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Medicines: policy, authorisation and monitoring

PHARM 851

PHARMACEUTICAL COMMITTEE
1 April 2025

Subject: Pharmaceuticals in the environment (Agenda item nr. 5)[1]

The final report on the work of the ad hoc working group on pharmaceuticals in the environment is attached as background for the discussion under Agenda item nr 5.

This report was also shared with members of the Committee by email in August 2024.

[1] This document has not been adopted by the European Commission and, therefore, it does not reflect an official position of the European Commission. It is only meant to be a tool for discussion and the views expressed therein do not necessarily reflect those of the Commission and its services.

Pharmaceuticals in the environment - Implement the EU strategic approach

Compilation of recommendations and best practices

Preface

As part of the European Union Strategic Approach to Pharmaceuticals in the Environment[1], communicated in 2019, an Ad Hoc Working Group was established by the Pharmaceutical Committee in 2020. The aim of the work of the group was to move forward towards the Unions zero-pollution ambition around pharmaceuticals. This cross-cutting report presents recommendations, good practices, and guidance that falls under the competence of the Member States to reduce the pollution of pharmaceuticals to the European environment.

13 Member States, European Medicinal Agency (EMA) and the European Commission participated in the work and 7 sub-working groups were established to deal with different aspects of the European Strategic Approach. An action plan was elaborated by the working group and adopted by Pharmaceutical Committee. The report, based on that plan, is now finished, and hereby presented to the Pharmaceutical Committee.

I would like to extend my sincere gratitude to the participants in the Working Group (Annex 9) without whom this report could not have been made and presented. And we are now looking forward to continuing the work in decreasing the pollution from pharmaceuticals to the environment in Europe.

Stefan Berggren
Chairman of the Ad Hoc Working Group on Pharmaceuticals in the Environment

[1] Communication from the Commission, European Union Strategic Approach to Pharmaceuticals in the Environment. COM (2019) 128 final. EUR-Lex - 52019DC0128 - EN - EUR-Lex (europa.eu)

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II. Summary

An ad hoc working group was established in March 2020 to focus on the EU strategic Approach on pharmaceuticals in the environment in relation to human medicines and their impact on the environment. The work has been based on the actions and measures of the Communication from the Commission[2] that falls under the competence of the Member States. The mandate for the ad hoc working group was originally set for three years, until end of 2023. It was extended until 31 Mars 2024 due to new work tasks in relation to the proposals for a new pharmaceutical legislation. 13 Member States, the European Medicinal Agency (EMA) and the Commission have been involved, and seven sub-working groups were established for the work. The scope of the sub-working groups was to provide recommendations for the topics presented in Table 1.

Table 1. The topics of the seven different sub-working groups and the countries that have been participants, as leader or collaborators, in the groups.

Action	Topic	Participants
1	Guidelines for healthcare professionals on the prudent use of pharmaceuticals.	Leader: NL Collaborators: CZ, ES, FI, FR, SE
2	Environmental aspects as a part of medical training and professional development programs	Leader: NL Collaborators: CZ, ES, FR, NL, SE
3	Environmental considerations in the advertising and prescription of medicinal products	Leader: FR Collaborators: EMA, FI, SE
4	Strategies to reduce waste of medicines	Leader: FR Collaborators: Commission, DE, EMA, ES, IT, SE
5	Exchange of best practices on the environmentally safe disposal of medicinal products and clinical waste	Leader: RO Collaborators: FR, NL, SE
6	Waste collection schemes of unused medicinal products	Leader: ES Collaborators: FI, NL, SE
7	Improve the level of environmental expertise in the Committees and networks	Leader: DE Collaborators: AT, CZ, EMA, ES, IE, NL, SE, SI

[2] Communication from the Commission, European Union Strategic Approach to Pharmaceuticals in the Environment. COM (2019) 128 final. EUR-Lex - 52019DC0128 - EN - EUR-Lex (europa.eu)

First, an inventory of the current situation was performed in the Member States participating in the ad hoc working group. Then, in 2021, a questionnaire was sent out through the Pharmaceutical Committee to all Member States and a compilation of the questionnaire was made in 2022.

Apart from the survey the working group have exchanged views and collected information on experiences, national initiatives, and best practices for the report in participating Member States. The group was also given the task of drafting a concept paper to bring support in the revision of the EU pharmaceutical legislation (Directive 2001/83/EC) on the following aspects:

- Strengthening the environmental risk assessment requirements and conditions of use for medicines and taking stock of the results of research under the innovative medicines initiative.
- Greener pharmaceuticals with respect to antimicrobial resistance.

The concept paper was finalized in March 2022 and the condensation was published in peer reviewed literature.[3] [4] Due to the additional task, the original deadline set to March 2023 was extended to March 2024.

A proposal for a compiled report was presented and discussed at a face-to-face meeting in Sweden in May 2023. In total there has also been 21 online meetings. According to the extended mandate of 2024, the finalization of the collaboration for pharmaceuticals in the environment, recommendations, good practices, and conclusions are presented in this report. In the following part an overview of the recommendations from all seven sub-working groups are presented. For more detailed information see the section and Annex for each action.

The ad hoc working group was also tasked to draft a revised mandate for discussion and possible endorsement by the Pharmaceutical Committee and the mandate were therefore further extended until the end of 2024.

[3] Moermond CTA, et al. Proposal for regulatory risk mitigation measures for human pharmaceutical residues in the environment. Regul Toxicol Pharmacol. 2023 Sep;143:105443. doi: 10.1016/j.yrtph.2023.105443. Epub 2023 Jul 9. PMID: 37433367. https://pubmed.ncbi.nlm.nih.gov/37433367/

[4] Gildemeister, D. et al 2022. Improving the regulatory environmental risk assessment of human pharmaceuticals: Required changes in the new legislation. https://pubmed.ncbi.nlm.nih.gov/37354938/

Recommendations Action 1 – Guidelines for healthcare professionals on the prudent use of pharmaceuticals

1.1 Use the current guidelines regarding infections and rational antibiotic use as examples to develop guidelines regarding the use of all pharmaceuticals and their correct prescription at the EU level (start with hormones and endocrine active substances).

1.2 Competent authorities of the Member States should promote the use of diagnostic tests before prescription depending on pathology, e.g., for antibiotics.

1.3 Guidelines should promote use of human medicinal products as indicated in the summary of product characteristics, e.g., relating to duration(s) of treatment and posology, and not according to outdated prescription habits.

1.4 Rational use should be promoted, and unnecessary use should be avoided, for prescription as well as over-the-counter medications. This by a combination of actions including guidelines, training, and education, for health care professionals as well as the general public.

Recommendations Action 2 – Environmental aspects as a part of medical training and professional development programs

2.1 Environmental aspects of pharmaceuticals should become a mandatory part of the education of healthcare-professional students and in continuous professional development programs of healthcare professionals (life-long learning).

2.2 Task forces should be formed at national and EU level consisting of experts having experience with or ambitions for including environmental aspects of pharmaceuticals into healthcare education/training. These task forces should include environmental as well as health care experts and should define which aspects should at a minimum be included in the curriculum.

2.3 Educational material regarding pharmaceuticals in the environment should be developed and become freely available online to reach more students and universities.

Recommendations Action 3 – Environmental considerations in the advertising and prescription of medicinal products

3.1 ***a.*** The competent health authorities should communicate the environmental impact of medicines to the public and the health professionals.

b. Information relating to the company's environmental policy should be published by MA holders, but only through corporate communication unrelated to the promotion of marketed medicinal products.

c. The MA holders should advertise and communicate environmental safety and appropriate waste handling to the public, dispensers, and prescribers. To raise awareness, different types of media could be used including social media.

3.2. ***a.*** Environmental claims can be made related to a medicine, but they should not be the main message of any advertisement and should be based on scientific and regulatory approved environmental safety information related to the substances in the product.

b. Medicinal product advertising should not contain environmental claims affecting the appreciation of the therapeutic value of the medicinal product advertised.

c. If a recycled material is used in the pharmaceutical product, it should be specified in which part of the product and the content of the recycled material.

3.3 Prescription status should be considered for any medicine containing an active pharmaceutical ingredient (API) presenting a risk or hazard to the environment according to the current environmental risk assessment (ERA) guideline.

Recommendations Action 4 - Strategies to reduce waste of medicines

4.1 ***a.*** Pack size of prescribed and over the counter medicines should be optimised with respect of the current therapeutic use. Especially products with an identified risk to the environment or to public health (e.g., high risk of antimicrobial resistance) should meet the unit-dose requirements or be available in different pack sizes, in order to dispense the exact quantity prescribed.

b. To reduce environmental impact, packaging requirements should be evaluated to encourage harmonization at EU level.

4.2 To reduce environmental impact, primary/secondary packaging with eco-design, sustainable life cycle of the material used for the packaging should be promoted when applicable to the pharmaceutical requirements.

4.3 Longer stability studies should be promoted by national and European competent authorities to approve longer shelf-lives for medicinal products.

Recommendations Action 5 – Exchange of best practices on the environmentally safe disposal of medicinal products and clinical waste

5.1 Promoting practices that reduce the volume of waste generated, for example replacing disposable products with reusable and recyclable options wherever it can be achieved without affecting patient care or worker safety.

5.2 Developing strategies and systems along with strong oversight and regulation to incrementally improve healthcare waste segregation, destruction, and disposal practices with the aim of meeting national and international standards.

5.3. Where feasible, favoring a safe and environmentally sound treatment of hazardous health care wastes (e.g. by autoclaving, microwaving, steam treatment integrated with internal mixing, and chemical treatment) over medical waste incineration.

5.4 Raising awareness regarding the environmental risks related to healthcare waste, and of safe practices. Develop training programs for healthcare professionals on the implementation of best practices in waste management.

Recommendations Action 6 – Waste collection schemes of unused medicinal products

6.1 ***a.*** The EU should provide guidelines to help the National Competent Authorities (NCAs) and stakeholders to design their own take-back schemes and, where possible, include the Extended Producer Responsibility concept.

b. Ensuring easy access to collection points.

c. Conducting an EU-wide survey on user adherence to the take-back schemes and other ways to disposal of pharmaceutical residues.

6. 2 ***a.*** Carry out active campaigns targeted at the general public to encourage citizens to return their unused, expired, or discontinued medications to take-back sites.

b. Inclusion of a (harmonized) pictogram on the outer packaging or leaflet (e.g., crossed toilet) could help to improve communication and to reduce improper disposal.

6.3 Extended Producer Responsibility (EPR) could be used by the Member States to finance take-back schemes and awareness campaigns to encourage citizens to return their unused or expired medicines to designated collection points.

Recommendations Action 7 – Improve the level of environmental expertise in the Committees and networks

7.1 Regular training opportunities should be installed by providing a comprehensive training program including annual training meetings and recorded webinars in addition to the offered training modules provided by the European Network Training Centre (NTC) at EMA.

7.2 A budget at EC level is proposed to address environmental risk assessment (ERA) training requirements, in particular with a new ERA guideline version and/or new legislative framework coming into force. Reimbursement of travel costs should be available for all ERA-assessors interested in attending the training in person or remotely.

The organization and content of ERA-trainings with the possibility to attend in person could be in the remit of for example an ERA Operational Expert Group (OEG) to be established under the umbrella of the Non-clinical Working Party (NcWP) at EMA and should not be dependent on the initiative of individual Member States (see also 7.6).

7.3 Creation of an online communication platform for ERA assessors from Member States where questions can be raised and answered by experienced assessors be considered. The platform could be hosted by e.g., EMA.

7.4 Experienced regulatory ERA experts, who could be consulted on ERA issues in general as well as on on-going procedures, should be appointed and their contact information provided in a database for example under the lead of an ERA-OEG or an ERA related European Specialised Expert Community (ESEC).

7.5 EC funding should be provided directly to the National Competent Authorities to contract external environmental experts and for qualification of non-clinical assessors.

7.6 A new ERA advisory group should be established at EMA. This could be a permanent ERA Working Party (human) inside the non-clinical domain under the responsibility of the CHMP or alternatively, a new ERA-OEG under the responsibility of the NcWP.

