

PGEU Position Paper on Pharmaceuticals in the Environment

Community pharmacists share the increasing concerns on the negative effects pharmaceuticals can cause on the environment, and as a result, on public and animal health. Environmental protection contributes to safeguarding the health and safety of future generations; at the same time medicines play a critical role in ensuring a high level of public health. A **right balance** needs to be achieved between increased awareness and appropriate policy approaches to **prevent the potential negative effects pharmaceuticals can cause on the environment** on the one hand, and **access to safe and effective medicines** with demonstrated benefits on public health on the other.

The European Commission has, as required by EU legislation^I, published a **Communication on a European Union Strategic Approach to Pharmaceuticals in the Environment**^{II} on 11th March 2019. It identifies six action areas concerning all stages of the pharmaceutical life cycle, both for pharmaceuticals for human and veterinary use, where improvements can be made. The areas that are most relevant for the European community pharmacy sector are discussed below.

1. Increase awareness and promoting prudent use of pharmaceuticals

According to the European Commission Communication, the largest source of pharmaceuticals entering the environment is their use. Generally between 30% and 90% of the orally administered dose of a wide range of commonly used pharmaceuticals are excreted as active substances in the urine and faeces^{III}. Due to the varying ability of wastewater treatment to eliminate pharmaceutical residues, the emissions mostly come from municipal wastewater systems following the consumption of medicines in households, with a smaller proportion coming from hospitals and health care facilities^{III}.

Still too often, the possible impact of a certain pharmaceutical on the environment is generally unknown, as well as the links between the presence of antimicrobials in the environment and the development and spread of antimicrobial resistance. It is crucial that these knowledge gaps are filled and that this information is appropriately integrated in policies and guidelines.

As part of their role in improving public health, community pharmacists see it as their duty to advise citizens on environmental health and safety. This includes advising on appropriate handling, adherence and disposal as well providing information to the public on the availability of 'greener' pharmaceuticals where such information is available^{IV}. In order to fulfil this role, the development of guidelines and information materials for healthcare professionals on the prudent use of pharmaceuticals posing a risk to or via the environment should be encouraged. The Joint FIP/WHO Guidelines on Good Pharmacy Practice^V highlight that an important requirement for the community pharmacy practice is to have access to evidence-based, unbiased, comprehensive, objective and current information about therapeutics, medicines and other health-care products in use, including

^I Article 8C of the Priority Substances Directive (2008/105/EC as amended by Directive 2013/39/EU)

^{II} http://ec.europa.eu/environment/water/water-dangersub/pdf/strategic_approach_pharmaceuticals_env.PDF

^{III} <https://publications.europa.eu/en/publication-detail/-/publication/5371e7bd-25db-11e9-8d04-01aa75ed71a1/language-en>

^{IV} <https://pgeu.eu/en/policy/48:pharmacy-2030-a-vision-for-community-pharmacy-in-europe.html>

^V https://www.fip.org/www/uploads/database_file.php?id=331&table_id=

potential environmental hazard caused by disposal of medicines' waste. Any guidelines or protocols to healthcare professionals should at the same time provide the healthcare professional with sufficient room for independent clinical decision-making on a case-to-case basis, so that at all time the health outcomes of the patient can be the key decision factor in any start or (dis)continuation of therapies.

In addition to professional guidelines, environmental aspects for pharmaceuticals posing a risk to or via the environment could also be included in the training of pharmacy students and continuous professional development programmes as part of a One Health approach. These measures can empower pharmacists in advising on environmental health and safety as well as allowing for a complete risk/benefit analysis of the medicines they are dispensing, taking into account environmental factors.

2. Promoting greener manufacturing

Some medicinal products have a negative impact on the environment in countries where they are sold, but more so in the countries where they are manufactured. Some of the active pharmaceutical ingredients (API) are being produced in environmentally friendly factories that use efficient sewage plants - but far too many do not. The result is pollution in nearby waters, such as lakes and rivers that can be an active reproduction area for amongst others antibiotic resistant genes^{VI}. We therefore welcome the European Commission recommendation to increase collaboration with Member States on setting environmental quality standards for pharmaceuticals posing a risk at national level and to encourage action in third countries where pharmaceutical emissions from manufacturing and other sources are suspected of contributing to the global spread of antimicrobial resistance.

