PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Building responsible supply chains

Position statement on PiE and AMR

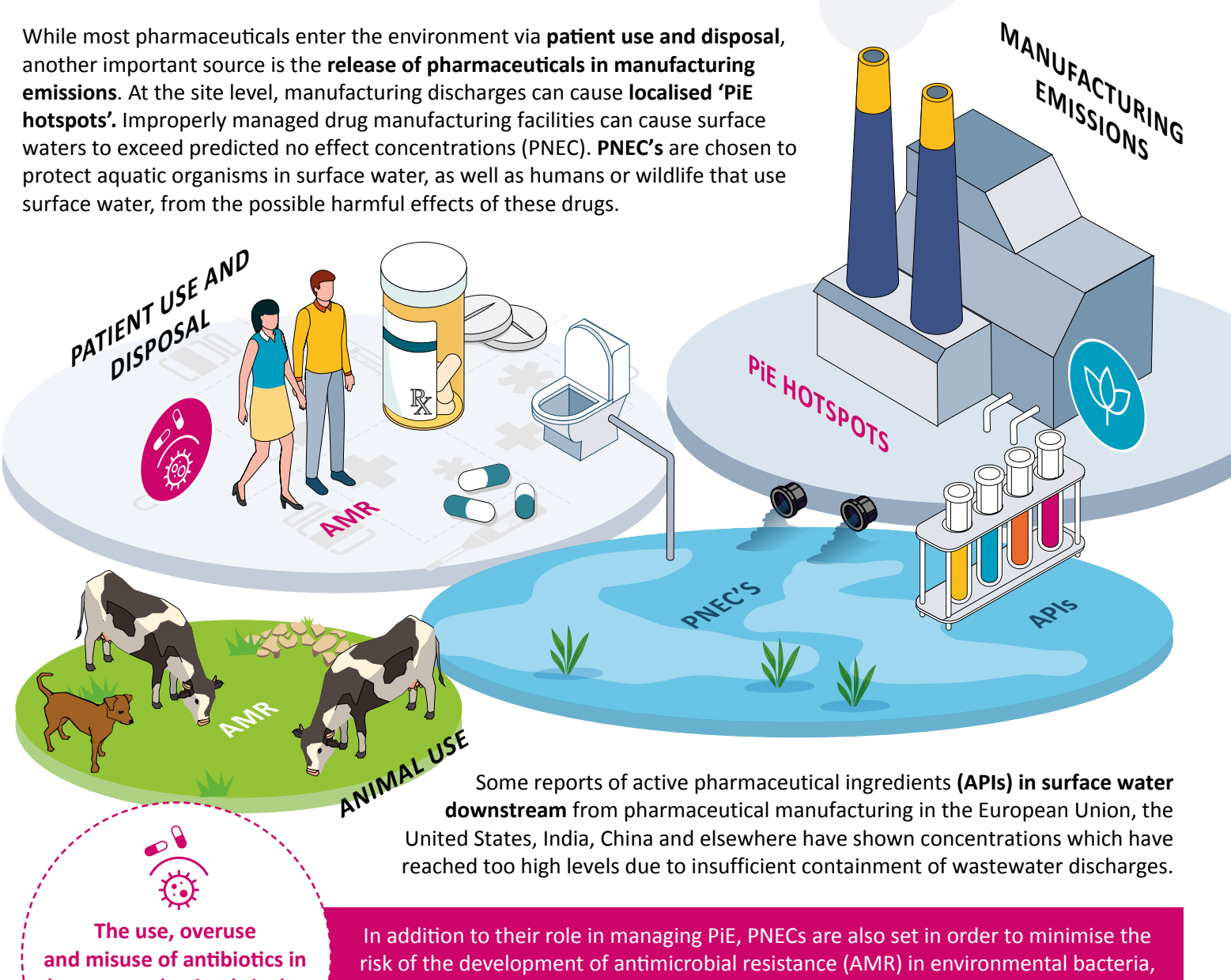
Stepping up efforts to combat two major global threats

In recent years, private sector organizations have been stepping up their efforts to address and combat two major challenges such as pharmaceuticals in the environment (PiE) and antimicrobial resistance (AMR). Pharma and biotech companies are acknowledging the essential role they play in making progress against these threats by, among other things, making public commitments, adhering to global standards, participating in cross-sector working groups, and calling for greater accountability and enforcement actions by governments.