III. Introduction

The mandate

The Pharmaceutical Committee endorsed in 2019, at the November and December meetings, the establishment of an ad hoc working group to focus on the EU strategic Approach on pharmaceuticals in the environment[5], in particular on the actions and measures that fall under the competence of the Member States. In March 2020 the Pharmaceutical Committee endorsed the mandate of the working group, originally set for three years.[6]

The scope of the working group was to provide recommendations for the following areas:

- Promote the development of guidelines for healthcare professionals on the prudent use of pharmaceuticals posing a risk to or via the environment.
- Explore, in cooperation with relevant stakeholders, how environmental aspects could become part of medical training and professional development programs.
- Foster best-practice exchanges between Member States on how environmental considerations are taken into account in the advertising and prescription of medicinal products and the choice of therapy more generally, where appropriate.
- Explore the possibility of reducing waste by optimizing the package size of pharmaceuticals so that medicines can be dispensed in quantities better matching needs, and by safely extending use-by (expiry) dates so that fewer medicines that are still usable have to be thrown away.
- Facilitate the exchange of best practices among healthcare professionals on the environmentally safe disposal of medicinal products and clinical waste, and the collection of pharmaceutical residues as appropriate.
- Assess the implementation of collection schemes for unused pharmaceuticals and consider how their availability and functioning could be improved, how to increase public awareness of the importance of using them, and how extended producer responsibility could play a role in reducing inappropriate disposal.[7]

The working group would also provide recommendations to "Improve the environmental risk assessment and its review for the human medicines" that fall under the competence of the Member States.

[5] COM (2020) 761 final, 25.11.2020, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020DC0761&from=EN

[6] Pharmaceutical Committee 12 March 2020, Agenda Item 10. Mandate of the ad-hoc working group to focus on the EU strategic Approach on pharmaceuticals in the environment.

[7] Commission Communication COM (2019) 128 final of 11 March 2019, from the sections 5.1, 5.3 and 5.4.

The tasks of the working group are related to human medicines. The working group would exchange views and information about the experience of Member States, examine national initiatives, share best practices and/or develop guidance or propose specific measures and further actions, where relevant, in relation to the above-mentioned actions in the Commissions Communication.

Following the adoption of the pharmaceutical strategy for Europe[8], the working group was also given the task to draft a concept paper to address the environmental challenges and reply to certain flagship actions of the strategy, to bring the necessary support in the revision of the EU pharmaceutical legislation. The concept paper would outline expert views that would be solutions oriented to bring the necessary support in the revision of the EU pharmaceutical legislation (Directive 2001/83/EC) and as considerations on main elements and business processes that may need to be reflected in the regulatory framework. The deadline for this concept paper was March 2022 with an interim deadline for a mature draft in January 2022. Due to the additional task the Pharmaceutical Committee endorsed a revised mandate of the ad hoc working group in 2021 that extended the mandate to 31 March 2024.[9] The mandate and the revised mandate are presented in Annex 8. The Pharmaceutical Committee had the possibility to further extend the duration and the scope of this mandate. For this reason, the ad hoc working group was also tasked to draft a revised mandate for discussion and possible endorsement by the Pharmaceutical Committee. Due to that extra task, the duration of the mandate got further extended until the end of 2024. During that time the working group are expected to finalize the report and produce a new mandate for the future work.[10]

The general process

The working group was established in March 2020 and was set up to focus on the EU strategic Approach on pharmaceuticals in the environment, in relation to human medicines and their impact on water systems, after use or incorrect disposal. During the work, the focus has shifted towards the overall environmental footprint, including for example greenhouse gas emissions, energy, water, and material use. Some of the recommendations do affect to the overall environmental footprint of pharmaceuticals in a positive way.

The working group included the Member States Austria, The Czech Republic, Finland, France, Germany, Ireland, The Netherlands, Slovenia, Spain, and Sweden, as well as the European Medicines Agency and the European Commission. The chairmanship was taken up by Sweden. A first meeting of the working group was organized on the 21st of February 2020 when the mandate and the working arrangements were discussed.

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[8] COM (2020) 761 final, 25.11.2020, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020DC0761&from=EN

[9] Pharmaceutical Committee, 1 December 2021. Revised mandate of the ad-hoc working group to focus on the EU strategic Approach on pharmaceuticals in the environment.

[10] Pharmaceutical Committee, 3 May 2024 (Decision by written procedure). Extension of mandate of the ad-hoc working group until end of 2024 and submission of a revised mandate for discussion in the Pharmaceutical Committee.

The working group was divided into seven sub-working groups based on the different areas and exchanged views and information about the experience of Member States, examined national initiatives and shared best practices.

First, an inventory of ongoing initiatives in the participating Member States was performed by the ad hoc working group members. Then a questionnaire was sent out to all Member States via the Pharmaceutical Committee in 2021 in order to identify best practices or examples. A compilation of the questionnaire was made in 2022 and was used by the subgroups as input for recommendations.

The group was also given the task of drafting a concept paper that should outline expert views that should be solutions oriented to bring the necessary support in the revision of the EU pharmaceutical legislation (Directive 2001/83/EC) and as considerations on main elements and business processes that may need to be reflected in the regulatory framework on the following aspects:

- Strengthening the environmental risk assessment requirements and conditions of use for medicines and taking stock of the results of research under the innovative medicines initiative.
- Greener pharmaceuticals with respect to antimicrobial resistance.

The concept paper was finalized in March 2022 and includes two topics that outline solutions oriented expert views that bring the necessary support in the revision of the EU pharmaceutical legislation (Directive 2001/83/EC). Two articles were published:

- Improving the regulatory environmental risk assessment of human pharmaceuticals: Required changes in the new legislation, with six purposes to strengthened environmental risk assessment for human medicines.[11]

- Proposal for regulatory risk mitigation measures for human pharmaceutical residues in the environment.[12]

A draft of the final report of the working group was presented and discussed at the meeting in Sweden in May 2023 during the Swedish Presidency to the European Council. In total there has been 21 online meetings. The progress of the work has been presented to the Pharmaceutical Committee on a couple of occasions during the work. Finalization of the work regarding recommendations, good practices, and conclusions are now presented.

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[11] Gildemeister D et al. Improving the regulatory environmental risk assessment of human pharmaceuticals: Required changes in the new legislation. Regul Toxicol Pharmacol. 2023 Aug;142:105437. doi: 10.1016/j.yrtph.2023.105437. Epub 2023 Jun 22. PMID: 37354938. https://pubmed.ncbi.nlm.nih.gov/37354938/

[12] Moermond CTA, et al. Proposal for regulatory risk mitigation measures for human pharmaceutical residues in the environment. Regul Toxicol Pharmacol. 2023 Sep;143:105443. doi: 10.1016/j. yrtph.2023.105443. Epub 2023 Jul 9. PMID: 37433367. https://pubmed.ncbi.nlm.nih.gov/37433367/

The questionnaire

The questionnaire was sent out to all Member States via the Pharmaceutical Committee in 2021. It was answered by Austria, Belgium, Croatia, Czechia, Cyprus, Denmark, Germany, Spain, Finland, France, Italy, Luxembourg, Norway, Poland, Romania, Sweden, and Slovenia. As an addendum, members of the ad hoc working group on Pharmaceutical in the Environment were asked to provide their insights on the best practices to be shared with the other Member States.

The questionnaire included questions to address the following actions:

- Actions 1 and 2 on prudent use and training of healthcare professionals
- Action 3 on advertising and prescription
- Action 4 on the pack sizes/packaging and expiry date (shelf-life) of pharmaceuticals
- Action 5 on the safe disposal of pharmaceuticals
- Action 6 on the collection schemes of unused pharmaceuticals.

For Action 7 on the improvement of the environmental risk assessment (ERA) and its review in human medicines the current situation in the Member States and resulting needs was concluded to be obvious. Therefore, this ERA subgroup developed its recommendations without adding further questions to this questionnaire.

The questions were chosen to give a comprehensive overview of the practices in all EU/EEA Member States concerning the pharmaceuticals in the environment. The replies from the responding EU/EEA Member States where further considered by the members of the ad hoc working group when drafting of recommendations that became further discussed within the work.

The questions and answers of the questionnaire are presented in the section of each action below.

Recommendations regarding the whole life cycle

The work included the whole life cycle of the medicinal products from the first step of drug development and approval via production to use, cassation and the final waste management. The life cycle of a medicinal product is presented in Figure 1.

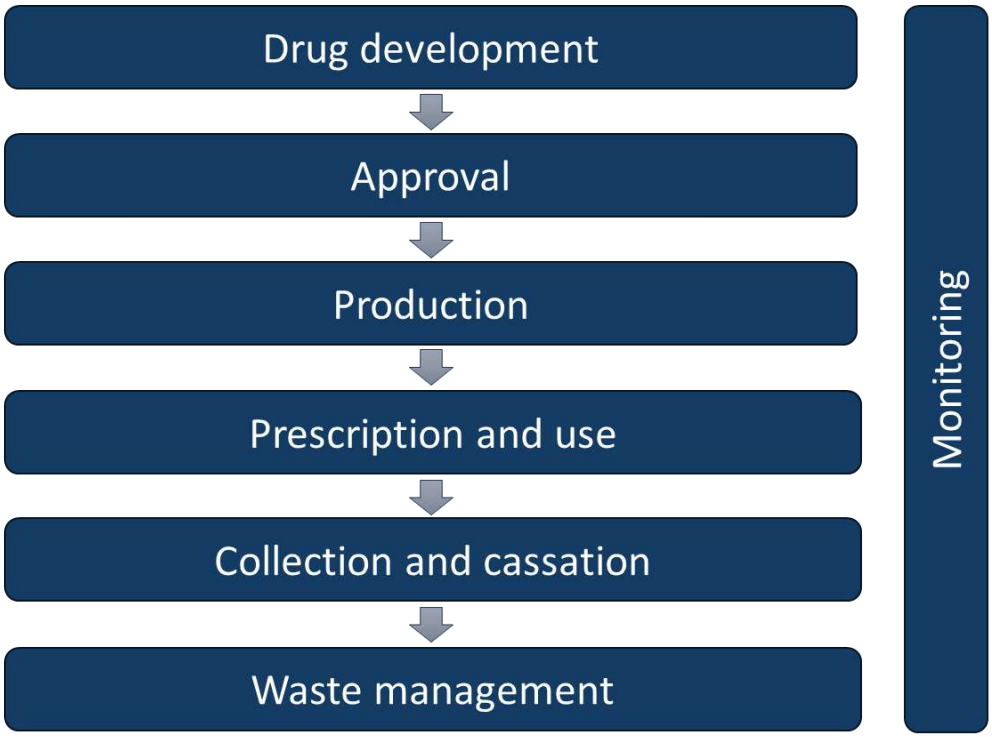

Figure 1. The life cycle of a medicinal product. The suggested recommendations include the life cycle of the medicinal products as drug development, approval, production, prescription and use, collection and cassation and waste management.

IV. The outcome of the sub-working groups

1. Guidelines for healthcare professionals on the prudent use of pharmaceuticals – Action 1

Introduction

The assignment for the sub working group was to promote the development of guidelines for healthcare professionals on the prudent use of pharmaceuticals posing a risk to or via the environment. Healthcare professionals need guidelines in their day-to-day work, to help them make informed choices. In action 1 examples of guidelines and best practices that take environmental aspects into account were identified. These existing guidelines and best practices could be used as an inspiration to other Member States who can adapted them to country-specific or local situations.

The guidelines should be practice-based and not too general. The task of action 1 was to elaborate on these guidelines, but not further develop them. Action 1 is strongly linked to action 2 (training of healthcare professionals), which addresses the education of healthcare professionals.

Overview of current known situation, examples

Many Member States have guidelines on prudent use of medicines, and some have guidelines for specific groups (e.g., antibiotics or polypharmacy). Most guidelines are developed and used on a national level. However, in some countries the healthcare system is organized on a more regional level, and thus guidelines may be developed on a regional or even a local scale. The different situations in different countries means that there is no perfect solution that will suit all.

