RESPONSIBLE MANAGEMENT OF PHARMACEUTICAL WASTE IN THE EU

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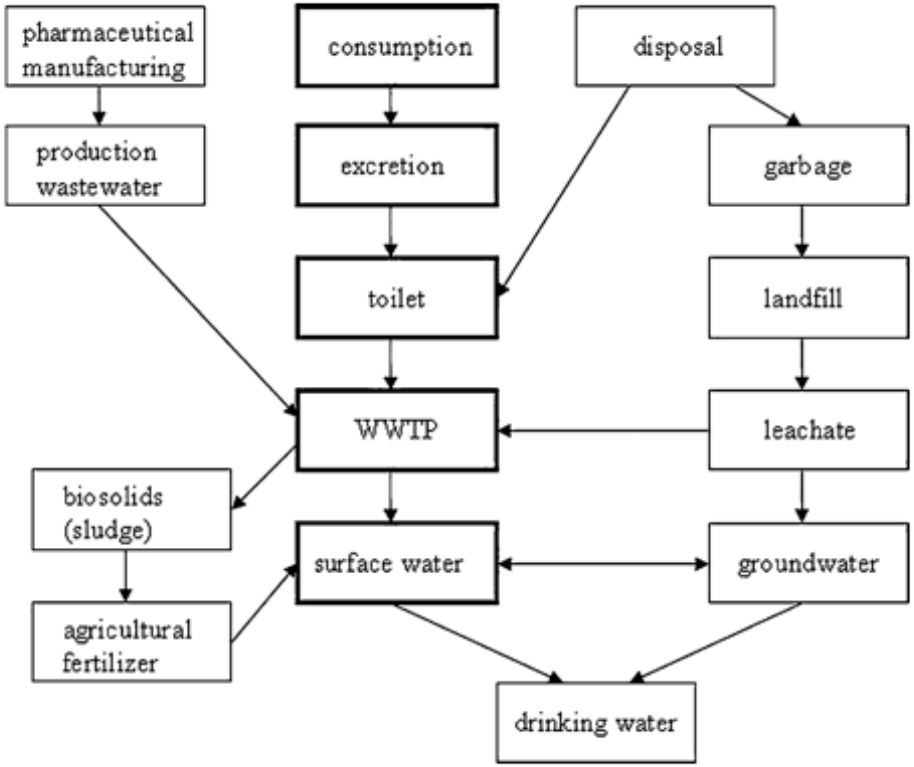
ARE WE FACING A PROBLEM?

- Known effects of the pharmaceuticals in the environment – rivers in the UK, vultures in India, …
- Raising scientific certainty
- Pharmaceuticals ones of other micropollutants – mainly in water

HOW DOES PHARMACEUTICAL WASTE GET TO THE ENVIRONMENT?

- Production processes
  - Local effects
  - Higher concentration
- Use
  - Highest share of pharmaceuticals in the environment
- Disposal
  - Mostly improper disposal