Most importantly, companies are working through organizations like PSCI to substantially minimize the impact of drug manufacturing on the growth and spread of both PiE and AMR.

Understanding the challenges posed by PiE and AMR

While most pharmaceuticals enter the environment via **patient use and disposal**, another important source is the **release of pharmaceuticals in manufacturing emissions**. At the site level, manufacturing discharges can cause **localised 'PiE hotspots'.** Improperly managed drug manufacturing facilities can cause surface waters to exceed predicted no effect concentrations (PNEC). **PNEC's** are chosen to protect aquatic organisms in surface water, as well as humans or wildlife that use surface water, from the possible harmful effects of these drugs.



Some reports of active pharmaceutical ingredients **(APIs) in surface water downstream** from pharmaceutical manufacturing in the European Union, the United States, India, China and elsewhere have shown concentrations which have reached too high levels due to insufficient containment of wastewater discharges.

The use, overuse and misuse of antibiotics in humans and animals is the largest contributing factor to the development of AMR.

In addition to their role in managing PiE, PNECs are also set in order to minimise the risk of the development of antimicrobial resistance (AMR) in environmental bacteria, driven by the presence of antibiotics in surface water.

Elevated concentrations of antibiotics downstream from some manufacturing facilities, can create a selection pressure to favour the development of antimicrobial resistance.

The need for partnership

While many suppliers have recognized and acknowledge their responsibility for leading on these issues, there remain significant differences in the levels of in-house expertise and resources available to each organization.

Our role is to help close these gaps and work with suppliers at all stages of the process to improve and enhance their efforts.

The core principles guiding our approach

The Pharmaceutical Supply Chain Initiative (PSCI) is committed to facilitating greater collaboration within the pharmaceutical sector, elevating global standards for suppliers and manufacturers and supporting the implementation of crucial multisectoral PiE/AMR management initiatives. This work is guided by a set of principles developed by PSCI with the aim to establish and promote responsible practices to continuously improve social, health, safety, and environmentally sustainable outcomes within our supply chains.

The Principles ask suppliers to have systems in place to ensure the safe management of waste, air emissions and wastewater discharges, in particular concerning any waste, wastewater or emissions with the potential to adversely impact human or environmental health.

The PSCI playbook for improving supplier capabilities

To help ensure every supplier has access to the tools they need to implement successful PiE/AMR programs, the PSCI operates a standalone sub-team that provides members and suppliers with materials and training needed to help improve their capabilities for managing environmental emissions during manufacturing operations, with a particular focus on wastewater effluent.

Since its founding in 2017, the PiE topic team has helped members improve their knowledge of how to minimize drug releases into the environment and prevent the emergence of localized PiE/AMR hotspots around manufacturing sites. The team also helps suppliers access PiE assessment and audit tools, build greater capacity for management of emissions and utilize best practices shared from others in the industry.

Working hand in hand with representatives from supplier organizations, PSCI has made significant strides in helping reduce and mitigate the presence of pharmaceuticals in the environment, while also increasing supply chain and manufacturing efficiency.

In addition to these member services, PSCI helps promote awareness of AMR amongst suppliers, collaborates with other organizations engaging in combating PiE and functions as a hub for industry news and thought leadership.

Assessment & auditing

Our member companies visit or audit hundreds of suppliers every year. The goal of these audits is to help eliminate deficiencies and identify opportunities for improvement within the supply chain. PSCI also promotes and supports a common framework for tackling anti-microbial resistance and managing antibiotic waste which is available from the AMR Industry Alliance along with a list of PNEC values for a wide range of antibiotics.