Besides the potential environmental risks of pharmaceuticals in general, for antimicrobials prudent use and reducing their presence in the environment is of particular importance due to the global increase of antimicrobial resistance. There are already many initiatives to reduce the use of antibiotics and most countries have extensive guidelines, as has the European Commission[13]. Some of these guidelines could also serve as examples on how to deal prudently with other pharmaceuticals.

Healthcare without Harm (HCWH) has published several guidelines[14], such as the Global Green and Healthy Hospitals (GGHH)[15] Waste Guidance Document which is accessible to members of the HCWH's Global Green and Healthy Hospitals network and sets out ways to meet the target

[13] EU-JAMRAI (Joint Action Antimicrobial Resistance and Healthcare-Associated Infections) Publications and Results. https://eu-jamrai.eu/results/
[14] Health Care Without Harm. https://noharm-global.org/
[15] Global Green and Healthy Hospitals (GGHH) guidance documents. https://greenhospitals.org/guidance-documents

of reducing, managing, and treating waste in the most sustainable way. The Pharmaceutical Group of European Union has published the report Best Practice Paper on Green and Sustainable Pharmacy in Europe[16].

There are only very few guidelines that deal with environmental aspects. Mostly, this is a bycatch – prudent use of pharmaceuticals may be of primary benefit for the patient (fewer side effects) or have economic gains (less use – less costs). Although the environment in those cases was not the reason for writing these guidelines, the environment also gains from them. In the Netherlands, the NHG (General Practitioner's Association) has since 2023 included the environmental risks of pharmaceuticals whenever they revise their guidelines. An example of this is a revised guideline on pain treatment where it is stated that nonsteroidal anti-inflammatory drugs (NSAID) have a higher impact on the environment than paracetamol [17]. In Sweden, the Drug and Therapeutics Committee at Region Stockholm, in conjunction to the database Pharmaceuticals and Environment, has compiled a list of 25 active pharmaceutical ingredients (APIs) considered as environmentally harmful[18] and suggested concrete proposals for such APIs on how to work towards reduced environmental impact.[19]

Recommendations

Recommendation 1.1

Use the current guidelines regarding infections and rational antibiotic use as example to make guidelines on the use of all pharmaceuticals and their correct prescription at the EU level (start with endocrine active substances).

For antibiotics, in many countries' guidelines exist for prudent use, to reduce the amount of antibiotics used and the associated risks of antibiotic resistance. These guidelines can be used as examples for other pharmaceutical products. Because of their specific risks to the environment, endocrine active substances receive special attention in the marketing authorization ERA.[20] They should also receive special attention when updating guidelines for medical professionals. A working party could be formed to start with this.

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[16] PGEU Best Practice Paper on Green and Sustainable Pharmacy in Europe. https://www.pgeu.eu/publications/pgeu-best-practice-paper-on-green-and-sustainable-pharmacy-in-europe/

[17] NHG-Richtlijnen. https://richtlijnen.nhg.org/standaarden/pijn#volledige-tekst-richtlijnen-diagnostiek

[18] Kloka listan, Janusinfo Region Stockholm. https://klokalistan.se/ updated in Swedish. In English: The Wise List https://janusinfo.se/inenglish/thewiselist2015inenglish.4.2baa5e3e161e6f22189240.html

[19] Förteckning över miljöbelastande läkemedel med åtgärdsförslag framtagen inom ramen för Region Stockholms miljöprogram 2017–2021. Forteckning-over-miljobelastande-lakemedel.pdf (janusinfo.se)

[20] European Medicines Agency. Environmental risk assessment of medicinal products for human use - Scientific guideline. EMEA/CHMP/SWP/4447/00 Rev. 1. 15 Feb 2024.

Recommendation 1.2

Competent authorities of the Member States should promote use of diagnostic tests before prescription depending on pathology, e.g., for antibiotics.

Being able to rapidly and accurately determine the causative pathogen in bacterial infections is a critical step in clinical management. Furthermore, with the growing global burden of antimicrobial resistance, rapid antimicrobial susceptibility testing (AST) is increasingly important to guide therapy. Given the necessity of reducing excessive antibiotic use, we also urgently need diagnostic strategies that can help exclude the presence of infection and define non-infectious inflammatory states for which antibiotics are not required.[21] [22] [23]

Recommendation 1.3

Guidelines should promote use of human medicinal products as indicated in the summary of product characteristics, e.g., relating to duration(s) of treatment and posology, and not according to outdated prescription habits.

In this way, the main dispensing posology, corresponding to an authorised pack size, would be promoted by prescribers. The Summary of Product Characteristics (SmPC) could be the support of this recommendation. The dispensing should be tightened to the prescribed quantity to reduce the number of expired/unused medicines.

As a general recommendation, it could be included in the SmPC mentioning that if, in the physician's opinion, the symptoms/parameters/signs indicate that the patient is not benefiting from continued treatment, the treatment should be discontinued. Patients should not keep on repeating treatment but consult for alternatives.

Environmental considerations related to treatment should be communicated by national competent authorities and based on scientific and/or regulatory approved information. If available, such information could become part of the guidelines, also to facilitate choices between active substances. Prescription/dispensation software can support this communication.

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[21] New Microbiological Techniques for the Diagnosis of Bacterial Infections and Sepsis in ICU Including Point of Care. 2021. A. M, Peri et al. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8207499/

[22] Antimicrobial susceptibility testing: An updated primer for clinicians in the era of antimicrobial resistance: Insights from the Society of Infectious Diseases Pharmacists. 2023. E. Wenzler et al. https://pubmed.ncbi.nlm.nih.gov/36825480/

[23] Update from the European Committee on Antimicrobial Susceptibility Testing (EUCAST). 2022. C. G. Giske et al. https://pubmed.ncbi.nlm.nih.gov/34346716/

Recommendation 1.4

Rational use should be promoted, and unnecessary use should be avoided, for prescription as well as over the counter medications, by a combination of actions including guidelines, training, and education, for health care professionals as well as the general public.

Preventing unnecessary use of medicines does not only benefit the environment, as it will reduce the load of pharmaceuticals entering water after use and the environmental footprints from production. It will often also benefit patients if they experience side effects. Examples of pharmaceutical use that are easy to avoid are prescription of antibiotics for viral infections, use of stomach medication when some easy lifestyle changes may also help, and use of NSAID gels on parts of the body where cooling gels without active ingredients work just as well.

2. Environmental aspects as a part of medical training and professional development programs – Action 2

Introduction

The assignment for the sub working group was to investigate how environmental aspects could become part of medical training and professional development programs. In healthcare, the focus is always on the patient. However, sustainability issues such as climate impact and water quality and quantity also affect our living environment and thus our population health. As such, healthcare is also responsible for their own sustainability aspects. Healthcare professionals can incorporate sustainability in their day-to-day-work, e.g., by promoting prudent use of pharmaceuticals and efficient waste management. Existing guidelines for these topics may be improved and new ones may be developed (see action 1). However, to make healthcare professions start using these guidelines in their daily practice, it is necessary to incorporate them in their education.

Although the focus of the current document is pharmaceuticals, actions regarding including environmental aspects of pharmaceuticals in the education are intertwined with other sustainability aspects, such as carbon footprints and (raw) materials use, often together defined as planetary health.

Examples and good practices

Examples of education initiatives in some Member States are presented below.
In Germany a joint project was performed on minimizing the input of human medicinal products into raw water (MinimEHR) by the Federal Institute for Drugs and Medical Devices (BfArM) and the Federal Environment Agency (UBA). A report, “Report UBA-BfArM project group on minimizing the input of medicinal products for human use into raw water (MinimEHR)”, was published in March 2017 to present the results of this research. One chapter was dedicated to actions to increase the current knowledge on the issue and/or fostering the elimination and removal of medicinal products. Actively involving public society and professionals through information and education was one of the proposed actions, including the idea of “Integrating environmental considerations into medical education and advanced training”.

In Finland the Generation Green project started in 2015. This project has introduced a holistic approach to the implementation of green principles and practices in educational programs in pharmaceutical and medical sciences at the University of Helsinki. Details on the evolution of green pharmacy practice in the Faculty of Pharmacy, following a previously published framework for change management, and the dissemination of the principles and good

practices into medical education were published by Siven et al.[24] The green pharmacy principles have been included as integrated contents in domain-specific studies in all aspects of medicines lifecycle instead of in stand-alone classes in the pharmacy studies (bachelor's and master's degree). The implementation in the Faculty of Medicine (for training of medical doctors) of the University of Helsinki has just started. A study with medical students who were introduced to environmental aspects of medicines at the University of Helsinki for the first time was recently published by Lapatto-Reiniluoto et al., 2022[25]. The results confirmed the suitability and feasibility of the approach to introduce this subject to students, and the authors propose that the same method can be used also when explaining the issue to medical professionals.

In France, environmental education is mandatory from 2023 and a digital educational module in Medicine and Environmental Health is provided in all 36 medical faculties.

The module targets second- or third-year medical students and aims to provide a "systemic, evolving, nuanced and complex", but also transdisciplinary and multi-scale (local-global, individual-collective) view. At the end of 2022, videos with around thirty speakers from different disciplines were produced and work was carried out on a platform. In total, the module includes around twenty videos and lasts six hours. It includes several blocks: approaches to health; planetary boundaries and health (environmental impact and dependence energy of the health system, biodiversity, ecosystems, etc.); environment, health and society; action levers (highly requested by the students).[26] [27]

In the Netherlands, environmental aspects, including pharmaceuticals in the environment, are currently not a formal part of the curriculum at universities and practical education for doctors, pharmacists, and other healthcare professionals. An overview of the current education with a plea to introduce sustainability in medical curricula, the barriers against this and ways to deal with those, was recently written by Prof. dr. Peter Blankestijn[28]. During the past few years, more and more universities are developing modules to include in their education modules. Examples are the Pharmacy Game[29], developed by Groningen University and implemented in 9 universities all over the world, where a sustainability module is added,

[24] Generation Green – A holistic approach to implementation of green principles and practices in educational programmes in pharmaceutical and medical sciences at the University of Helsinki. 2020. https://www.sciencedirect.com/science/article/pii/S2352554119303778
[25] Medicines, environment and clinical pharmacology. 2022. O. Lapatto-Reiniluoto et.al. https://pubmed.ncbi.nlm.nih.gov/35603459/
[26] A la rentrée prochaine, les étudiants en médecine seront formés à la santé environnementale. 2023. https://francais.medscape.com/voirarticle/3609739?form=fpf
[27] Quand l'environnement s'invite dans les études de médecine. https://www.letudiant.fr/etudes/medecine-sante/quand-lenvironnement-sinvite-dans-les-etudes-de-medecine.html
[28] Towards sustainable environmental development in nephrology care, research and education. 2020. https://www.nature.com/articles/s41581-020-00353-8
[29] The Pharmacy Game, website. https://pharmacygame.education/

and the P-scribe system[30], where Maastricht University has added modules to teach students how to take sustainability into account when making prescription choices.

In the third Dutch Green Deal on Sustainable Healthcare, starting in 2023, one of the five pillars is aimed at education. This pillar is mainly aimed at sustainability and planetary health, which are very wide topics, but this also provides a chance to add specific blocks focusing on medicines and the environment. End 2023, an ERASMUS+ project has started with 9 University Medical Centers (5 from the Netherlands and 4 from other Member States) to provide education materials for sustainable prescribing.[31]

Pharmacotherapy audit meetings (PTAM; FTOs in Dutch) are used in the Netherlands for professional education. These PTAMs consist of local groups of 8 to 12 general practitioners and 1 to 3 pharmacists. The groups meet around 6 times a year for one to two hours to discuss new developments, (medication) guidelines and their own medication prescribing and delivery policy. In 2018, the IVM (Dutch Institute for Rational Use of Medicine) together with the professional organizations of general practitioners (NHG) and pharmacists (KNMP), developed a module on pharmaceuticals in the environment. The module is currently adapted so it can also be used for professional education in hospitals and other care homes.

