



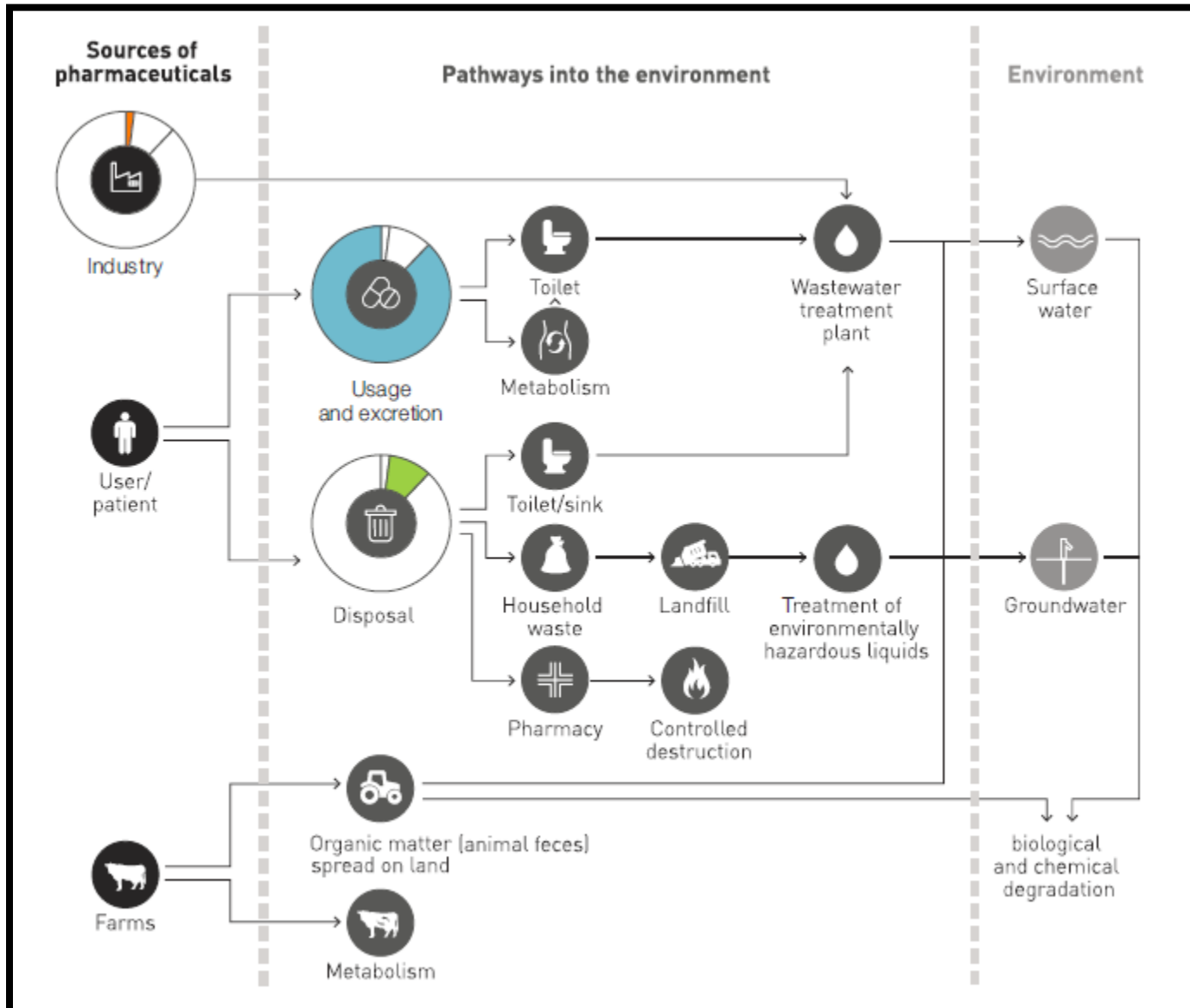
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# Industry Comments to EU COM PIE Strategy Consultation

&

# Industry Initiative EPS (ECO-PHARMACO- STEWARDSHIP)

# How do pharmaceuticals enter the environment?



# History of Policy Topic Development on PIE (Pharmaceuticals in the Environment)

- **2013** – Water Framework Directive requires the EU COM to develop a “strategic approach to Pharmaceuticals in the Environment (PiE)
- **2014** – Commission publishes report on 80 legislative and non-legislative options for a strategy and holds a workshop with stakeholders with the aim of prioritize between the options
- **Nov 2017:** EU COM publishes public consultation for citizens (DL 21 Feb 2018) and targeted consultation for experts (DL 21 Jan 2018) to comment the 30 strategy options
- **Jan and Feb 2018** Industry through AESGP-EFPIA-MfE submits responses
- **Jun 2018** COM is expected to publish the strategic approach to enable it to go in a working plan of current COM.

