Environmental Criteria in Public Procurement of Pharmaceuticals

- LMI and Sykehusinnkjöp, Oslo May 9, 2018 -

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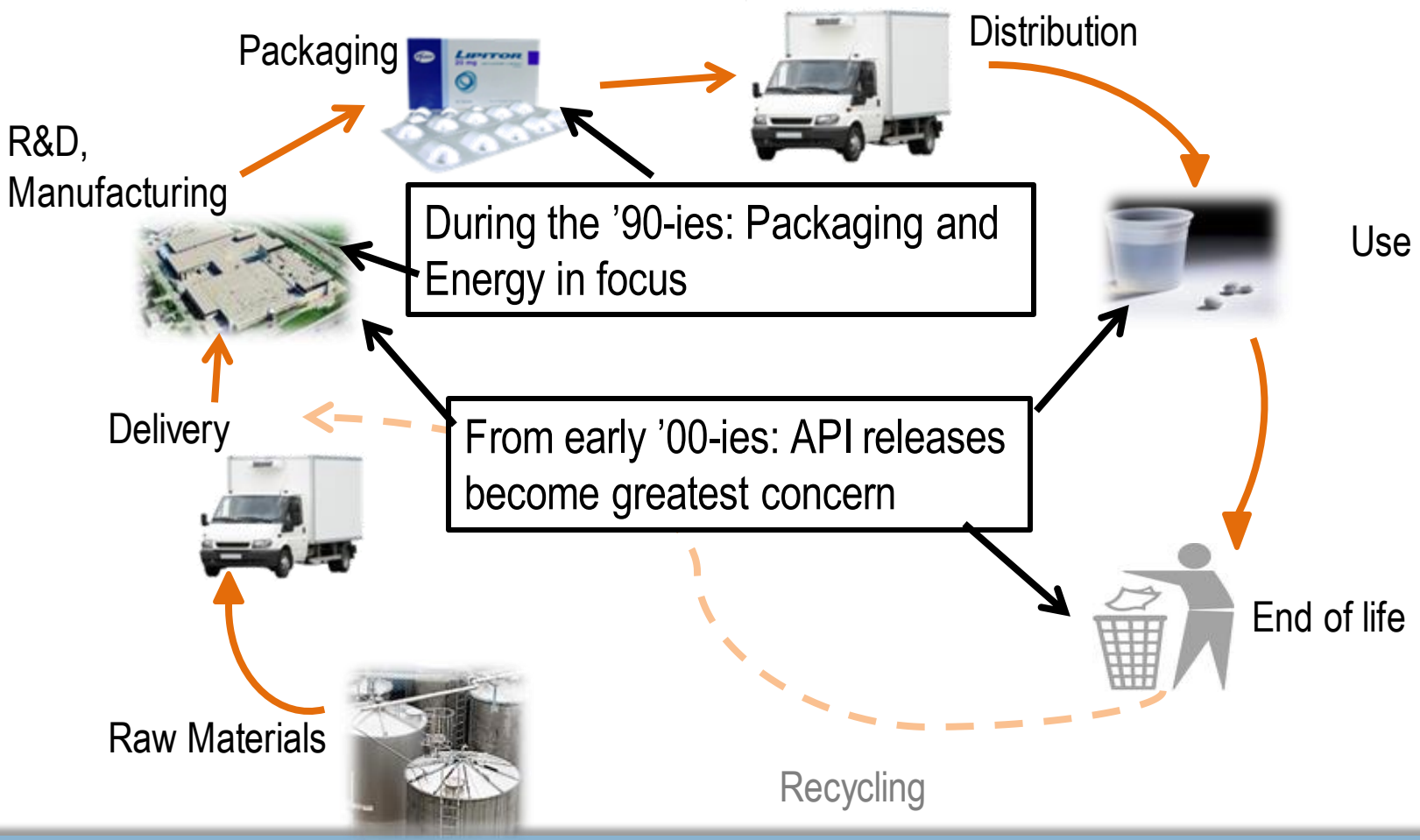
LIF