In Spain, the Pharmacy Faculty of the Basque Country University (UPV) has recently developed an 8-months post-graduate course on pharmaceutical pollution. It is intended for healthcare professionals and consists of two modules covering the (1) problems of pharmaceuticals in the environment and (2) the solutions (including greener pharmacy, take-back schemes, and improvements of legislation among others)[32].

In Sweden, to increase the knowledge about the environmental impact of pharmaceuticals and what to do as a prescriber, an e-learning course (E-learning course on pharmaceuticals in the environment, Region Stockholm) has been produced within the framework of the environmental program for Region Stockholm 2017–2021 (Environmental program for Region Stockholm 2017-2021). Uppsala University has in collaboration with the Knowledge Center for Medicines in the Environment, Swedish MPA, established the course Drugs in the Environment (7.5 credits) for pharmaceuticals students. This is a freestanding course in pharmaceutical sciences that covers environmental aspects of drugs during the whole life cycle.[33]

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[30] Pscribe internationaal e-learning platform voor farmacotherapie onderwijs. https://www.pscribe.nl/nl-NL/Entrance/Home/Index
[31] Planetary Health Education in Prescribing. https://www.prescribingeducation.eu/planed_prescribing/
[32] Experto o Experta de Universidad. Universidad del Pais Vasco. https://www.ehu.eus/es/web/graduondokoak/experto-universidad-farmacontaminacion
[33] Drugs in the Environment. Uppsala universitet. https://www.uu.se/en/study/course?query=3FS011

Conclusions and recommendations

The main findings on which the recommendations are built upon are as follows:

- Environmental aspects related to the drug development, manufacturing, distribution, use, and end-of-life of pharmaceuticals are not systematically included in pharmacy and medicinal studies/training programs and continuous professional development programs for healthcare professionals within EU.
- The environmental aspects are not a mandatory topic in most healthcare professionals teaching/training curricula in EU Member States.
- Some Member States offer optional programs covering selected environmental aspects. Some of them are focusing on specific aspects on pharmaceuticals and environment, such as release of antibiotics (Norway), pharmaceuticals pollution (Spain), and handling of biological and chemical products (waste), including medicines (Norway, Denmark, France, Italy).

Following the responses and additional inputs from the members of the Ad-hoc WG-PiE, as well as the available literature, innovative approaches and best practices have been identified regarding how environmental aspects could best be incorporated in the education/training of healthcare professionals. These have led to the following recommendations.

Recommendation 2.1

Environmental aspects of pharmaceuticals should become a mandatory part of the education of healthcare-professional students and in continuous professional development programs of healthcare professionals (life-long learning).

Recommendation 2.2

Task forces should be formed at national and EU level with experts having experience with or ambitions for including environmental aspects of pharmaceuticals into healthcare education/training. These task forces should include environmental as well as health care experts and should define which aspects should at a minimum be taken up in the curriculum.

Recommendation 2.3

Educational material on pharmaceuticals in the environment should be developed and become freely available online to involve more students and universities.

3. Environmental considerations in the advertising and prescription of medicinal products – Action 3

Introduction

The assignment for the sub working group was to focus on environmental aspects on advertising and prescription of medicinal products. The Directive 2001/83/EC on the Community code relating to medicinal products for human use sets out a general framework on advertising and prescription that every european country details in its national health legislation.
The link between environmental considerations of pharmaceuticals and advertising/prescribing is under consideration (concept paper on environmental challenge and revision of pharmaceutical legislation). However, the choice of therapy should remain independent of the environmental considerations.

Current situation

Advertising of medicinal products in Europe and in some Member States

Europe

According to the Directive 2001/83/EC (article 97), the advertising of medicinal products shall be subject to effective and adequate monitoring. It addresses all types of pharmaceuticals including prescription medicines and non-prescription medicines, vaccines, blood and blood components, gene therapy products and advanced therapies.

In article 98, the directive states that the Marketing Authorization Holder (MAH) shall establish a scientific service in charge of the information about medicinal products and ensure that the decisions taken by the authorities or bodies responsible for monitoring advertising of medicinal products are compliant with. Nevertheless, the Directive does not give precise rules regarding the control of pharmaceutical advertising, leaving the Member States a certain degree of freedom in the implementation of such monitoring.

A ruling from the Court of Justice of the European Union (Case C-374/05) sets precedence as to how the directive relates to national legislation. The ruling states that the Directive brought about complete harmonisation in the field of advertising of medicinal products and lists expressly the cases in which Member States are authorised to adopt provisions departing from the rules laid down by that directive. Some of the national European implementations of the directive are detailed below.

In parallel, the European Federation of Pharmaceutical Industries and Associations (EFPIA) regularly publishes a Code of Practice which constitutes the collection of ethical rules for promotion of medicinal products to HealthCare Professionals (HCPs). Section 20.01. of the EFPIA Code of Practice 2019 states that each EFPIA member company must establish a scientific service in charge of medicinal products information and specifies that this scientific

service must include a medical doctor or a pharmacist who will be responsible for approving any promotional material before release.

Finland

Finnish Medicines Agency (Fimea) is the competent authority for supervising advertising of all medicines in accordance with the standards of the Medicines Act and the Medicines Decree in Finland. All statutes regarding the marketing of pharmaceuticals are based on the EU Directive 2001/83/EC relating to products for human use. In the supervision of advertising of medicines, the jurisprudence of the EU Court of Justice is taken into account with its details.

The Medicines Act and the Medicines Decree define the requirements for the information content of the promotion of medicines and legal target groups and the standards related to medicinal sales promotion targeting the health care personnel. Sections 91-93 of the Act and section 25 of the Decree specify in detail the minimum information that must be included, and the restrictions to be observed, when marketing a medicinal product.

In the advertising of prescription medicines in accordance with the regulations of the Medicines Act and the Medicines Decree, the aim should be to provide the most complete, up-to-date information about the medicinal product in accordance with the Summary of Product Characteristics. In addition to the product's indication for use, the information to be provided should cover the most important properties, therapeutic indications, efficacy and safety information. Advertisements must also include information on the conditions of prescribing and delivery, as well as information on the price and reimbursement information of the medicinal product. In the advertising of prescription medicines, it is necessary to give a realistic picture of the medicinal value of product as a whole and in relation to other treatment options. In appropriate advertising of medicines, the comparison of products is carried out individually, accurately and unambiguously. If non-identified, irrelevant or superficial claims have been used in the comparison, the advertisement cannot be considered in accordance with the legislation standards.

In 2023 environmental considerations are not used in advertising single medicinal products but mainly in companies’ corporate image marketing/ information in Finland.

France

French National Agency for the Safety of Medicines and Health Products (ANSM) is the competent authority for supervising advertising of all human medicines in accordance with law 2002-303 of March 4, 2002 and the law of December 29, 2011. All statutes regarding the marketing of pharmaceuticals are based on the EU Directive 2001/83/EC relating to products for human use. In the supervision of advertising of medicines, the jurisprudence of the EU Court of Justice is taken into account with its details.

Advertising intended for the public and advertising intended for health professionals is subject to prior authorization from the ANSM, called "advertising visa". In addition to the regulations, ANSM establishes advertising recommendations aimed to disseminate objective information about medicines and promoting their proper use. These recommendations may be general or relate to a particular class of drug or substance. Mandatory information has been defined such

as information relating to the benefit/risk, the therapeutic strategies or the level of reimbursement.

In 2023, environmental considerations are not formally prohibited in promotional communications for a particular drug. However, the information disseminated must be factual, verifiable and concerning the promoted product, and cannot constitute a main axis of communication insofar as this type of information cannot be sufficient for the recipient of advertisement to appreciate the therapeutic value of medicine.

For example, claims concerning a specific recycling circuit for the product administration device might be accepted. On the contrary, any claim or axis of communication specifically linking the promoted drug to a global environmental policy of the laboratory or claiming an unjustified positive environmental impact of the product, is refused.

However, to date, there is no specific advertising recommendation from ANSM, the evaluation of advertisements is made on a case-by-case basis. Reflections are underway on the methods of application of a new law (AGEC: anti-waste for a circular economy), in particular concerning the information that may appear in advertisements to the general public in favor of medicines.

Sweden

No pre-approval or pre-vetting of advertising. The Swedish Consumer Agency is responsible for supervision, not the Medical Products Agency. In Sweden, the Marketing Act sets the rules on environmental claims, and it relates in turn to Directive 2005/29/EG. This is supervised by the Swedish Consumer Agency.

More information about the situation of medicine advertising in other Member States is available on the website of CMS law firm.[34]

Conclusion

Despite the common basis which is in the EU Directive 2001/83/EC, promotional regulation is governed by different texts and structures in the different EU countries. There are local variations in each country regarding the responsible person and its roles and duties for validation of promotional material for example. Pharmaceutical companies must fulfil many local requirements to be in line with local regulations before promotional activities can be started at local level in EU countries. Among Member States, France and Sweden start to frame environmental considerations in pharmaceutical advertisements.

[34] CMS Expert Guide to advertising of medicines and medical devices. https://cms.law/en/int/expert-guides/cms-expert-guide-to-advertising-of-medicines-and-medical-devices

Prescribing of medicinal products in Europe and in some Member States

Europe

Prescription act is regulated by several guidelines and directives in the European Member States.

Title VI (i.e. Articles 70 to 75) of Directive 2001/83/EC defines the classification of medicinal product subject or not to medical prescription. The guideline on legal status for the supply to the patient of centrally authorised medicinal products addresses the criteria to be followed by the Committee for Medicinal Products for Human Use (CHMP) when determining the Legal Status of a medicinal product, as well as the way the Legal Status is implemented in the CHMP opinion. By the regulation (EC) No 726/2004, when adopting its opinion, the CHMP shall include a proposal concerning the criteria for the prescription or use of the medicinal products in accordance with Article 70(1) of Directive 2001/83/EC. The Directive 2011/24/EU Article 11 permits the recognition of prescriptions issued in another Member State.

The Guideline on changing the classification for the supply of a medicinal product for human use is used by competent authorities to facilitate harmonization in this classification, within the Community, of medicinal products restricted to medical prescription and of medicinal products available without a medical prescription.

France

According to Article 8 (article R.4127- 8 of public health code, in French code de la santé publique (CSP)), “within the limits fixed by law, the doctor is free to prescribe, which will be those he considers most appropriate in the circumstances”.

However, this freedom is restricted as certain medicinal products are subject to special prescription and dispensing conditions due to the constraints and risks of their use, their degree of innovation or for other public health reasons. They cannot be prescribed by all doctors, even if justified by the patient's condition. They are classified into five main categories (article R.5121-77 of the public health code):

- Hospital use only (prescription, supply and administration).
- Hospital prescription only.
- Or initial hospital prescription only.
- Secialists prescription only.
- Special supervision throughout the treatment.

According to Article 6 (article R.4127- 8 of public health code), a physician, a dentist (dental care), a midwife (restricted list), a biologist-head of a medical biology laboratory (biological exams), a EU professional healthcare authorized to prescribe in EU, an advanced practice nurse (conditions in article R5132-6 of public health code) can prescribe medicines for human use likely to present a direct or indirect danger to health, medicines for human use containing substances whose activity or adverse effects require medical supervision and any other product or substance presenting direct or indirect health risks (article L5132-6 of public health code).

Conclusion

Despite the common basis which is in the EU Directive 2001/83/EC, prescription regulation is governed by different texts and structures in the different EU countries. There are local specificities in each country regarding the over-the-counter /non-prescribed medicines and prescribed medicines, the way to prescribe with the e-prescription in force in several EU Member States authorized by Directive 2011/24/EU.

Examples, good practices and recommendations

Advertising

In most of EU countries, there is no guideline or practice dealing with environmental considerations concerning advertising of medicines and the choice of therapy. There is no objection to do such claims by the national legislation if it respects the requirements of the national legislation in advertising of medicinal products. However, the environmental claims should be supported by summary of product characteristics (SmPC) information in Austria, Spain, Finland, Poland and Sweden and by exact, up-to-date and verifiable information in Belgium.

