good example of the pharmaceutical industry engagement.

Manufacturing of bulk APIs and finished drug products requires a global supply chain and extends beyond companies' own manufacturing sites. Potential environmental risks are site-specific, and therefore, a local risk-based approach must be applied. Compliance with local laws, regulations and environmental permits is a prerequisite for all API and drug product manufacturing operations.

Additionally, the member companies of AESGP, EFPIA and Medicines for Europe – as part of the PiE inter association taskforce - have developed a set of principles for responsible effluent management for their own, and supplier, manufacturing sites which focus on the following areas:

- Compliance with applicable company standards
- Implementation of defined wastewater management programs that are based on risk management and good engineering principles
- Definition of site and API specific discharge targets based on safe concentrations in the receiving surface waters
- Discharge of manufacturing wastewater containing API must have an environmental risk assessment