Environmental Aspects from Pharmaceuticals

- R&D, manufacturing, distribution, marketing & sales, use, disposal -



Moving forward: Both API-emissions and Resource Efficiency/Carbon Footprint will be important

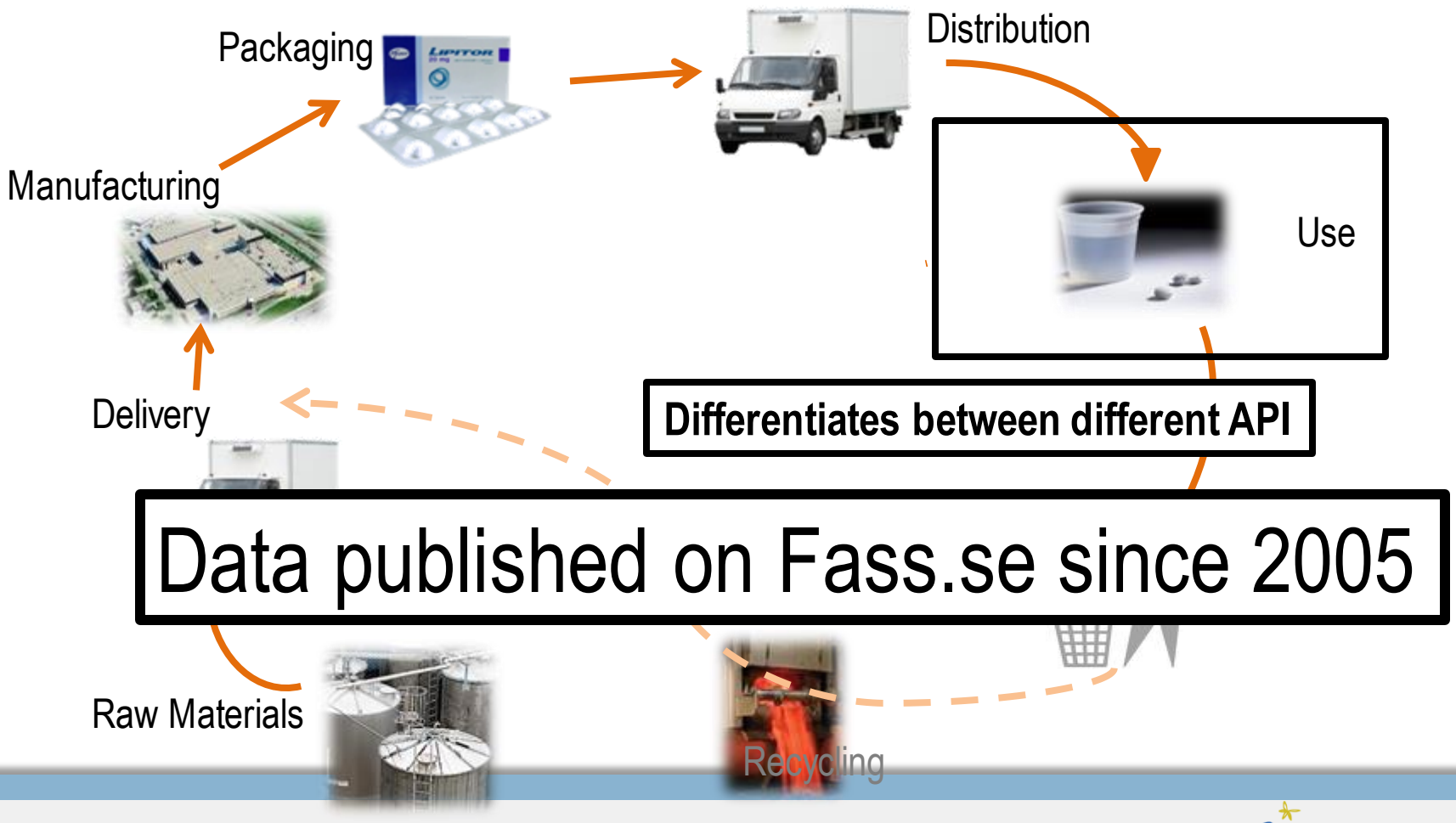
LIF welcomes sustainability criteria in public procurement – *The Swedish Example*