# EU COM PIE Strategy – Industry Comments

- Industry supports the development of a PIE Strategy, aiming to identify and fill knowledge gaps and exploring how to protect the environment, while safeguarding access to effective pharmaceutical treatments.
- We support several policy options addressed in the EU COM PIE Strategy Consultation, many of them in alignment with our EPS initiative.
- Our Eco-Pharmaco-Stewardship (EPS) lifecycle approach presents:
  - Extended Environmental Risk Assessment scheme (eERA)
  - Ways for introducing improved data transparency and access
  - Enhanced implementation of medicines waste collection
  - Promoting research areas which we would support in the existing programmes (IMI project iPiE) and in possible new research projects.

# Why is it important to engage? *Securing that measures undertaken are relevant, appropriate and do not jeopardize access to medicines*

Cost and burden might be unproportional to the benefit and may jeopardise patient access to medicines.

PIE is a highly political, value-based topic, while the scientific evidence should be the basis for decisions.

Policy options Industry does not support include:

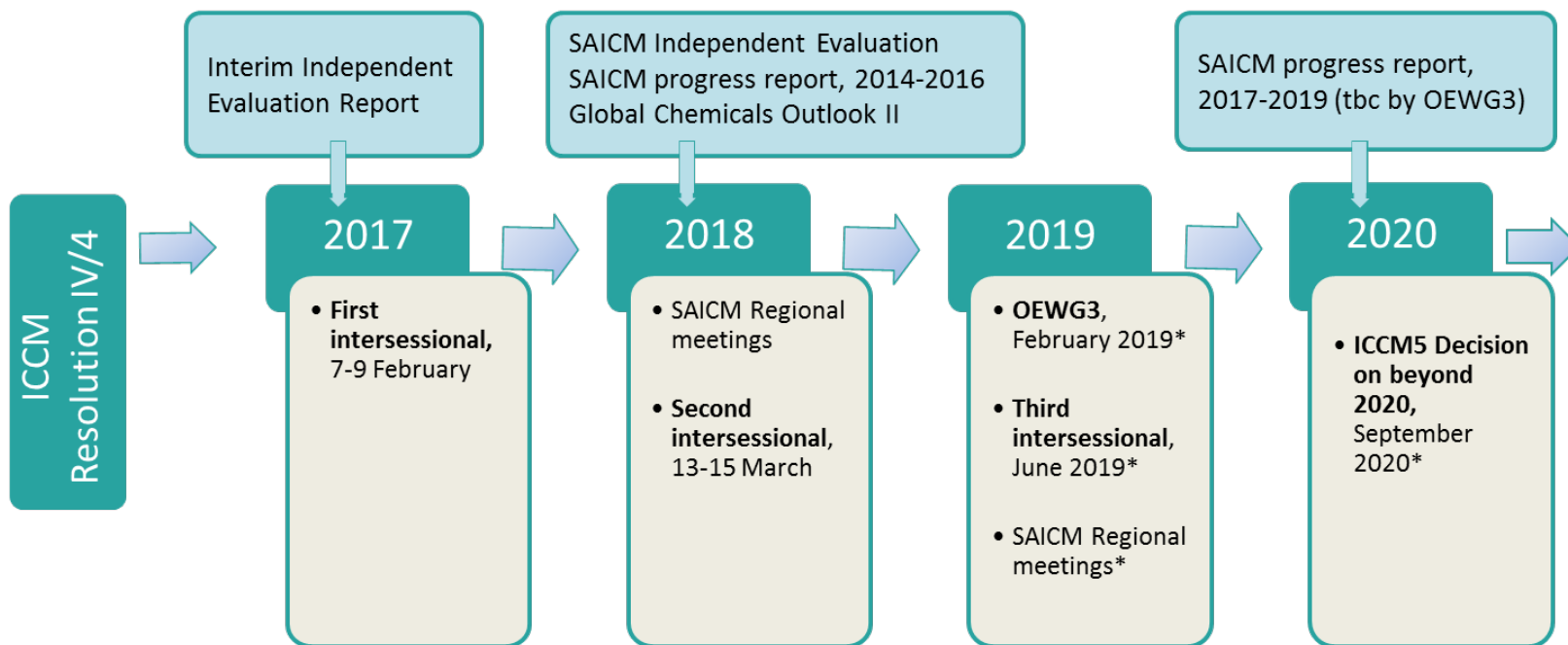
- Adding environmental aspects as part of Good Manufacturing Practice (GMP)
- Including Environmental Risk Assessment (ERA) as part of medicinal products' Benefit/Risk assessment
- Adding environmental aspects to the pharmacovigilance regulation
- Developing a monograph type of repository for environmental data on all substances
- OTC to prescription switch as part of (environmental) risk minimisation measures

