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# Potential EU & UN policy on antimicrobial-resistant bacteria and pharmaceuticals in the environment (AMR/PiE)

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# Consulted sources


- (PW14) **Proceedings of EU Workshop of 11 September 2014** on the development of a strategic approach to pollution of water by pharmaceutical substances, Helen Clayton, Water Unit, DG Environment, European Commission;
- (RM) **Roadmap** Strategic approach to pharmaceuticals in the environment, DG ENV C1 and B2, 28/04/2017;
- **Response to the Roadmap** Strategic approach to pharmaceuticals in the environment, May 26 2017, Stichting Huize Aarde;
- (BD) **Background Document** for public consultation on pharmaceuticals in the environment  Bio Intelligence Service, Milieu Ltd, Ineris and Pr. Klaus Kümmerer September 2017. Interim report for European Commission contract number: 07.0201/2015/721866/SER/ENV.C.1;
- (PW17) **Proceedings of EP Workshop of 29 November 2017** Pharmaceuticals in the Environment by Water & Agriculture Working Group;
- **Reply to EU policy proposals** PiE 2018; and **Additional Comments** on the EU Strategic approach to PiE, Stichting Huize Aarde, January 20 2018.
- **Recommended sub-goals for the Sustainable Development Goals** that also reduce the environmental cycle of medicines and multi-resistant micro-organisms, June 25 2018, Stichting Huize Aarde, The Netherlands.


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# History of EU AMR/PiE Policy

| policy documents | about | policy |
|---|---|---|
| - COM(2008) 666 final<br>- Regulation (EU) No 1235/2010<br>- Directive 2010/84/EU | Pharmacovigilance legislation | Measures needed to monitor risks of pharmaceuticals to the environment and public health. |
| - COM (2011) 748 | Action Plan on Microbial Resistance | Action 8 Reduction of environmental pollution by antimicrobial medicines. |
| - Directive 2000/60/EC<br>- Directive 2008/105/EC<br>- Directive 2013/39/EU | Water Framework Directive; Water quality standards | Develop strategic approach to PiE (risk assessment and measures) |
| - Decision No 1386/2013/EU | Environmental Action Programme | Action for non-toxic environment |
| - 2030 Agenda for Sustainable Development (UN, 2015) | Sustainable Development Goals | SDG 6 Clean Water and Sanitation |

**Sources:** EU Roadmap 2017; Proceedings of EP Workshop of 29 November 2017

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# UN Sustainable Development Goals* & AMR/PiE I

| Theme of SDG | Theme of subgoals | By SHA recommended sub-goals |
|---|---|---|
|  | 3.5 Substance abuse | 3.5 Reduce addiction to medicines. |
| | 3.9 Hazardous chemicals | 3.9 Categorise all medicines as potentially hazardous chemicals. |
| | | 3.10 By 2030 halve no. of deaths and illnesses caused by irresponsible use of medicines. |
|  | 6.3 Water quality | 6.3 Categorise medicines in the environmental cycle as hazardous chemicals, and stop their discharge. |
|  | 9.4 Sustainable industries | 9.4 Include environmentally friendly production of medicines in import conditions. |
| | 9.5 R&D research | 9.5 More R&D to intercept the environmental cycle of medicines at the early stages of the product chain. |

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* SDG's are from the 2030 Agenda for UN Sustainable Development, 2015.