PHARMACEUTICALS WASTESTREAMS

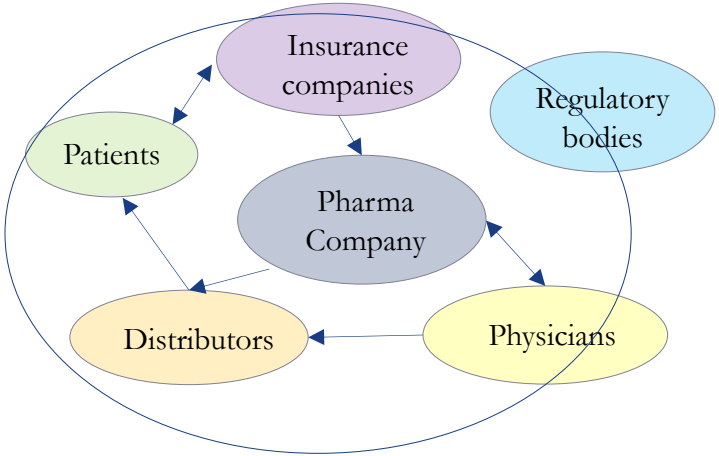


SCATTERED REGULATION IN THE EU

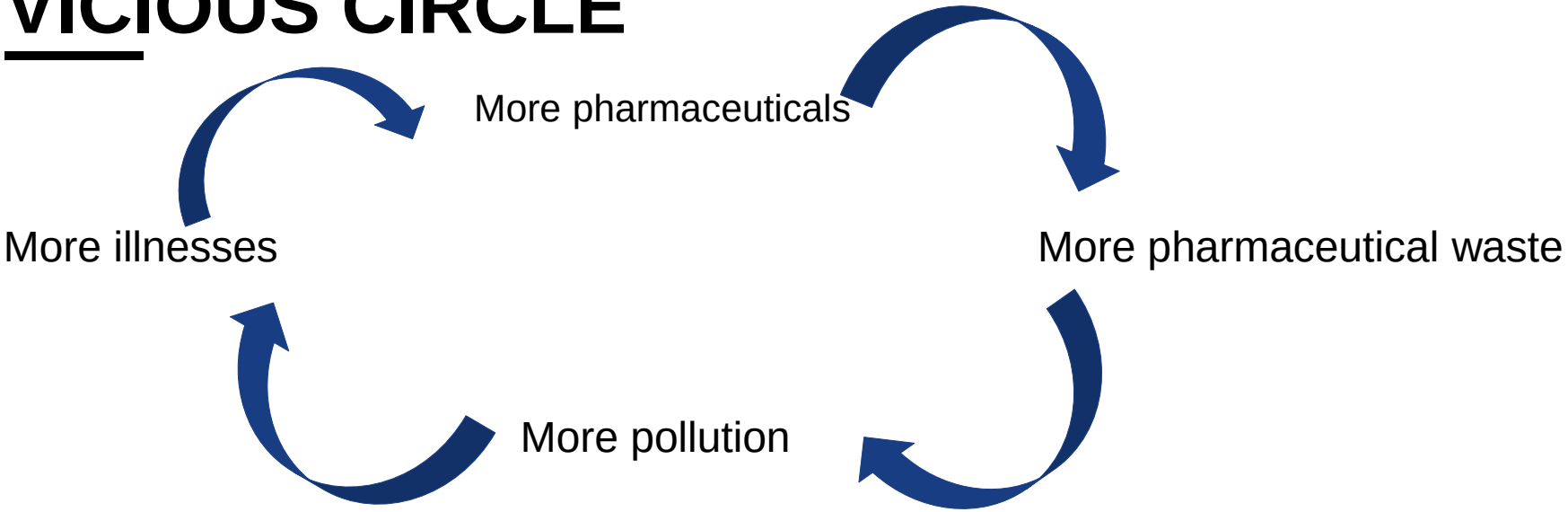
- Water Framework Directive (2000/60/EC)
  - a list of priority surface water pollutants for which environmental quality standards must be set - currently NO pharmaceuticals contained on this list
  - 2013/39/EU (art. 8b) - watch list: diclofenac, E2 and EE2 + other 3 APIs
  - 2013/39/EU (art. 8c) – Commission's obligation to adopt strategic approach (by 2015) and propose measure to be taken (by September 14, 2017)
- Community code relating to medicinal products for human use (2001/83/EC)
  - Environmental risk assessment – arts. 8, 26, 28 and 28a
  - Take-back schemes - art. 127b: '*Member States shall ensure that appropriate collection systems are in place for medicinal products that are unused or have expired*.'
- Other relevant regulation: REACH, Waste Framework Directive, Industrial Emissions Directive, Sewage Sludge Directive

WHY THERE IS NO MORE COMPREHENSIVE FRAMEWORK?

- Balancing major interests
  - › Public health x environment
- Complexity of the pharmaceutical market
- Scientific uncertainty, especially in respect to:
  - › Consistent exposure to low levels of APIs
  - › Exposure to mixtures of APIs
  - › Risks sub-lethal, BUT …
  - › Precautionary principle – solution or an excuse for inaction?



VICIOUS CIRCLE



WHAT CAN BE CHANGED? HOW TO ACHIEVE A COMPREHENSIVE LEGAL FRAMEWORK?

- Precautionary principle combined with life-cycle thinking
- Going back to the waste pyramide

Source: ec.europa.eu

DISPOSAL

- If disposal, than proper!

- Unification of **take-back schemes** – legal regulation should consult behavioral science
- Classifying selected APIs as **hazardous waste** (connection to Water Framework Directive)
- Improvement of **wastewater treatment** methods – establishing stricter rules for hotspots
    - Hollistic approach (’killing two flies with one swat’) – removing other micropollutants as well
    - Polluter pays principle?

RECOVERY

- Incineration of waste preferable over disposal – hollistic approach
  - Incidental removal of pharmaceutical waste
  - A way to deal with mixtures
  - Governments could specifically target waste from hotspots first

RECYCLE

- Not relevant in respect to pharmaceuticals

REUSE

- Increasing attention to possible re-use of pharmaceuticals returned to pharmacies
  - Major legal issues – liability for quality and safety?

PREVENTION

- Environmental Risk Assessment (2001/83/EC)
  - Stricter rules – possibility to refuse marketing authorization or impose risk management measures (risk/benefit analysis) – market for green products
  - Applicability of ERA to ‘old’ products (authorized prior to 2005)
  - Public availability of ERA data
  - Post-authorization updates – connecting ERA to WFD data

- Good manufacturing practices
  - No need for further regulation, can be implemented under the current framework
  - Exporters must obtain a license to import APIs – must implement GMP to obtain this license
  - Current GMP guidelines focused on quality

PREVENTION

- Fighting overconsumption
    - Packaging size
    - Fighting bribery
    - Education and awareness

Avoid ‘paralysis by analysis’

EEA, Late lessons from early warnings, 2001

Thank you for your attention!

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