# Why it is important to engage? *Likelihood for EU COM PIE Strategy to Influence SAICM (UN Strategic Approach to International Chemical Management), i.e. "EU PIE Policy goes global"*

## SAICM Progress, to-date

### Timetable for the Intersessional Process

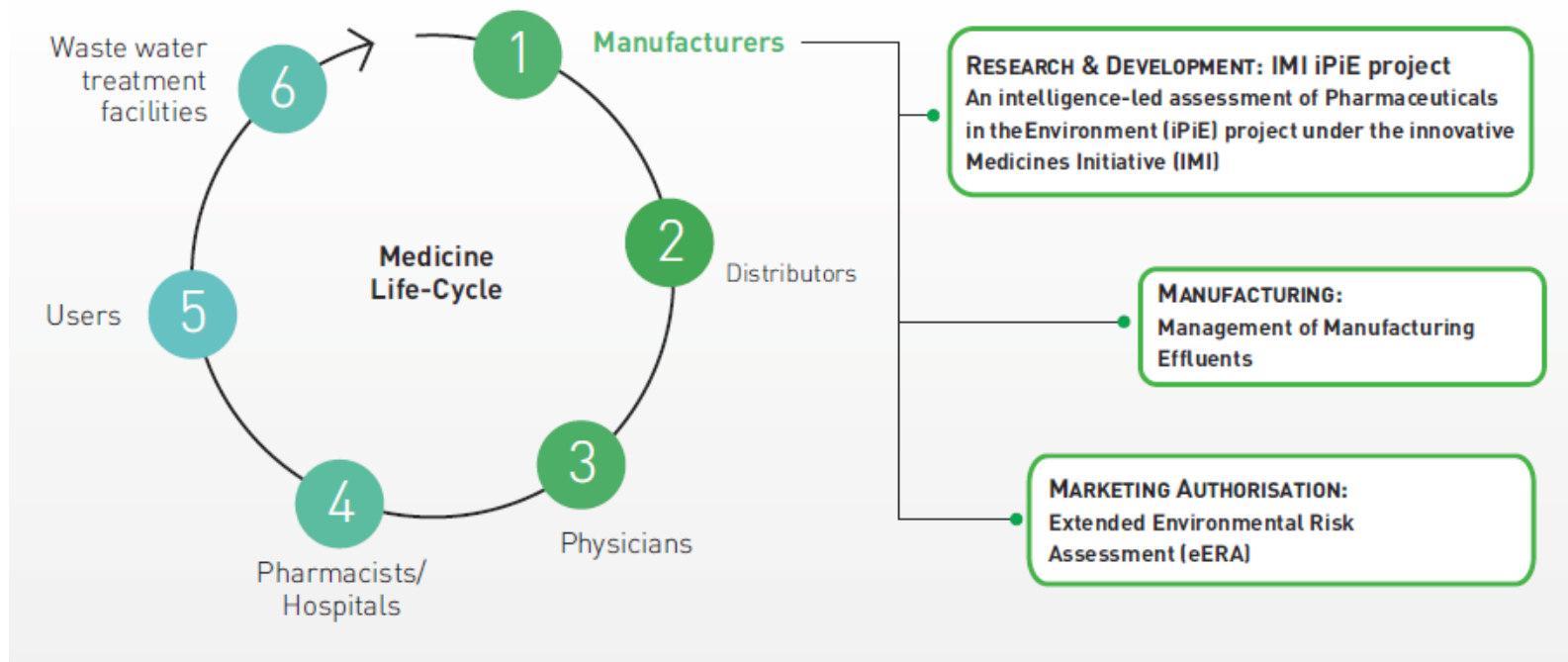
#### SAICM and the sound management of chemicals and waste beyond 2020



\* Dates to be confirmed

# Eco-Pharmaco-Stewardship (EPS): A life-cycle approach

Objective: Providing knowledge and data enabling assessments of sustainability of pharmaceuticals



Pharmaceuticals can enter the environment at all stages of the product's life-cycle. Therefore, we believe that only a collaborative approach will allow us to meaningfully increase our mutual knowledge and understanding on how to minimise any potential impact, issue or concern that pharmaceuticals in the environment might pose.

