the campaign for

HEALTH CARE WITHOUT HARM

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HCWH Europe's Recommendations on Pharmaceuticals in the Environment

Although pharmaceuticals play an extremely important role in modern healthcare and in improving quality of life, once in the environment their residues can impair public health and damage the environment. Health Care Without Harm (HCWH) Europe is working to raise awareness and to promote policies that reduce pharmaceutical emissions. To this end, HCWH Europe calls on the European Commission to develop a strong Strategic Approach to pharmaceutical pollution to protect humans and the environment from long-term damage.

HCWH Europe Demands:

✓ **Develop testing methods on the environmental fate of pharmaceuticals**

Standard risk assessment methods and endpoints are not currently able to measure the environmental fate of pharmaceuticals. Investing in research to develop appropriate testing methods is critical to understanding how pharmaceuticals affect human health and the environment.

✓ **Gather data on the presence of pharmaceuticals in the environment**

To better understand pathways and sources of pharmaceuticals in the environment, monitoring programmes should be implemented to gather data and measurements of pharmaceutical residues in environmental compartments.

✓ **Develop concentration limits for pharmaceuticals in water**

Although two synthetic oestrogens and diclofenac have been added to the Watch List of substances subject to EU-wide monitoring, they should be placed on the Priority List subject to systematic monitoring and environmental quality standards to prevent further damage to human health and the environment.

✓ **Report pharmaceutical sales**

The EU market for pharmaceuticals has grown significantly in the past 25 years.[1] The European institutions should require reporting of pharmaceutical sales, including over-the-counter and Internet sales, to understand buying behaviour and consumption patterns.

✓ **Promote development of green and sustainable pharmaceuticals**

To address pharmaceutical pollution at its source, it is time to invest in development of environmentally safe pharmaceuticals that produce minimal waste during manufacturing, have increased bioavailability, and do not persist in the environment. A market for green and sustainable pharmaceuticals should be developed by giving producers economic incentives, for example extending patent

[1] BIO Intelligence Service (2013), Study on the environmental risks of medicinal products, Final Report prepared for Executive Agency for Health and Consumers. Page 18.

protection periods, waiving authorisation fees, providing protocol assistance or otherwise providing some market exclusivity.

✓ **Expand the influence and scope of the environmental risk assessment**

Though an environmental risk assessment (ERA) has been required for human medicinal products placed on the market since 1993, the ERA itself is not grounds for denying an authorisation. Regulators should require that the ERA be taken into account in the risk benefit analysis for purposes of market authorisation, and should require ERAs for all existing pharmaceuticals.

✓ **Use ERA data to inform regulatory decision making and prioritise action**

ERA data that has been generated for pharmaceutical authorisations should be made available to environmental and water authorities so they can systematically assess existing active pharmaceutical ingredients and develop and prioritise necessary regulatory action.

✓ **Improve pharmaceutical collection schemes**

Member States must ensure that appropriate collection systems are in place for unused or expired medicinal products,[2] but collection schemes vary widely from one Member State to another, and on average 50% of unused medical products is not collected.[3] Member States must be held accountable for ensuring the implementation of collection schemes and should be subject to systematic reporting obligations. To promote best practices, guidance documents should be developed at the EU level. HCWH Europe also supports the creation and implementation of a harmonised pharmaceutical collection system at the EU level.

✓ **Make the pharmaceuticals industry responsible for pharmaceutical waste**

To reduce the burden on local government and pharmacies which operate or finance collection schemes, Member States should hold the pharmaceuticals industry responsible for the costs of pharmaceutical collection schemes under the extended producer responsibility clause of the Waste Framework Directive.[4]

✓ **Raise public awareness**

A 2013 survey conducted by HCWH Europe in six Member States revealed that lack of information was one of the main reasons cited for not using the collection system.[5] Raising public awareness of collection programs is necessary for collection schemes to succeed. Public information campaigns, labelling packaging and training for medical professionals are a few ways to increase public awareness.

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[2] Directive 2001/83/EC (as amended) of the European Parliament and of the Council of 1 November 2001 on the Community code relating to medicinal products for human use, Article 127b.

[3] BIO Intelligence Service, page 18.

[4] Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives, Article 8.

[5] Health Care Without Harm Europe (2013), Unused pharmaceuticals: Where do they end up? A snapshot of European Collection Schemes. Page 26.

Health Care Without Harm (HCWH) is an international coalition whose mission is to transform the healthcare sector so that it becomes ecologically sustainable and a leading advocate for environmental health and justice. This paper was created in preparation for the Pharmaceuticals in the Environment workshop carried out by the European Commission and AMEC Environment & Infrastructure UK Limited on 11 September 2014.

To learn more about pharmaceuticals in the environment, please visit:
www.pharmaenvironment.org