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# UN Sustainable Development Goals & AMR/PiE II

| Theme of SDG | Theme of subgoals | By SHA recommended sub-goals |
|---|---|---|
|  | 11.6 Waste management | 11.6 Promoting a source oriented approach to AMR/PiE. |
|  | 12.4 Environmental sound management of chemicals | 12.4.1 Categorise medicines in the environmental cycle as hazardous chemicals.<br>12.4.2 Communicate AMR/PiE as unwanted, and formulate a package of measures. |
| | 12.5 Generation of waste | 12.5 Include medicines in this sub-objective. |
| | 12.6 Sustainable practices of transnational companies | 12.6 Include pharmaceutical companies and apply this goal also to imported medicines. |
| | 12.8 Information and awareness | 12.8 Divulge relevant information about the environmental cycle of medicines. |

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# UN Sustainable Development Goals & AMR/PiE III

| Theme SDG | Theme of subgoals | By SHA recommended subgoals |
|---|---|---|
|  | 14.1 Marine pollution | 14.1 Combating marine pollution by including persistent medicines in the targets. |
|  | 15.5 Degradation of natural habitats | 15.5.1 Include the harmful influence of chemicals such as medicines on the quality of biodiversity.<br>15.5.2 Improve quality of STP effluent reaching nature reserves<br>15.5.3 Convert agriculture and aquaculture near natural areas to organic farming. |

**Source:** Recommended sub-goals for the Sustainable Development Goals that also reduce the environmental cycle of medicines and multi-resistant micro-organisms, June 25 2018, Stichting Huize Aarde, The Netherlands.

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# Objectives of AMR/PiE Strategy

1. Address the potentially harmful impacts on environment and public health at EU Level (RM);
2. Propose measures to be taken at Union and/or Member State level (RM);
3. **Take non-legislative measures for EU guidance and information ("no specific policy proposals or commitments will be made") (RM);**
4. Consider, inter alia, the opportunities for innovation (RM);
5. Address pharmaceuticals in the environment generally: in water and soil (RM);
6. Obtain better knowledge of the issue through research, monitoring and reporting (BD);
7. Include policy options relating to the whole lifecycle of pharmaceuticals (RM);
8. Prefer source control over end-of-pipe solutions (PW17);
9. Identify sustainable production, consumption and disposal in line with circular economy (BD);
10. Safeguard access to effective and appropriate pharmaceutical treatments (RM);
11. Maintain competitiveness of EU healthcare system (BD);
12. Publish Strategy as a "Commission Communication" (RM).

**Sources:** Roadmap 2017 (RM); Background Document 2017 (BD); Proceedings of EP Workshop 2017 (WP17)

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# Ten main action areas in the life cycle of pharmaceuticals

