



Council of the  
European Union

Brussels, 7 December 2015  
(OR. en)

15014/15

ENV 780  
SAN 425  
CHIMIE 73  
AGRILEG 241  
PHARM 53  
RECH 306

**NOTE**

---

From: General Secretariat of the Council  
To: Delegations

---

Subject: Sustainable methods of producing and consuming medicine and managing  
the resulting waste  
- Information from the Swedish delegation

---

Delegations will find attached an information note from the Swedish delegation on the above subject, to be dealt with under "Any other business" at the Environment Council meeting on 16 December 2015.

**Sustainable methods of producing and consuming medicine and managing the resulting waste****Information from the Swedish delegation**

In the framework of Directive [2013/39/EU](#) on priority substances in the field of water policy, the Commission has been asked to develop a strategic approach to water pollution by pharmaceutical substances by the end of 2015. Sweden would like to invite the European Commission to take concrete measures for more sustainable production, consumption and waste management of medicinal products.

Sweden proposes that the following measures should be considered as part of the strategic approach to be developed by the Commission:

- due account should be taken of the risk of development of microbial resistance resulting from pharmaceutical residues in the environment;
- requirements for environmental testing should be updated and tailored to the specific properties of active pharmaceutical ingredients;
- environmental data submitted in the authorisation process should be made easily available to the authorities, research institutions, actors within the health care system, water companies, etc. to facilitate assessment and mitigation of risks;
- discharge and emissions of active pharmaceutical ingredients from manufacturing of pharmaceuticals outside the EU needs to be addressed in EU pharmaceuticals legislation, e.g. in the ongoing negotiations on a new regulation for veterinary medicinal products;
- the performance of take-back systems needs to be strengthened;
- the development and testing of new techniques for removal of active pharmaceutical ingredients in waste water treatment plants should be promoted.

Medicinal products are a fundamental component of both modern and traditional medicine. At the same time, pharmaceutical substances are often engineered so that they remain unchanged during their passage through the human body. Unfortunately, this stability means that they also persist outside the human body, mainly ending up in the aquatic environment. The substances are discharged into the environment at manufacturing sites and through excretion by patients via waste water treatment plants.

In addition, improper disposal of medicinal products and leakage from sewage sludge can also contribute to contamination.

Research findings recognise that the pollution of water and soil by pharmaceutical residues is a cause for environmental concern. Various scientific studies also recognise that emissions from production sites outside the EU contribute to the development of drug-resistant microorganisms that risk being spread worldwide. Tackling the pollution of waters by pharmaceuticals is therefore a mutual concern for health, environment and agriculture ministers.

---