3. Reducing wastage and improve the management of waste

It is estimated that around 8-10% of pharmaceutical substances in the environment originate from improperly disposed medicines - flushed down the toilet, poured into drains, or otherwise disposed inappropriately in household waste by patients or even by medical institutions^{VII,VIII}. Educating citizens across the EU can therefore lead to a change in behaviour that can make a substantial difference.

In order to raise public awareness about the correct disposal of unused and expired medicines, several European stakeholder organisations have collaboratively initiated, on a voluntary basis, the #medsdisposal campaign^{IX}. In addition to conducting social media campaigns in different languages, the campaign's public website contains a map with information on the disposal of medicines in the different European countries.

In addition to several State or government-led disposal and collection schemes for medicines, the majority of the European population can return expired or unused medicines to their community pharmacy, although the organisation and financing of these schemes varies.^{IX}. Since community pharmacies are easily accessible and frequently visited by the public, Member States should ensure that, where implemented, pharmacy-led disposal and collection schemes are appropriately funded in

^{VI} <https://www.frontiersin.org/articles/10.3389/fmicb.2014.00648/full>

^{VII} Kümmerer, 2009: The presence of pharmaceuticals in the environment due to human use: present knowledge and future challenges. *J. Environ. Manage.*, 8:2354–2358

^{VIII} European Environmental Agency, *Pharmaceuticals in the environment*, 2010

^{IX} <http://medsdisposal.eu/>

order to make the best use of these resources. Today, still in too many EU countries pharmacies are asked to finance these systems themselves, which leads to insufficient uptake and is in our perspective an unfair and incorrect approach taking into account the positive results observed in countries where pharmacies are empowered in this role. At the same time, it is also key that for certain risk medicines the quantity of medicines dispensed matches the duration of treatment as much as possible in order to reduce the amount of leftover medicines, for example by optimising the package size of certain risk medicines.

Recommendations

PGEU calls for a number of coordinated actions that should be taken at different policy levels to reduce and prevent the negative impact of pharmaceuticals in the environment. In particular, PGEU calls on:

1. Member States, in close collaboration with the European Commission and the European Medicines Agency (EMA), to:
 - a. **Take action to increase the public awareness on the prudent use and waste collection of pharmaceuticals.** Community pharmacists are, as medicine experts, ideally placed to advise patients on the appropriate handling and disposal of pharmaceuticals and should therefore be closely engaged in any public campaigns.
 - b. **Develop guidelines and information materials for healthcare professionals on the prudent use of pharmaceuticals.** For community pharmacists, these guidelines should be developed in close collaboration with the national and local pharmacy associations to ensure an appropriate integration in pharmacy practice.
 - c. **Explore the inclusion of environmental aspects for pharmaceuticals posing a risk to or via the environment in the training of pharmacy students and continuous professional development programmes** as part of a One Health approach.
 - d. **Develop and ensure compliance with environmental quality standards for pharmaceuticals** as a measure to promote greener manufacturing.
 - e. **Ensure appropriate funding of pharmacy-led disposal and collection schemes for medicines**, where implemented, as an easily accessible channel for the public to correctly dispose of their leftover or expired medicines.
 - f. **Reduce pharmaceutical waste caused by leftover medicines** by ensuring that systems are in place that encourage the dispensing of quantities of certain risk medicines matching the duration of treatment as much as possible.
2. The European Commission to:
 - a. Ensure that actions to address the risk of pharmaceuticals in the environment do **not jeopardise sufficient room for independent clinical decision-making by healthcare professionals on public health grounds.**
 - b. **Foster best-practice exchanges between Member States** on measures addressing the growing presence and negative impact of pharmaceuticals in the environment.
 - c. **Fund and encourage more research** to fill current existing knowledge gaps on the potential negative impact of pharmaceuticals on the environment as well as the links between the presence of antimicrobials in the environment and the development and spread of antimicrobial resistance.
 - d. **Encourage action in third countries** where pharmaceutical emissions from manufacturing and other sources are suspected of contributing to the global spread of antimicrobial resistance.