**Source:** EU Background Document, 2017

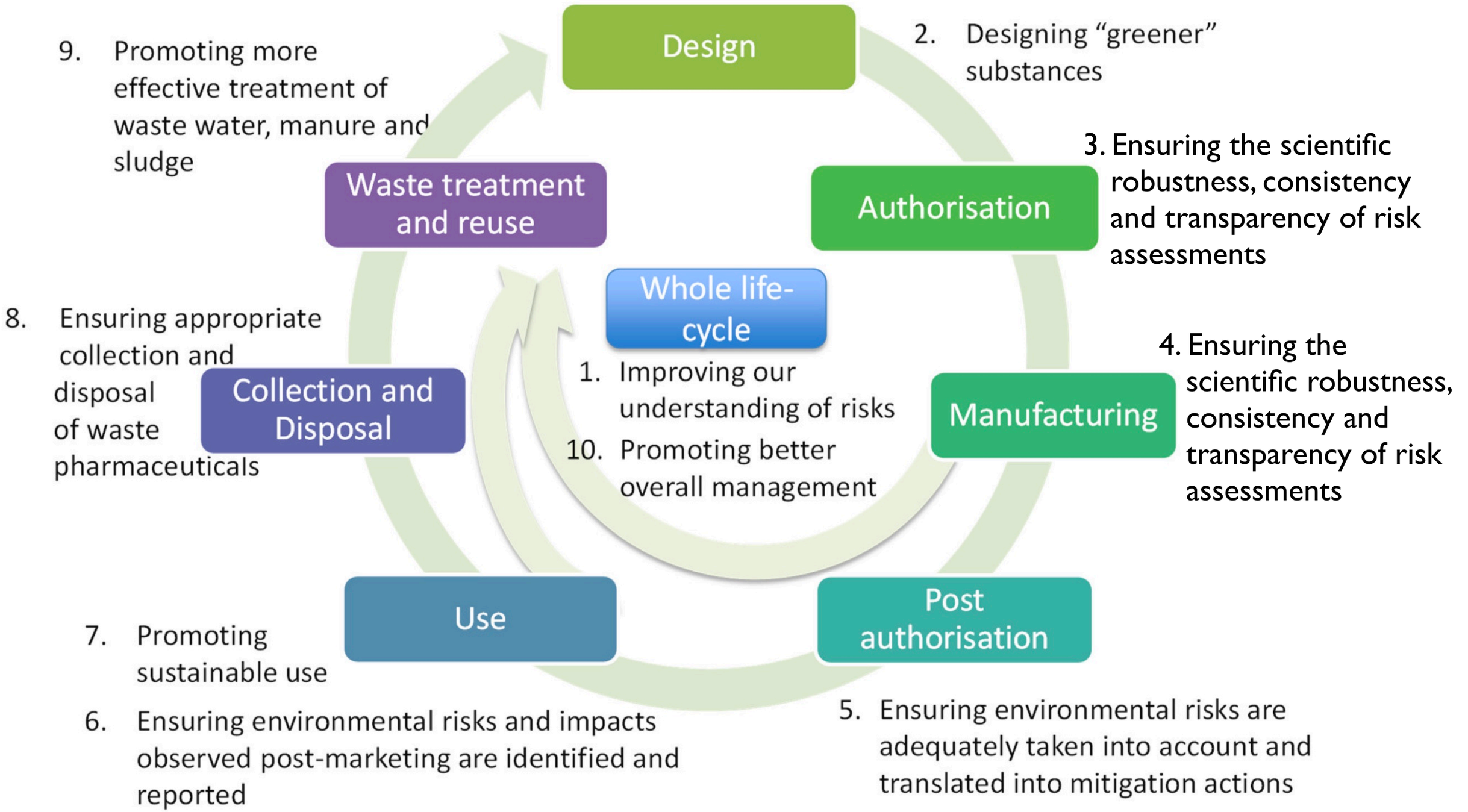
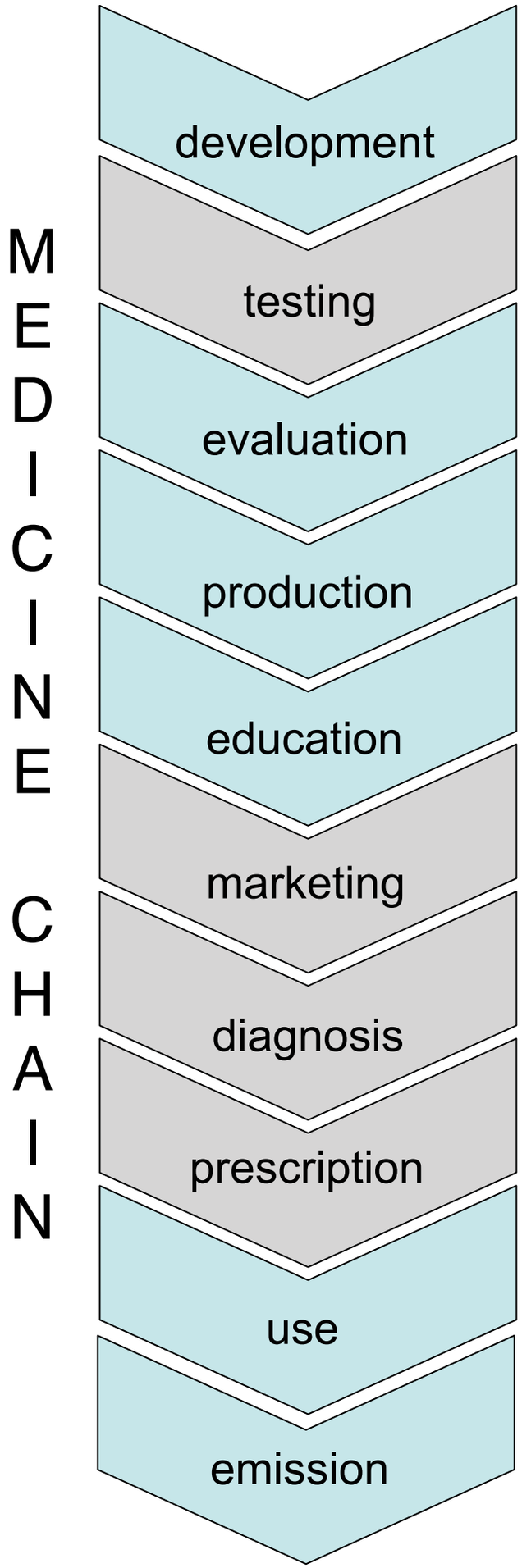