- Environmental risk of the API (activ… …cal ingredient)
  - Environmental data publ… …ss.se
- Environmental op… …ures in place to control relea… …om manufacturing facilities
- Proc… …to secure social responsibility t… …supply chain

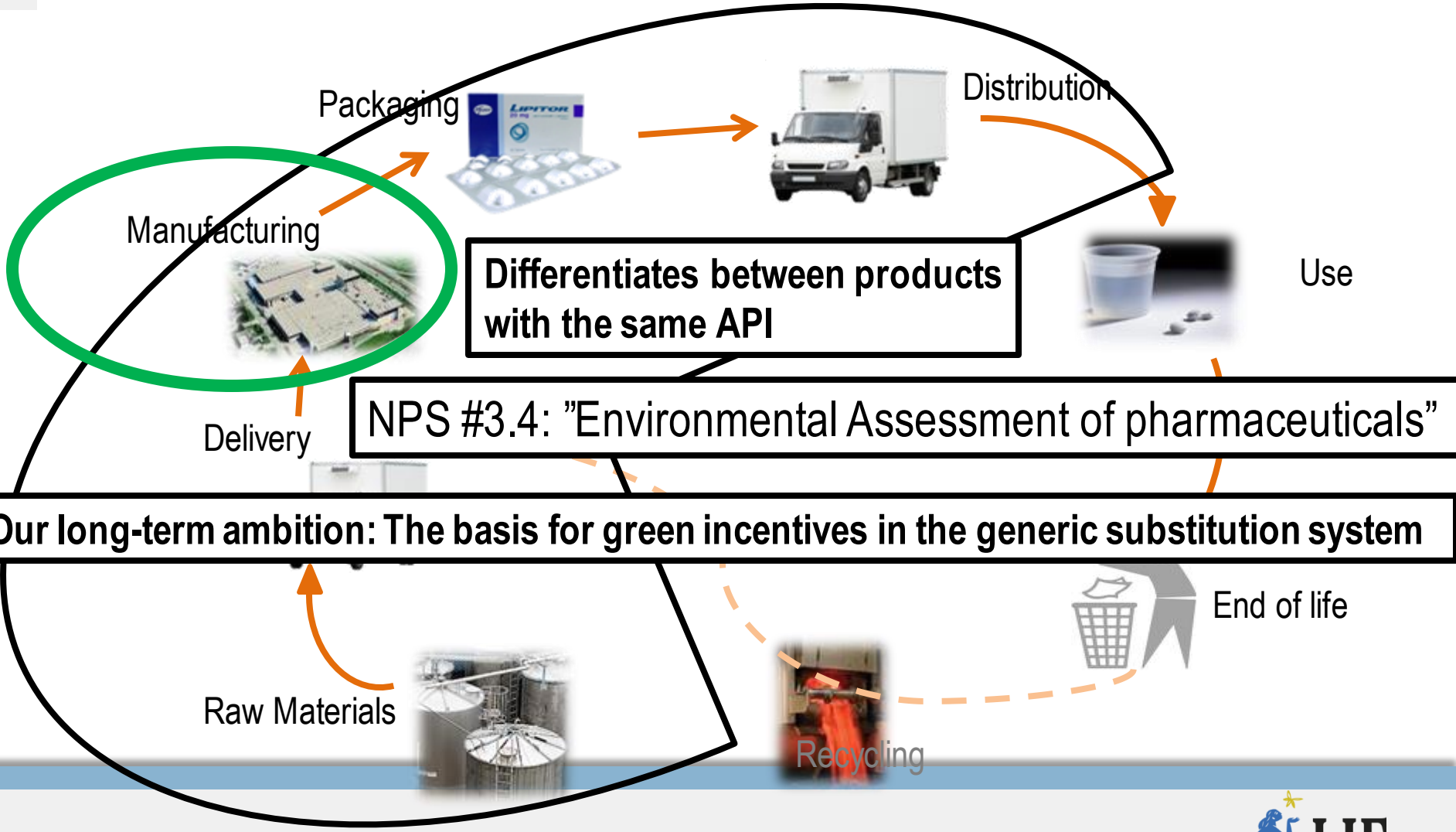
Sustainability criteria under revision by Swedish Public Procurement Agency (UHM) – due 2017/2018