PSCI has a range of resources, publicly available on the website to drive good practices in the management of APIs at manufacturing sites to minimise the impact of PiE and AMR. Our online portal, 'the Link', helps connect suppliers with the information they need to improve their operations.

Capability building

Our capability building program helps suppliers meet their desired standards. The aim of our capability building program is to build supplier knowledge and expertise, to help them identify and solve safety, social, environmental and ethical issues for themselves.

KEY ACTIVITIES INCLUDE:

PiE webinar
A 4-part series designed to spread awareness on PiE and communicate best practices.

AMR webinar
A training guide on AMR, covering the issues associated with antimicrobial drugs in wastewater, targets for environmental risk assessment of antimicrobial drugs, and how to assess the risk of antimicrobial drugs in wastewater. as well, as demonstrating PSCI's PEC:PNEC calculator tool applied to antibiotic APIs.

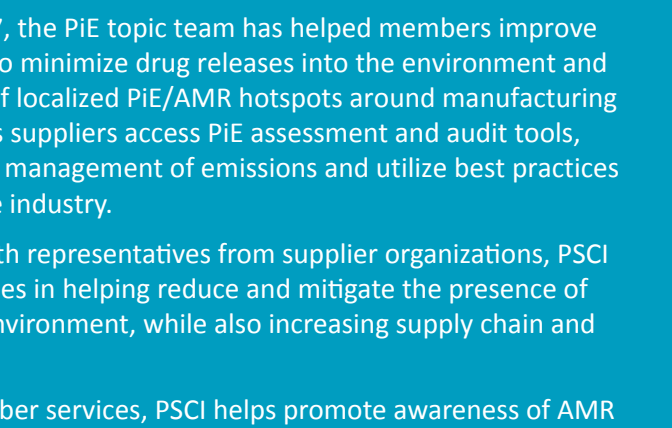
A technical seminar exploring and providing training on how sites can manage the release of APIs into the environment.

PNEC calculator tool
(Total Discharge) to enable manufacturing facilities to calculate their wastewater effluent discharges based on site-specific parameters and compare estimated surface water concentrations (PECs) to the PNEC discharge targets for their APIs.*

*Made available freely to all, and has already been downloaded over 500 times" – 2019 Annual Report, 18

Best practice development

Specialists drawn from member companies contribute their knowledge and insights to the PiE topic team, enabling the group to effectively draw on the best practices and technical expertise from across the industry and a wide portfolio of pharmaceutical products.
The group then applies these best practices to the work we do with suppliers.



Advocacy and stakeholder engagement

PSCI works closely with global stakeholders on PiE and AMR to incorporate the latest science into engagements. Whilst PSCI does not define standards or discharge targets, the members of the Sub-Team do work closely with organisations that carry out such activities – including the AMR Industry Alliance Manufacturing Group, the European Federation of Pharmaceutical Industries and Associations (EFPIA), Medicines for Europe, Association of the European Self-Care Industry (AESGP) and the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) – to help promote best practice into the supply chain.

The benefits of working with PSCI

While many suppliers have some resources to help address PiE and AMR risks, they are incentivized to partner with the PSCI for several reasons

COMPLIANCE EFFICIENCIES
Working with PSCI lowers the overall costs associated with regulatory compliance.

CONTINUOUS IMPROVEMENT
Collaborating with PSCI can help free up suppliers' time, allowing them to implement cost-saving continuous improvement initiatives.

LOWER OPERATING COSTS

AUDITING
After supplier approval, audits conducted by companies can be shared with other organizations on our platform, reducing costs for both suppliers and members.

PROCESS OPTIMIZATION
Information from the PSCI resource library can also help suppliers optimize their existing processes and reduce engineering control costs.

NEW BUSINESS OPPORTUNITIES
By working with PSCI, suppliers can demonstrate their commitment to reducing the amount of antimicrobials in the environment to future or prospective buyers, many of whom are part of the PSCI organization.

REPUTATIONAL ENHANCEMENT
Working with PSCI can help suppliers enhance their reputation, differentiate from competitors and enhance their overall standing in the eyes of a wide range of stakeholder groups.