# Eco-Pharmaco-Stewardship (EPS): A life-cycle approach



## PILLAR 1

### ENCOURAGING FURTHER RESEARCH TO ASSESS THE IMPACT OF PIE

#### Intelligence-led Assessment of Pharmaceuticals in the Environment

- Public-private partnership with the European Commission under the umbrella of the Innovative Medicines Initiative (IMI).
- The project is being run from 2015-2018 and aims to develop a framework in which tools, assays and models could enable industry, regulators and interested academic researchers to **identify and prioritise medicines that are most likely to present a risk for the environment**.
- This multi-stakeholder project has created a database on environmental information including more than 2000 studies for hundreds of existing active pharmaceutical ingredients.
- You can find all details and the progress report on the project website: [www.i-pie.org](http://www.i-pie.org)



# Eco-Pharmaco-Stewardship (EPS): A life-cycle approach



## PILLAR 2

### MANAGING EFFLUENTS FROM PHARMACEUTICAL SITES EFFECTIVELY

- We are continuously implementing initiatives which further reduce discharges from manufacturing plants through **the exchange of good practices**. We identify improvement needs by a risk-based approach and take measures where needed.
- Coupled with this, we have developed a ‘**maturity ladder**’ aimed at **helping companies and their suppliers to gauge their performance and continuously improve**.
- Additionally, many of our members are actively involved in the **Pharmaceutical Supply Chain Initiative (PSCI)** ([www.pscinitiative.org](http://www.pscinitiative.org)), a group of pharmaceutical and healthcare companies who have joined forces to promote responsible supply chain management and better business conditions across the industry.
- Furthermore, we continue to monitor the issue of environmental impacts **from the production of antibiotics**. We have initiated several health-based commitments and are working, directly or via our member companies, through the **AMR Industry Alliance** to manage potential risks.

# Eco-Pharmaco-Stewardship (EPS): A life-cycle approach



## PILLAR 3

### LIFE-CYCLE ASSESSMENT OF THE ENVIRONMENTAL RISK

#### Extended Environmental Risk Assessment (eERA)

- The current legislation requires that a pharmaceutical company assess the environmental risk only theoretically and only once, before the drugs are approved and launched, or when they are going to be used in new indications or combinations. We want to extend this framework.
- We believe that the ERA should be reviewed and, if necessary, updated **throughout the product's life-cycle** to reflect the latest information on the product's potential impact on the environment.
- However, we believe the focus should be on the level of the substance entering the environment (not the product, as it is now) and that resources should be **prioritised only on those substances that actually pose a potential risk to the environment.**

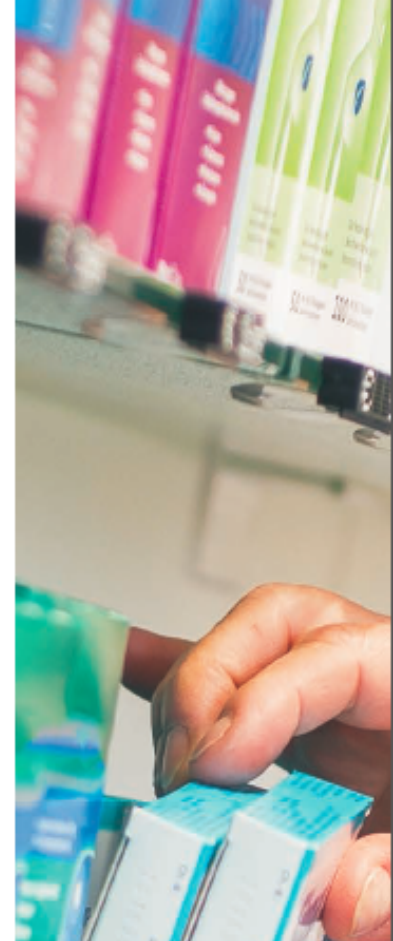


**#medsdisposal** is a campaign to raise awareness on how to appropriately dispose of unused or expired medicines in Europe. A dedicated website and other virtual media material have been developed, providing information on current disposal schemes in European countries in a 'one-stop shop'.



This is a joint initiative between several European healthcare, industry and student organisations.

Most European countries have special medication disposal schemes in place in order to prevent pharmaceuticals from ending up in the environment. By using the interactive map on the webpage [www.medsdisposal.eu](http://www.medsdisposal.eu) you can easily find information for your country.



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# Summary

- **Eco-Pharmaco-Stewardship (EPS)** is the industry-proposed approach to provide a framework of environmental stewardship for pharmaceuticals covering the life-span of a pharmaceutical product
- **EPS** effectively responds to environmental concerns around PIE, e.g. as expressed in the consultation of the EU COM PIE Strategy, **without hindering access to medicines for patients.**