*Figure 1: Ten main action areas across the life cycle of pharmaceuticals*




<—Green design, option 3

<—(Post-)authorisation ERA, option 1 - 2, 4 - 8, 12 - 18

<—Cleaner production, option 9 -11

<—Training & information option 19 - 20

# Proposed EU options allocated to product chain

(**Source:** EU Background Paper, 2017)

<—Package size, option 21

<—Waste handling, option 22 - 23

<—Treatment of water, sludge and manure, option 24 - 30

# Remarks on proposed EU PiE Strategy

- 29 out of 30 options formulated are for symptom control.

- Focus lies on the environment only (8 options about ERA's) and not on environmental cycle.

*Why? It is mainly a DG ENV exercise; little collaboration between involved sectors.*

- No stimulus for (funding of) innovation of source oriented solutions, except green design.

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# Proposals might have been diluted

## Antibiotic apocalypse: EU scraps plans to tackle drug pollution, despite fears of rising resistance

**Leaked documents reveal discarded proposals to ward off antibiotic resistance through closer scrutiny of drug firms**


▲ A bin containing empty drug bottles at a pig-fattening farm in Germany. Antibiotic use on farms remains a problem despite the introduction of tighter controls in many European countries. Photograph: Alamy

The EU has scrapped plans for a clampdown on pharmaceutical pollution

The Guardian, June 8 2018

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# What could be erased or diluted?

| 2017 Options* | Leaked draft** | Remarks |
|---|---|---|
| **Options 9 - 11** Re: complementing of agreements (BREF; SRD/EMAS; GMP) on environmental criteria for medicine **production** in EU. | Replaced by: “the possibility of using procurement policy to encourage greener pharmaceutical design” | - Options 9-11 are about greening production standards & emissions (rather than green design).<br>- Could procurement encourage greening of pharmaceuticals?<br>To this day an alternative list of medicines is not available. |
| **Option 20.** Re: proposing sustainable **use** of pharmaceuticals | Replaced by: “prudent use of pharmaceuticals” | The term 'sustainable' may be misinterpreted. |
| **Option 25.** Re: monitoring of pharmaceuticals and AMR in **emissions** by industry, health care and livestock farms. | Deleted | Regular monitoring of hotspots is needed to ensure transparency and effectiveness of measures. |

* Options in Background Document 2017
** Following The Guardian, June 8 2018

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# Upcoming steps regarding AMR/PiE

**Sources:** Helen Clayton, Policy Officer DG ENV, in email Jan 3 2019; Background Document 2017; Roadmap 2017; Proceedings of EP Workshop of 29 November 2017

**EU-Strategy:**

- Reporting on the public consultation and stakeholder consultation: **early 2019**;
- Adopt Strategy by European Commission: **before 31 Oct 2019.**

**EU-legislation:**

- Elaborate details regarding implementation of specific options at a later stage (BD; PW17);
- Build on existing comprehensive legislation (RM);
- Take related EU-measures in the Water Framework Directive WFD and Urban Waste Water Directive UWWTD (PW17).

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