Criteria need to be followed-up,
and good performance should be rewarded

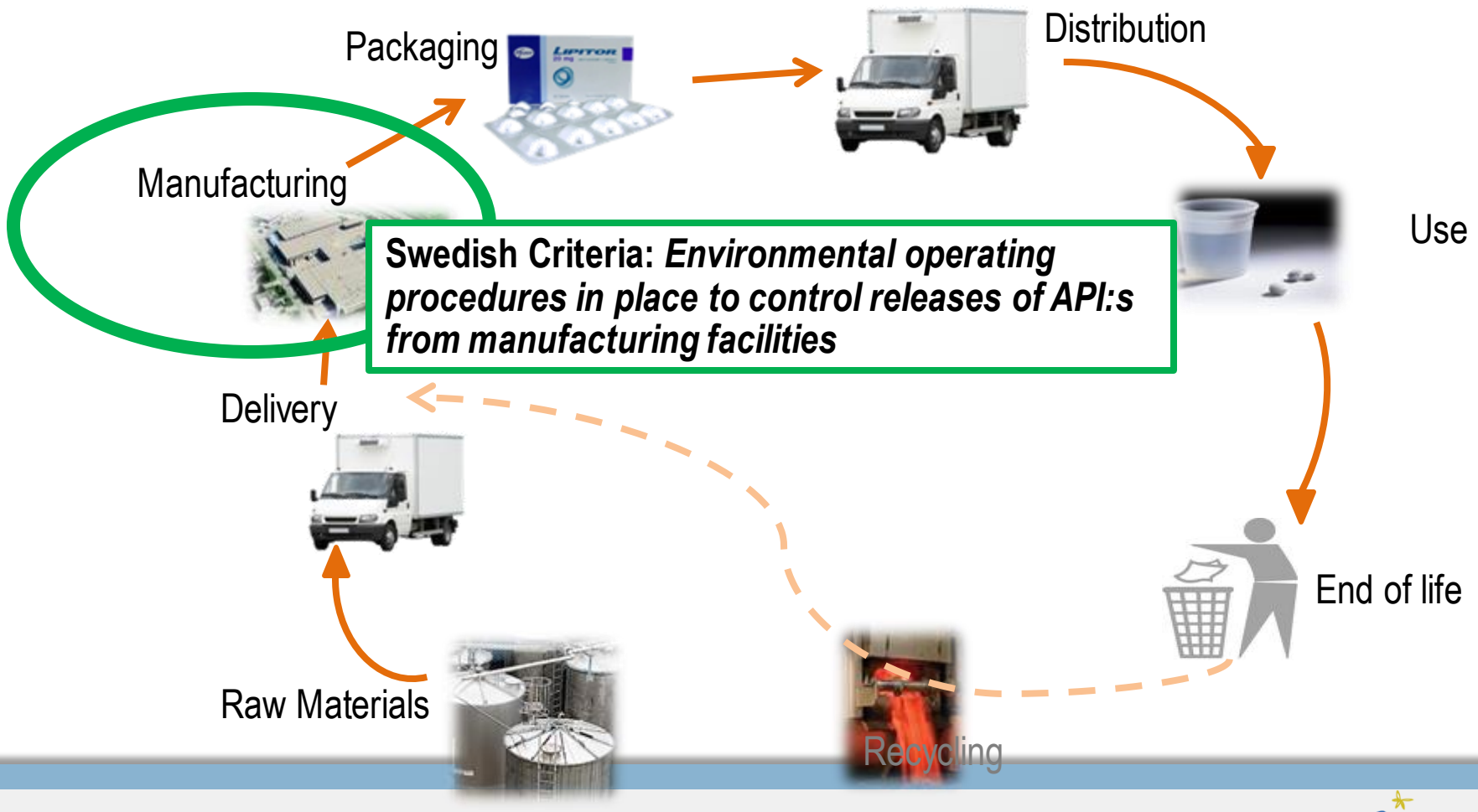
Environmental Assessment of Pharmaceutical Substances