There is no explicit mentioning of environmental aspects in articles 86-100 of Directive 2001/83/EC or Articles 119-122 of Regulation (EU) 2019/6. However, changes should be proposed taking into account the Concept paper on environmental challenges, January 31, 2022 and the ongoing revision of the pharmaceutical legislation.

The recommendations could be included in the revision of the Directive 2001/83/EC from the proposal of amending Directives 2005/29/EC and 2011/83/EU to ensure a good practice of environmental claims in human medicines products advertising. To this date, there are no EU authorized classifications or codes/symbols for demonstrating environmental safety for certain substances or medicinal products.

Since March 2022, the European Commission is proposing to update the EU consumer rules to empower consumers for the green transition, especially to step up the protection of consumers against greenwashing practices (i.e. misleading environmental claims).

Recommendation 3.1

a. The competent health authorities should communicate on the environmental impact of medicines to the public and the health professionals.

b. Information relating to the company's environmental policy should be published by MA holders, but only through corporate communication unrelated to the promotion of the marketed medicinal products.

c. The MA holders should advertise and communicate on environmental safety and appropriate waste handling of general public, dispensers and prescribers. To raise awareness, different types of media could be used including social media.

Recommendation 3.2

a. Environmental claims can be made related to a medicine, but they should not be the main message of any advertisements and should be based on scientific and regulatory approved environmental safety information related to the substances in the product.

b. Medicinal product advertising should not contain environmental claims affecting the appreciation of the therapeutic value of the medicinal product advertised.

c. If a recycled material is used in the pharmaceutical product, it should be specified in which part of the product or/and the percentage of the product issued from this recycled material.

Prescription

In most of the EU Countries, no guidelines or practices are in place on how to take into account environmental considerations in the prescription of medicines and the choice of therapy . In three countries (Austria, France and Spain), guidelines are only available for antibiotic prescribing to prevent antimicrobial resistance.

Recommendation 3.3

Prescription status should be considered for any medicine containing an active pharmaceutical ingredient (API), presenting a risk or hazard according to the current environmental risk assessment (ERA) guideline.

At the time of the prescription, the prescriber should give information, instructions including waste disposal of medicines and prudent use of medicines.

4. Strategies to reduce waste of medicines – Action 4

Introduction

The assignment for the sub-working group was to bring strategies to reduce waste of medicines. An ageing demographic, the rise of chronic health conditions, the availability of inexpensive generic treatments, and the advent of "lifestyle medicines" have been the key drivers of increased use of medicines within the European Region.[35] [36] Moreover, the onset of e-commerce, the increase of over-the-counter (non-prescribed) medicines, substitution of reference products by multiple generics and biosimilars, medical device development and universal (or near-universal) coverage of health care costs for a core set of services, are driving an expanding use of pharmaceuticals within European countries. This rise in pharmaceutical use and "misuse". The resulting increase in environmental exposure of medicines could have significant adverse repercussions on wildlife and ecosystems. In addition to reducing the environmental burdens of the drug products and particularly the active pharmaceutical ingredient (API), efforts should also be made to reduce the volume and weight of packaging materials, and to eliminate packaging which is non-essential for the protection of the contents of medicinal products.[37]

It is important that several strategies aiming at mitigating the environmental impact of human medicinal products are put in place for a reduction in their use and better management without compromising their effectiveness, availability, or accessibility. Optimizing the pack size of pharmaceuticals and/or the amount of package material and extending their expiry dates may be a part of this strategy.

Current situation

Medicine pack size, packaging, and their environmental impact

The provisions related to labelling and package for Centrally Authorised Products (CAPs), Mutual Recognition Products (MRPs), Decentralised Authorised Products (DCPs) and Nationally Authorised Products (NAPs) are determined in the Title V of the Directive 2001/83/EC[38].

The pharmaceutical form and the content by weight, by volume or by dosage units of the product are among these particulars (Art. 54c). The total contents (weight/volume/dosage units) contribute to the dimension of the pack size.

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[35] Pharmaceutical waste in the environment: Thomas, Felicity. Issue 1, Public Health Panorama: s.n., 2017, Vol. volume 3.
[36] The Advent of Lifestyle Medicine. Kong, Byung-Il Yeh and In Deok. 1, March 2013, J Lifestyle Med, Vol. 3, pp. 1-8.
[37] WHO. Guidelines on packaging for pharmaceutical. WHO Technical Report Series, 2002, No. 902.
[38] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.

The Notice to Applicants, Guideline on the packaging information of medicinal products for human use[39] recommends that:

"When presenting a range of pack sizes for a medicinal product it is important that the principles of rational use of medicinal products are taken into consideration. As a EU marketing authorisation is valid throughout the EU, every pack size covered by the authorisation may be available in any Member State. Therefore, the appropriate range of pack sizes should be chosen in accordance with the duration(s) of treatment and in accordance with the posology in the summary of product characteristics, and not in accordance with local traditions or prescription habits. For example, there could be: - one pack size for a short course of treatment, - one pack size for a monthly course of treatment - and one pack size for each multiple of the above."

Apart the above recommendation, there is no provision in the EU legislation regarding the pack sizes in terms of number of dosage units or total amount in the container (e.g., cream, paste). There is neither provision concerning environmental aspects with regards to the choice of pack size. As a rule, it remains the choice of the Marketing Authorization Holder (MAH) which pack sizes of the approved range that are marketed. However, the principles of rational use of medicinal products should be taken into consideration and there might be national provisions for certain pack sizes. Additionally, the concept paper on environmental challenges propose to add to the legislation, that products with an identified risk to the environment or to public health (e.g., high risk of antimicrobial resistance) should meet the unit-dose labelling requirements in order to be dispensed to the exact quantity prescribed.

In March 2022, the Global Leaders Group of WHO on Antimicrobial Resistance called for enforcing laws and policies to reduce or eliminate antimicrobial use that is not under the guidance of a trained healthcare provider in the human and animal health sector. WHO coordinates the antimicrobial resistance (AMR) program for every WHO country. Additionally, in the Annexes of a WHO meeting report about awareness-raising on antimicrobial resistance, recommendations are developed to increase public awareness on one of the environmental challenges for greener pharmaceuticals, antimicrobial resistance.[40]

Directive 94/62/EC of 20 December 1994 on packaging and packaging waste[41] (currently under revision[42]) covers all packaging placed on the market in the Community and all packaging waste, whether it is used or released at industrial, commercial, office, shop, service, household, or any other level, regardless of the material used including pharmaceutical waste:

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[39] Notice to applicant's guideline on the packaging information of medicinal products for human use authorized by the Union April 2021, Final Revision 14.6.
[40] WHO Meeting report 2022. Awareness-raising on Antimicrobial Resistance: Report of global consultation meetings. https://www.who.int/publications/m/item/awareness-raising-on-antimicrobial-resistance
[41] European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A31994L0062
[42] Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on packaging and packaging waste, amending Regulation (EU) 2019/1020 and Directive (EU) 2019/904, and repealing Directive 94/62/EC. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022PC0677

Article 20*: "The Commission is empowered to adopt delegated acts in accordance with Article 21a in order to supplement this Directive where necessary to deal with any difficulties encountered in applying the provisions of this Directive, in particular, to inert packaging materials placed on the market in very small quantities (i.e. approximately 0.1 % by weight) in the Union, primary packaging for medical devices and pharmaceutical products, small packaging and luxury packaging."*

This Directive includes the prevention of impact of environment in the management of packaging with several articles:

- **Article 6 paragraph 4**: "*Member States shall, where appropriate, encourage the use of materials obtained from recycled packaging waste for the manufacturing of packaging and other products by: (a) improving market conditions for such materials; (b) reviewing existing regulations preventing the use of those materials."*
- **Article 12**: Member States must set up national databases to provide information on the *"magnitude, characteristics and evolution"* of packaging and packaging waste flows at national level, to help Member States and the European Commission monitor implementation of the Directive.
- **Annex II**: Member States must ensure that packaging complies with certain "*Essential Requirements. These include minimisation of packaging weight and volume to the amount needed for safety, hygiene and consumer acceptance of the packed product, minimisation of noxious or hazardous constituents, and suitability for reuse, material recycling, energy recovery or composting."*

Extension of expiry dates to limit unused medicines

Expiry dates are supported by stability testing of a drug product assessing the physical, chemical, biological, and microbiological attributes which ensure the maintenance of safety and efficacy of the medicinal product over a period at specific storage conditions (temperature, light, humidity). Stability testing is performed to establish the expiry date for a new product, or to collect data in ongoing support of an already existing expiry date for a commercial/marketed product. Shelf life is typically expressed in units of months or years and determines the *"expiry date"*.

Stability product specifications will vary depending on the nature of the pharmaceutical form (i.e., powder, tablet, capsule, liquid/gel, cream/ointment, etc.) but three major parameters in product specification, regardless of product type, are to be considered. These parameters are the Three P's:

- Potency: measure of biological/chemical activity of the product,
- Physicochemical Characteristics (i.e., molecular weight),
- Purity as impurities may be generated or increased during manufacture and/or storage of the drug product.

The stability ensures the desired quality, considering safety and efficacy of the drug product. Several scientific guidelines (ICH) are used to determine the expiry date of medicines [43] [44] [45] [46] [47] [48] [49] [50] [51] [52] [53] [54] [55]. They are based on the following principles: the duration of stability studies is set up by the MAH who claims the shelf-life which is approved by the competent authority based on provided stability data.

The claimed shelf-life can be shorter than the available stability data even if evidence that the quality attributes of the medicine are maintained beyond the expiry date. None of these guidelines mentioned above link the shelf-life with the environmental impact by avoiding throwing away usable medicines.

The above consideration led to questions to be answered by Member States representatives of the Pharmaceutical Committee, for questions and detailed responses see Annex 4.

Results of the questionnaire

Few Member States have developed guidance on customizing pharmaceuticals pack sizes/packaging. Most of them limit the pharmaceutical pack size for toxicity/safety reasons for the patient in some therapeutic areas, i.e., painkillers, antibiotics, and opioids, and not to deal with environmental issues related to packaging, e.g., greener packaging. The development of these guidelines at the EU level is requested by some Member states.

The drug packaging is proposed by the applicant and assessed/accepted according to the EU guidelines and Ph. Eur. requirements by the regulatory authority in all Member states. Few prescribers and pharmacists in Member States take initiatives to increase public awareness on the impact of pack size/packaging on environment. These initiatives are limited at the level of academia, health institute, hospital pharmacies and pharmacies.

All Member States agree with the need to optimize the way how the expiry date is currently set to safely extend it (if allowed by existing stability data).

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[43] ICH Q1A (R2) Stability testing of new drug substances and drug products.
[44] ICH Q1B Photostability testing of new active substances and medicinal products.
[45] ICH Q1C Stability testing: requirements for new dosage forms.
[46] ICH Q1D Bracketing and matrixing designs for stability testing of drug substances and drug products.
[47] ICH Q1E Evaluation of stability data.
[48] ICH Q5C Stability testing of biotechnological/biological products.
[49] Stability testing of existing active ingredients and related finished product.
[50] ICH Q1F Stability data package for registration in climatic zones III and IV.
[51] In-use stability testing of human medicinal products.
[52] Stability testing for applications for variations to marketing authorization.
[53] Start of shelf-life of the finished dosage form (Annex to the note for guidance on the manufacture of the finished dosage form).
[54] EMA, 1998. Maximum shelf-life for sterile products for human use after first opening or following reconstitution. https://www.ema.europa.eu/en/maximum-shelf-life-sterile-products-human-use-after-first-opening-or-following-reconstitution-scientific-guideline
[55] EMA, 2007. Declaration of storage conditions for medicinal products particulars and active substances (Annex). https://www.ema.europa.eu/en/declaration-storage-conditions-medicinal-products-particulars-active-substances-annex-scientific-guideline

Examples, good practices and recommendations

Pack size/packaging and environmental impact

By Directive 94/62/EC of 20 December 1994 (consolidated text), the minimisation of environmental impact is applied on all packaging and all packaging waste placed on the market in the Community including pharmaceutical waste. The opportunity to implement this Directive concerning the medicines is included in the Article 20.