Environmental Assessment of Pharmaceutical Products



Environmental Assessment of Pharmaceutical Products



Information needs to be gathered…

- Step 1
  - Connect to your Swedish colleagues, who may have built a "tender package" already used in Sweden
  - Connect to your global colleagues in "Corporate EHS" (Environmental, Health & Safety)
- Step 2
  - Adjust the "global/Swedish package" for your use
  - **If no package is available**: Search for relevant information and data on your global website and on the intranet
    - ***Example**: Publicly available info from AstraZeneca*

AstraZeneca

Making science accessible

Sustainability Report 2017

Strategy

Our scientific approach to environmental sustainability strives to reduce our environmental impact by protecting our air, land and water, reducing our dependence on natural resources and ensuring the environmental safety of our products. We have taken the position of industry leader on the issue of pharmaceuticals in the environment (PIE).

AstraZeneca's Executive Vice President, Sustainability and Chief Compliance Officer is responsible for environmental matters. In 2017, our global Safety, Health and Environment (SHE) Policy was the overarching document for our environmental management system. It applies to all functions and locations and is supported by global standards and procedures that establish mandatory requirements in key risk areas. We monitor and manage performance through comprehensive assurance programmes that include performance reporting, internal auditing and an annual management review.

We've invested $60 million in environmental efficiency innovations over the last three years through our Natural Resources Reduction Governance Group (NRRGG) Fund, and we will continue to invest at a similar level through to 2025 to help us meet our natural resources strategy targets. We use site water stress assessments and natural resource audits to identify opportunities for management and investment.

Our strategy addresses the four environmental sustainability issues identified by our materiality assessment: reducing our greenhouse gas (GHG) emissions to combat climate change; protecting natural resources through energy, waste and water management; leading the way to minimise PIE; and preserving biodiversity. We have described our targets, governance and outcomes for these priorities in this report. We continue to manage other aspects – for example, site risk registers – to ensure our sites comply with regulatory and industry standards at a minimum, while aiming much higher.

Accessing a cleaner future

We've made progress in improving the environmental performance of our value chain since we began a focused effort in 2011, but we still have work to do. Our current targets, set using 2015 baselines, guide us through to 2025. We are building on our prior goals and adjust periodically to strengthen our impact.

See additional performance indicators in our data summary online.

Commitment	Target	Progress	Status
Environmental safety of our products Minimise the environmental impact of our products	Lead the industry to manage pharmaceuticals in the environment (PIE) by 2025	On plan ●●○	**EcoPharmacoVigilance (EPV) programme** to monitor product risks post launch ran through 2017 with no significant risks identified **Co-authored 14 peer-reviewed publications** on PIE **100% of API discharges*** from AstraZeneca sites demonstrated as safe **>90% of API discharges*** from globally managed direct suppliers demonstrated as safe
	Ensure 90% of active pharmaceutical ingredient (API) syntheses meet resource efficiency targets at launch by 2025	On plan ●●○	**50% of API syntheses** (one of two) have met target at launch since the start of the strategy period
	Develop resource efficiency targets for biologic products by 2020	On plan ●●○	In 2017, we participated in a **cross-sector benchmarking** through the ACS GCIPR for a biologic products resource efficiency metric
	Develop a product environmental sustainability index and pilot our approach by 2019	Not yet started ○○○	We have **conducted 14 life-cycle analyses** (LCA) on our products to date **We will start development** of a product environmental sustainability index in 2018

* Scope is 50 APIs for which data is available to calculate safe API discharge limits and based on 2016 manufacture.