In Spain, SIGRE, the not-for-profit organisation setup to ensure proper environmental management of medicines and their packaging prepares three-year plans aimed at MAHs with measures for reducing the environmental impact of packaging from medicines.

In Finland, some packaging does not include package leaflets to minimize unneeded waste. The FSC symbol (forest stewardship council) is allowed to be included in the inner side of the packaging.

In most of the EU Countries, the National competent authorities decide on the authorised pack sizes after proposal of the MAH. The authorities are assessing the adequacy of the proposed pack sizes regarding the therapeutic treatment according to the Guideline on the packaging information of medicinal products for human use authorised by the union.

- In Germany, pack sizes which exceed the largest authorised pack size cannot be reimbursed by statutory health insurance.
- In France, there is a difference in pack size between community pharmacies and hospital pharmacies with the largest one adapted to hospital pharmacies.
- In Italy, the choice of the pack size is established by the MAH. The NCA then decides which of the pack size can be granted city or hospital reimbursement.
- At the national level, guidance to regulate pack size exists in some therapeutic areas such as opioids in Belgium [56], antibiotics in France[57] and Belgium.

Prescribing/dispensing medicinal products

To manage this optimisation, pharmaceuticals prescription can be limited to specialised physician and the pharmaceuticals delivery to specialised place, hospital pharmacies (e.g., in Belgium and Italy). In Cyprus, the Health Insurance Organisation imposes to pharmacists to dispense through the e-prescribing system, which is based on the maximum dose of each medicine and its pack size for a one-month supply of the medicine. In Finland, dose dispensing activities are in place. MAHs can apply for a separate authorisation for a dose-dispensing pack size, which is used when dispensing medicines as single doses for individual patients for a specified treatment period. Application examples:

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[56] Afmps, 2022. Ligne directrice Statut de délivrance et taille de conditionnement des analgésiques opioïdes en Belgique. https://www.afmps.be/sites/default/files/content/POST/MAH/85-Richtlijn_opio%C3%AFde_pijnstillers_FR.pdf

[57] Ministère du travail de la santé et des solidarités. Les antibiotiques: des médicaments essentiels à preserver. https://solidarites-sante.gouv.fr/prevention-en-sante/les-antibiotiques-des-medicaments-essentiels-a-preserver/

- The dispensing of long-term treatment drugs for several months at one time.
- Smaller pack size should be considered.
- During titration phase: treatment initiation pack.
- To start a new chronic treatment (response of the patient is not yet known).
- For medicinal products with a short shelf life.
- For a short-term of treatment: in the case of acute disease which resolve in a few days (e.g., semi-solid or liquid preparations for topical use that expire within a few months after opening).

Dispensing good practices should be developed or updated, to limit the environmental impact as well. Their principles should be based on dispensing only the dose needed. For examples, by dose-dispensing for individual patient needs (but attention to maintain traceability in supply chain), unnecessary quantities (package waste) of medicines can be avoided. The microbial resistance should be reduced by this action and by prioritizing the alternative therapy of antibiotics. As regards prescriptions, some initiative should be done to harmonize antibiotics recommendations at the EU level.

Attention should be paid to guide prescribers on the best packaging size, for example to start new medicine treatment (treatment initiation pack) with smaller packages, especially for long-term treatment.

This issue is also addressed in the sub-working groups of action 1 and 3 of Pharmaceuticals in the Environment.

Recommendations

Recommendation 4.1

a. Pack size of prescribed and over the counter medicines should be re-evaluated with respect of the current therapeutic use. Especially products with an identified risk to the environment or to public health (e.g., high risk of antimicrobial resistance) should meet the unit-dose requirements or different pack sizes allowing different unit number, in order to dispense the exact quantity prescribed.

b. To reduce environmental cost impact, packaging requirements should be investigated to encourage harmonization at EU level.

Recommendation 4.2

To reduce environmental impact, primary/secondary packaging with ecodesign, sustainable life cycle of the material used for the packaging should be promoted when applicable to the pharmaceutical requirements.

Incentives should be created via the three main principles: rationale use, eco-design packaging, and use of materials produced from renewable sources, biosource.

Recommendation 4.3

Longer stability studies should be promoted by national and European competent authorities in order to approve medicinal products with longer shelf-lives.

- The reduction of shelf-life should be limited to cases where the safety, quality and efficacy of the medicinal product cannot be guaranteed.
- As regards shelf-life extensions, financial incentives should be proposed by NCAs to encourage MAHs to prolong as much as possible the shelf-life.

5. Exchange of best practices on the environmentally safe disposal of medicinal products and clinical waste – Action 5

Introduction

The assignment of the sub working group was to facilitate the exchange of best practices among healthcare professionals on the environmentally safe disposal of medicinal products and clinical waste, and the collection of pharmaceuticals residues as appropriate.

According to World Health Organization[58], of the total amount of waste generated by clinical waste, also named healthcare activities, about 85 percent is general, non-hazardous waste. The remaining 15 percent is considered hazardous material that may be infectious, toxic or radioactive. The volume of waste generated by the healthcare sector recently increased in healthcare generated waste because of the COVID-19 outbreak and increased use of single use personal protection equipment both protective equipment kits and use of vaccines, disinfectants, antibiotics[59]. Europol, the European Union's law enforcement agency, has revealed that in some countries this has resulted in illegal disposal methods being used[60].

Healthcare waste comes from many sources, including major sources such as hospitals, clinics, and laboratories, as well as minor sources such as doctors' offices, dental clinics, and convalescent homes. It also applies to veterinary services, pharmaceutical dispensaries, and research and development labs, nursing homes, home treatment, ambulance services, prison clinics, funeral parlours, and mortuaries.

The distinct categories of healthcare waste are sharps, infectious waste, pathological waste, pharmaceutical (including cytotoxic) waste, hazardous chemical waste, radioactive waste and non-hazardous general waste. Infectious waste can be further classified as waste contaminated with blood or other body fluids, cultures and stocks, and waste from isolation wards. Hazardous chemical waste includes halogenated and non-halogenated solvents, disinfectants, toxic metals such as mercury, and other organic and inorganic chemicals.

Adverse health outcomes associated with healthcare waste and by-products also include sharps-inflicted injuries, toxic exposure to pharmaceutical products and to substances such as

[58] WHO, 2018. Health-Care Waste.https://www.who.int/news-room/fact-sheets/detail/health-care-waste#cms

[59]WHO, 2022. Tonnes of COVID-19 health care waste expose urgent need to improve waste management systems. https://www.who.int/news/item/01-02-2022-tonnes-of-covid-19-health-care-waste-expose-urgent-need-to-improve-waste-management-systems

[60] Europol Environmental Statement 2021. https://www.europol.europa.eu/cms/sites/default/files/documents/Europol-EMAS-Environmental-Statement_2021.pdf

mercury or dioxins, chemical and radiation burns, thermal injuries, air pollution arising because of the release of particulate matter during medical waste incineration (see annex for detail).

Treatment and disposal of healthcare waste may pose health risks indirectly through the release of pathogens and toxic pollutants into the environment. Healthcare waste potential hazards may include drug-resistant microorganisms which spread from health facilities into the environment (see annex 5 for details). It can be noted that transformation to more sustainable waste management with low health risks entails substantial economic costs[61].

Overview of current known situation

Five principles are widely recognized as underlying the effective and controlled management of wastes[62]. These principles have been used by many countries when developing their policies, legislation, and guidance.

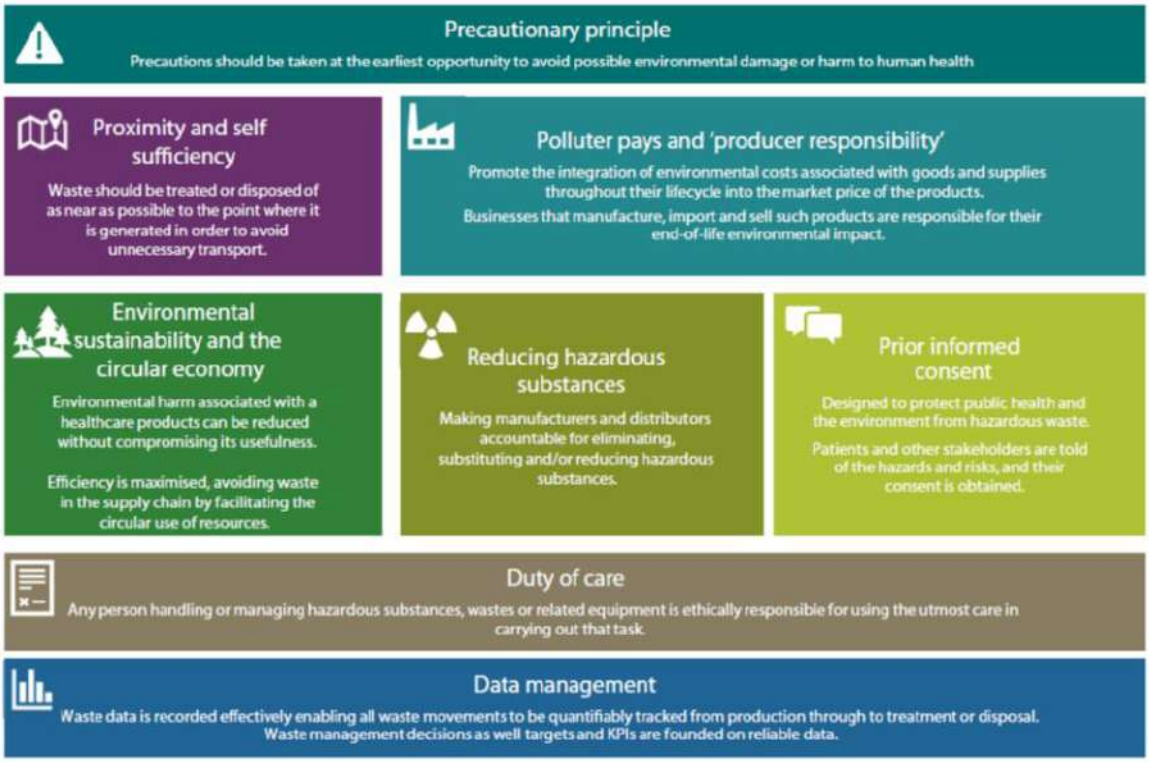

Figure 2. Key principles in sustainable waste management.[63]

[61] WHO European region (2023) Economics of the health implications of waste management in the context of a circular economy. https://iris.who.int/bitstream/handle/10665/365579/WHO-EURO-2023-5536-45301-64839-eng.pdf?sequence=1

[62] WHO (2014). Safe management of wastes from health-care activities, 2nd ed. https://www.who.int/publications/i/item/9789241548564

[63] Technical Brief: Sustainable Health Care Waste Management. 17 FEBRUARY 2020 GENEVA https://greenhealthcarewaste.org/wp-content/uploads/2020/12/The-Global-Fund-Technical-Brief-Sustainable-HCWM.pdf

Figure 3. The foundation of EU waste management is the five-step "waste hierarchy", established in the Waste Framework Directive. It establishes an order of preference for managing and disposing of waste.[64]

- **Prevention**. Measures, taken before a substance, material or product has become waste, that reduce the quantity of waste, including through the reuse of products or the extension of the life span of products.
- **Preparing for reuse**. Checking, cleaning or repairing recovery operations, by which products or components of products that have become waste are prepared so that they can be reused without any other preprocessing.
- **Recycling**. Any recovery operation by which waste materials are reprocessed into products, materials or substances, whether for the original or other purposes. It includes the reprocessing of organic material (e.g. composting) but does not include energy recovery and reprocessing into materials that are to be used as fuels or for backfilling operations.
- **Recovery** (e.g., energy recovery). Any other operation the principal result of which is waste serving a useful purpose by replacing other materials which would otherwise have been used to fulfil a particular function, or waste being prepared to fulfil that function, in the plant or in the wider economy.
- **Disposal**. Any operation which is not recovery, even where the operation has as a secondary consequence the reclamation of substances or energy (e.g., landfilling, incineration).[65]

[64] European Commission. Waste Framework Direction. https://environment.ec.europa.eu/topics/waste-and-recycling/waste-framework-directive_en
[65] Directive 2008/98/ec of the European parliament and of the council. Waste Framework Directive. https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=LEGISSUM:waste_hierarchy

Categories of healthcare waste[66]

Table 2. Description and examples of waste categories.

Waste Categories Hazardous HCW	Descriptions and Examples
Sharps waste	Used or unused sharps, e.g., intravenous, hypodermic or other needles, syringes with attached needles, auto-disable syringes, infusion sets, scalpels, knives, blades, pipettes, broken glass and vials
Infectious waste	Waste suspected of containing pathogens and presenting a risk of disease transmission, e.g., laboratory culture and microbiological stocks, waste contaminated with blood and other body fluids, waste including excreta and other materials that have been in contact with infected patients with highly infectious diseases in isolated wards
Pathological waste	Human and animal organs, tissues or fluids, body parts, fetuses, placentas, unused blood products, contaminated animal carcasses
Pharmaceutical waste	Expired pharmaceuticals, unused, contaminated vaccines and drugs, items contaminated by or containing pharmaceuticals
Cytotoxic waste	Waste containing substances with genotoxic properties (mutagenic, carcinogenic or teratogenic substances), e.g., cytotoxic drugs used in cancer therapy and their metabolites
Chemical waste	Waste containing chemicals, e.g., expired or unused disinfectants or laboratory reagents, unused, solvents, waste with high heavy metal content, such as batteries, blood pressure gauges, mercury-containing equipment and devices (e.g., old thermometers)
Radioactive waste	Waste containing radioactives, e.g., unused radiotherapy liquids, radioactive diagnostic material, contaminated packages, absorbent paper or glassware, urine and excreta from patients tested or treated with radionuclides, radioactive sealed sources
Non-hazardous or general HCW	Waste, which does not pose any particular biological, chemical, physical or radioactive hazard

Adverse health outcomes associated with health care waste and by-products include[67]:

- Sharps-inflicted injuries.
- Toxic exposure to pharmaceutical products, in particular, antibiotics and cytotoxic drugs released into the surrounding environment, and to substances such as mercury or dioxins, during the handling or incineration of health care wastes.
- Chemical burns arise in the context of disinfection, sterilization, or waste treatment activities.
- Air pollution arises as a result of the release of particulate matter during medical waste incineration.
- Thermal injuries occurring in conjunction with open burning and the operation of medical waste incinerators.
- Radiation burns.

Indirect health risks caused by treatment and disposal of healthcare waste through the release of pathogens and toxic pollutants into the environment:

- Drug-resistant microorganisms.
- The disposal of untreated health care waste in landfills can lead to the contamination of drinking, surface, and ground waters if those landfills are not properly constructed.

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[66] Janik-Karpinska, E.; Brancaleoni, R.; Niemcewicz, M.; Wojtas,W.; Foco, M.; Podogrocki, M.; Bijak, M. HealthcareWaste—A Serious Problem for Global Health. Healthcare 2023, 11, 242. https://doi.org/10.3390/healthcare11020242

[67] WHO (2014). Safe management of wastes from health-care activities, 2nd ed. https://www.who.int/publications/i/item/9789241548564

- The treatment of health care wastes with chemical disinfectants can result in the release of chemical substances into the environment if those substances are not handled, stored and disposed in an environmentally sound manner.
- Incineration of waste has been widely practiced, but inadequate incineration or the incineration of unsuitable materials results in the release of pollutants into the air and in the generation of ash residue. Incinerated materials containing or treated with chlorine can generate e.g., dioxins, which are human carcinogens and have been associated with a range of adverse health effects. Incineration of heavy metals or materials with high metal content (in particular lead, mercury and cadmium) can lead to the spread of toxic metals in the environment.
- Only modern incinerators operating at 850-1100 °C and fitted with special gas-cleaning equipment can comply with the international emission standards for dioxins and furans.
- Alternatives to incineration such as autoclaving, microwaving, steam treatment integrated with internal mixing, which minimize the formation and release of chemicals or hazardous emissions should be given consideration in settings where there are sufficient resources to operate and maintain such systems and dispose of the treated waste.

Relevant international conventions which have implications for Health Care Waste

Legislation in the European Union

The general principles for an effective waste management system are laid down in the Waste Framework Directive and the directive on Hazardous Waste, which provide the structure for waste management in the European Union.[68] These directives lay down the requirement to recover or dispose of waste without endangering human health and without causing environmental damage. In addition, the rules lay down the measures to be taken when dealing with hazardous waste and the conditions for its incineration.

Several international agreements and conventions are particularly relevant to the management of wastes from healthcare facilities, the protection of the environment and sustainable development as the Basel convention and the Stockholm convention (see annex 5 for the link to access the text of these agreements and conventions). More information about European legislative and regulatory aspects are presented in annex 5.

The Waste Framework Directive[69] sets the basic concepts and definitions related to waste management, including definitions of waste, recycling, and recovery. From a general point of view, the waste management follows a hierarchy and is generally depicted in the form of an inverted pyramid with the most preferred options at the upper end and disposal at the bottom as the last-resort solution to managing waste.

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[68] Waste Framework Directive https://environment.ec.europa.eu/topics/waste-and-recycling/waste-law_en

[69] Directive 2008/98/ec of the European parliament and of the council. Waste Framework Directive. https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=LEGISSUM:waste_hierarchy

Table 3. Overview of international conventions which have implications for Health Care Waste.

CONVENTION	DESCRIPTION
Basel Convention[70]	Aims to protect human health and the environment against the adverse effects from the generation, management, transboundary movement, and disposal of hazardous and other wastes.
Stockholm Convention[71]	Global treaty to protect human health and the environment from highly dangerous, long-lasting chemicals.
Rotterdam Convention[72]	Promotes shared responsibilities and cooperation among parties in international trade of certain hazardous chemicals to protect human health and environment from potential harm.
Bamako Convention[73]	Treaty of African nations prohibiting the import of hazardous waste.
Aarhus Convention[74]	Grants the public rights, and imposes obligations regarding access to information, and public participation and access to environmental justice.
Minamata Convention[75]	Signatory countries to undertake measures to reduce the human and environmental impact of anthropogenic mercury.

Technical guides

Technical guidelines should be practical, sufficiently detailed, and directly applicable to local managers and staff. They can be written by public or non-governmental organizations.

International guides

WHO developed the first global and comprehensive guidance document, *Safe management of wastes from health-care activities*, now in its second edition and more recently a short guide

[70] Basel Convention. http://www.basel.int/TheConvention/Overview/TextoftheConvention/tabid/1275/Default.aspx
[71] Stockholm Convention. http://www.pops.int/TheConvention/Overview/TextoftheConvention/tabid/2232/Default.aspx
[72] Rotterdam Convention. http://www.pic.int/TheConvention/Overview/TextoftheConvention/tabid/1048/language/en-US/Default.aspx
[73] Bamako Convention https://www.informea.org/en/treaties/bamako/text
[74] Aarhus Convention. https://www.unece.org/env/pp/treatytext.html
[75] Minamata Convention on Mercury http://www.mercuryconvention.org/Convention/Text/tabid/3426/language/en-US/Default.aspx

that summarizes the key elements[76]. The guide addresses aspects such as regulatory framework, planning issues, waste minimization and recycling, handling, storage and transportation, treatment and disposal options, and training. The document is aimed at managers of hospitals and other healthcare facilities, policy makers, public health professionals and managers involved in waste management.

National guides

There is a lot of documentation, but guides are in the national language or not publicly available. A few European examples are gathered in annex 5 for information.

Results of the questionnaire

The collected answers are presented in annex 5. They did not allow to gather sufficient relevant information about healthcare disposal.

However, in the summer of 2020, Health Care Without Harm Europe (a non-profit network of European hospitals and healthcare providers, healthcare systems, local authorities, research/academic institutions, and environmental and health organizations) conducted a survey of its members to better understand waste management practices and challenges within European hospitals. Responses pointed out that (25 responses from 10 countries):

- Over 50 percent reported that national legislation requires incineration of hospital waste.
- Respondents provided an extensive list of over 55 different categories that are treated this way.
- More than half respondents (14) do not have access to other technologies to treat infectious waste. Those who have such facilities reported the use of autoclaving, microwaving, high temperature, and/or physico-chemical treatment.
- The most frequently reported challenges in switching to non-incineration technologies were cost and the lack of supportive regulation.
- Over half of respondents (60 percent) reported that recycling companies refuse to collect and recycle certain waste from hospitals – primarily from fear of contaminated materials. The majority of respondents (68 percent) did report, however, that they are able to recycle packaging from medical supplies including paper & cardboard, plastic, glass, and metal, as well as from other sources.
- Almost all respondents (92 percent) have a dedicated training program on waste segregation and collection – 68 percent of respondents have a dedicated program.[77]

[76] WHO (2014). Safe management of wastes from health-care activities, 2nd ed. https://www.who.int/publications/i/item/9789241548564

[77] Health Care Without Harm (HCWH) https://noharm-europe.org/content/europe/member-survey-hospital-waste-results-analysis

Best practices

Healthcare waste minimization

Minimization is always preferable to generating waste and then handling and managing its recovery, treatment, and disposal. Avoidance and prevention mean limiting the demand for products and material resources, thereby preventing the generation of waste. These are some examples of good practices[78] [79]:

- Avoiding unnecessary tests, procedures, and other actions that generate waste.
- Procuring products and equipment with less packaging.
- Purchasing safer alternative products with no or fewer hazardous substances.
- Good storage and stock rotation to use products prior to expiration.
- Going digital and changing practices to reduce the use of materials, such as replacing film for X-rays by digital imagery.
- Purchasing more robust goods, durable items, encouraging repair, remanufacture and disassembly for recycling at the end of life.
- Extending the life of equipment, through regular maintenance and care.
- Designing out waste by using effective dispensers that prevent taking more than required, for example for gloves and wipes.
- Emplacing a procurement policy which explicitly precludes purchasing products that contain toxic materials such as mercury, PVC or glutaraldehyde; and setting progressive targets for those which cannot yet be eliminated.
- Sourcing products derived from recycled materials, including packaging.
- Inventory controls to reduce purchase of surplus products.
- Prioritizing use of reusable products vs single-use products, such as swapping disposable cleaning wipes with use of handcloths, using washable sheets and surgical/nursing gowns.
- Procuring alternatives to single-use medical items, where safe to do so.
- Using reusable medical waste containers instead of those made with single-use plastics.
- Regarding food service, using washable cups, plates, and glasses rather than the paper kind.
- Educating healthcare staff in the efficient use of products and materials to prevent generating avoidable waste.
- In surgery and emergency departments, having specific kits suited for each treatment (instead of a general-purpose kit, most of its component not being used and going straight to the waste collector).

[78] England NHS: Health Technical Memorandum 07-01: Safe and sustainable management of healthcare waste 2022.