Learn more about our approach to sustainability and our outcomes by exploring these global policies, reports, videos, infographics and other materials.

- Bioethics Policy
  PDF 197KB
- Business Travel Policy v5.0
  PDF 422KB
- Code of Ethics in English
  PDF 47KB
- Communications Policy v6.0
  PDF 133KB
- Corporate Information Technology Usage Policy v2.0
  PDF 701KB
- Data Privacy Policy v3.0
  PDF 147KB
- Environmental risk data relating to our medicines
  PDF 226KB
- Ethical Interactions & Anti-Bribery/Anti-Corruption Policy v6.0
  PDF 70KB
- Expectations of Third Parties Handbook
  PDF 251KB
- Global People Policy v3.0
  PDF 151KB
- Global Policy Legal and Intellectual Property Policy v3.0
  PDF 643KB
- Global Publications Policy v13.0
  PDF 150KB
- Global Standard Expectations of Third Parties
  PDF 134KB
- Human Rights Statement
  PDF 861KB
- Our Commitment to Deliver our Science to Patients
  PDF 1,099KB
- Quality and Regulatory Compliance Policy
  PDF 184KB
- Safeguarding Company Assets and Resources Policy v4.0
  PDF 53KB
- Safety, Health and Environment (SHE) Policy v5.0
  PDF 30KB
- Tax Policy
  PDF 371KB

AstraZeneca's Environmental Risk Summaries

As part of AstraZeneca's commitment to data transparency, this document provides environmental risk summaries for the Active Pharmaceutical Ingredients (API) found in our global brands. The summaries are consistent with the environmental information provided as part of our marketing applications, or where this is not available, from currently available data including scientific literature, where appropriate.

For each API, the potential environmental risk is calculated from the ratio between the Predicted Environmental Concentration (PEC) of the API in the aquatic environment (e.g. rivers) and the Predicted No Effect Concentration (PNEC), which is the concentration, based on available tests, below which no adverse effects on the ecosystem are expected to occur. For human pharmaceuticals, it is primarily the aquatic compartment that is of interest, since human medicines may be excreted partly or wholly unchanged by patients, subsequently entering the sewage system and ultimately rivers and other surface waters. The PEC is calculated using a worst-case scenario, assuming no metabolism by the patient or removal/degradation of the API during sewage treatment and using the total sales volumes for the API in the European country with the highest per capita use[1]. The sales volumes are based on all human medicines containing the API, including products marketed by other companies, where applicable. The PNEC is estimated by division of the lowest value for toxicity with the relevant assessment factor, as outlined by the European Chemicals Agency[2] and European Medicines Agency[3].

The environmental risk is divided into four different categories depending on the PEC/PNEC ratio. The categories, described below, are consistent with the classification system[4] for environmental information on www.fass.se, the web version of the Swedish Prescribing guide.

The risk categories are as follows:

PEC/PNEC ≤ 0.1	Use of the substance has been considered to result in **insignificant** environmental risk.
0.1 < PEC/PNEC ≤ 1	Use of the substance has been considered to result in **low** environmental risk.
1 < PEC/PNEC ≤ 10	Use of the substance has been considered to result in **moderate** environmental risk.
PEC/PNEC > 10	Use of the substance has been considered to result in **high** environmental risk.

Environmental risk data relating to our medicines

The table below provides an overview of the environmental risk of AstraZeneca's medicines. This information will be updated, if appropriate, as new data become available. The active pharmaceutical ingredients are listed alphabetically by their generic name. Where an API is used in a combination product (a medicine that contains more than one API) the brand name is followed by the generic name of the additional API contained within the product, in parenthesis.