[79] Waste minimisation in healthcare-User guide https://www.health.vic.gov.au/sites/default/files/migrated/files/collections/policies-and-guidelines/w/waste-minimisation---pdf.pdf

Ensuring proper segregation of waste

Segregation is the process of separating different categories of waste. Correct segregation of waste helps to maximize opportunities for reuse, recycling, and recovery, and helps to enable effective and safe management of waste. The incorrect disposal of general waste items into biohazardous waste containers is a common, yet preventable source of excess regulated medical waste. The incorrect categorization of medical waste unnecessarily inflates the amount of waste destined to be treated as hazardous. By categorizing waste according to its type – general, infectious, hazardous, radioactive, etc. – hospitals can better determine the disposal methods that are both safe and environmentally friendly. Here are some examples:

- Color-code containers (color depends on the country). The colour-coding system aims to ensure immediate, easy, and unambiguous (clear) identification and segregation of the waste. Based on the type of hazards involved, a different colour code and type of container is assigned.
- Restrict access whenever possible. As much as possible, avoid placing medical waste containers in patient-accessible areas. If there is no way around it, provide a small container for medical waste and a larger one for regular waste. Using smaller containers for regulated medical waste (RMW) in patient rooms makes it more difficult and thereby less likely that patients or staff will use them as trash bins. Where practical, making RMW containers accessible only to staff, as patients are much more likely to place waste in the wrong receptacle than staff.
- Maintain physical separation between different waste bins. It is usual to find different waste containers side-by-side but doing so makes it too easy to drop waste into the wrong container. Human error can be significantly reduced by placing the general waste container away from your regulated medical waste collection bin.
- Post strategic signage. Place signs throughout the facility that indicate the types of waste that can be placed into each container to help staff and patients understand the policies and remind them to make the right choices.
- Include waste audits and periodic spot-checks to assess whether paper, cardboard, plastics, and regulated medical waste are being properly disposed of.

Collection

- Collection times should be fixed and appropriate to the quantity of waste produced in each area of the healthcare facility.
- General waste should not be collected at the same time or in the same trolley as infectious or other hazardous wastes.
- Waste bags and sharps containers should be filled to no more than three quarters full. Once this level is reached, they should be sealed ready for collection.
- Plastic bags should never be stapled but may be tied or sealed with a plastic tag or tie.
- Replacement bags or containers should be available at each waste-collection location so that full ones can immediately be replaced.
- Waste bags and containers should be labelled with the date, type of waste and point of generation to allow them to be tracked through to disposal. Where possible, weight should also be routinely recorded.

- Collection should be daily for most wastes, with collection timed to match the pattern of waste generation during the day. For example, in a medical area where the morning routine begins with the changing of dressings, infectious waste could be collected mid-morning to prevent soiled bandages remaining in the medical area for longer than necessary. Visitors arriving later in the day will bring with them an increase in general waste, such as newspapers and food wrappings; therefore, the optimum time for general and recyclable waste collection would be after visitors have departed.
- In comparison with this general type of medical area, a theatre would generate a high proportion of potentially infectious waste and could have several collections during the day to fit in with the schedule of operations.

Storage

- All healthcare waste storage areas must have enough capacity to hold the waste generated until it can be disposed of properly. This will depend on the waste generation rate of individual health facilities as well as the frequency of collection and disposal.
- Storage areas must be large enough so they do not overflow, and separate spaces must be provided for different types of waste.
- Storage areas should be well signed, dry, and secure from unauthorized persons, pests and disease vectors.

Transfer and transport

The method used to transport healthcare waste should be appropriate to the individual circumstances of health facilities and compliant with national transport regulations. Non-hazardous and hazardous waste should not be moved together.

Treatment and disposal methods

Many healthcare waste-treatment systems are commercially available today. The choice of technology depends on the characteristics of the waste of the healthcare facility, the capabilities and requirements of the technology, environment and safety factors, and costs. Treatment technologies employ thermal, chemical, irradiative, biological, or mechanical processes. The common types of treatment technologies are[80].

- Autoclaves - come in a wide range of sizes and can be classified according to the method of air removal.
- Integrated or hybrid steam-based treatment systems.
- Microwave treatment technologies.
- Dry-heat treatment technologies.
- Chemical treatment technologies.

[80] Shareefdeen, Z.; Ashoobi, N.; Ilyas, U. Medical Waste Management and Treatment Technologies. In Hazardous Waste Management;Shareefdeen, Z., Ed.; Springer: Cham, Switzerland, 2022 https://link.springer.com/content/pdf/10.1007/978-3-030-95262-4_5.pdf

- Incinerators. Incinerators should have flue gas cleaning systems to minimize pollutant releases and meet national or international emission limits. Small-scale incineration is a transitional means of disposal for healthcare waste. When investing in new technologies, priority consideration should be given to technologies that do not produce dioxins or furans.

Regardless of the technology, the healthcare facility should have an annual budget for periodic maintenance and repair.

Further information on healthcare waste treatment technologies can be found in the UNEP/IETC compendium, module 15 of the GEF / UNDP Global Healthcare Waste Project[81], and in the WHO guidance on technologies for the treatment of infectious and sharp waste from healthcare facilities[82].

Treatments can be on or off site. Off-site treatment and disposal typically require the transfer of healthcare waste to a private contractor, government entity, or the informal sector and is subject to the availability of third-party operated HCW treatment and/or disposal infrastructure. It is important to make sure the organization transporting the waste off-site is treating and disposing of it properly, to avoid environmental contamination, damage to human health and potential legal liability.

Training, education, and public awareness

The overall goals of training are to:

- Prevent occupational and public health exposures to the hazards associated with healthcare waste.
- Raise awareness of the health, safety and environmental issues relating to healthcare waste.
- Ensure that healthcare staff are knowledgeable about best practices and technologies for healthcare waste management and can apply them in their daily work.
- Foster responsibility among all healthcare workers for healthcare waste management.

[81] UNEP/IETC compendium, module 15 of the GEF / UNDP Global Healthcare Waste Project https://wedocs.unep.org/bitstream/handle/20.500.11822/8628/IETC_Compendium_Technologies_Treatment_Destruction_Healthcare_Waste.pdf?sequence=3&isAllowed=y

[82] Overview of technologies for the treatment of infectious and sharp waste from health care facilities, WHO, 2019 https://iris.who.int/bitstream/handle/10665/328146/9789241516228-eng.pdf?sequence=1&isAllowed=y

Recommendations

Recommendation 5.1

Promoting practices that reduce the volume of waste generated (for example replacing disposable products with reusable and recyclable options wherever it can be achieved without affecting patient care or worker safety).

Recommendation 5.2

Developing strategies and systems along with strong oversight and regulation to incrementally improve healthcare waste segregation, destruction, and disposal practices with aim of meeting national and international standards.

Recommendation 5.3

Where feasible, favoring the safe and environmentally sound treatment of hazardous health care wastes (e.g. by autoclaving, microwaving, steam treatment integrated with internal mixing, and chemical treatment) over medical waste incineration.

Recommendation 5.4

Raising awareness of the environmental risks related to healthcare waste, and of safe practices and develop training programs for healthcare professionals on the implementation of best practices in waste management.

Establishing a mechanism for continuous monitoring, reporting on best practices, and feedback collection. Audits may be carried out as part of a continuous improvement process.

6. Waste collection schemes of unused pharmaceuticals – Action 6

Introduction

The assignment for the sub-working group was to assess the implementation of collection schemes for unused pharmaceuticals and consider how their availability and functioning could be improved, how to increase public awareness of the importance of using them, and how extended producer responsibility could play a role in reducing inappropriate disposal.

In most of the EU countries there is a take-back scheme in place for unused or expired medicinal products (Directive 2001/83 art. 127b). There is wide diversity in terms of level of organisation (local, regional, or national), entity responsible of the scheme (pharmacies, local authorities, pharmaceutical industries) and application or not of the extended producer responsibility (EPR) principle. The development of EU guidance would help to align the existing schemes and to make them more efficient.

There are already sporadic efforts in what regards to public awareness, but the scarce data on user adherence to the take-back scheme suggest that public awareness should be stronger and continuous to achieve higher amounts of unused pharmaceuticals disposed through take-back schemes.

The few surveys carried out also show that the number of users disposing unused medicines via sink or toilet (what implies higher risks for the environment) can be relevant in certain countries.

Only some countries have carried out surveys among the users, often sporadically. Frequent and standard surveys carried out at EU-level are necessary in order to understand the level of adherence of the users to the scheme and to assess the effectiveness of awareness campaigns and take-back schemes.

Most Member States do not have EPR schemes for waste collection. EPR schemes may help fund initiatives like periodic surveys or awareness campaigns. However, as EPR has now been introduced to fund the upgrading of wastewater treatment plants and thus to finance end-of-pipe measures, it may not be possible anymore to also oblige MAHs to pay for other measures.

At household level, the use of medicines generates waste (expired and unused medicines) that is not always disposed of properly. The improper disposal of medicines (e.g., disposal through the sink where residues end up in surface waters or via normal waste, where it may end up in landfills) leads to emissions and subsequent risks to the environment. To avoid this, collection schemes for unused and expired pharmaceuticals should be put in place combined with education materials.

This chapter reviews the current collection systems in the EU/EEA and methods used to communicate to the public. We will focus exclusively on human medicinal products used in households.

The present document also explores the application of Extended Producer Responsibility (EPR) schemes for the collection of waste. The chapter ends with conclusions and recommendations.

Disposal routes

The pharmaceutical waste produced in households can be disposed of in several ways:

- Disposal using a specific **take-back scheme** for pharmaceuticals will lead to the destruction of the residue by incineration. By these means, the environmental risk of the pharmaceutical residues will be minimal as all residues will be burnt. Care should be taken that the pharmaceutical residues are appropriately handled and in a separate workflow than household waste (which is incinerated at lower temperatures).

- Disposal through **household waste** may lead to high risks to the environment. The pharmaceutical residues will only be eliminated if the household waste is incinerated, which happens with 55 percent of the total waste produced in the EU/EEA. Nevertheless, disposing the household waste in landfills is still relevant as this happens with 45 percent of the total waste in Europe[83]. The environmental risks due to the presence of pharmaceutical residues in landfills are mainly related to leaching of active ingredients to groundwater and the emission to surface waters. It must be considered that the percentage of waste disposed in landfills or incineration is not spread homogenously across the EU. Some countries (e.g., FI, DE, AT, BE, NL) incinerate almost all the household waste, while others (HR, RO, MT, ES) mainly dispose waste in landfills, although incineration occurs at different levels. Consequently, disposal of unused pharmaceuticals via household waste poses a higher risk to the environment in those countries where disposal in landfills prevails.

- Disposal through the **sink or toilet** leads to the highest risk for the environment. For example, in relation with diclofenac, the EC states in a Working Paper[84] that "One 10-tablet blister of a typical 50 mg dose can pollute up to 5 million litres of water with concentration above the EQS [Environmental Quality Standard]". In the same paper the EC concludes that the risks related to the improper disposal of ethinylestradiol would be even higher, as one blister of pill would be able to pollute the daily production of wastewater of a city of 100,000 inhabitants. These exemplary calculations illustrate that improper disposal by only very few users may already lead to considerable risks to the environment.

  Only limited information is available related to disposal through the sink or toilet, showing large differences across countries. In the Baltic Sea Report, it was shown that the share of surveyed people flushing unused pharmaceuticals to sewer could be as high as 33 percent in Poland and as low as three percent in Finland. A representative survey in Germany[85] also showed that nearly half of the respondents reported an occasional incorrect disposal of liquid medications and tablets via toilet or sink.

[83] Municipal waste statistics. Eurostat, 2023.
[84] Impact assessment accompanying the document proposal for a Directive of the European Parliament and of the Council amending Directives 2000/60/EC and 2008/105/EC as regards priority substances in the field of water policy. European Commission, 2012.
[85] Ergebnisse einer Repräsentativbefragung zu Medikamentenrückständen im Wasserkreislauf und zur Medikamentenentsorgung. KA Korrespondenz Abwasser, Abfall 61 (12), 1102-1105.2014. Götz, K. et al.

Collection schemes (take-back schemes)

The need for a take-back scheme in the EU is regulated since 2004 in Directive 2001/83/EC, which states in article 127b that "Member States shall ensure that appropriate collection systems are in place for medicinal products that are unused or have expired". Nevertheless, since the entry into force, there has been no check of the level of implementation. Using the data sources mentioned above, this section describes the take-back schemes currently in place in the EU.

Level of implementation of take-back schemes

According to the results of the EU survey, in most EU Member States a system exists to collect unused pharmaceuticals from patients. Mostly, these are returned to the pharmacy. Differences between countries are whether the collection is done on a mandatory or voluntary basis and who is responsible for the costs of destruction. Only Romania and Cyprus reported the lack of take-back schemes, although the latter Member State is currently preparing regulations on disposal of unused pharmaceuticals.

These results are largely in line with a 2013 report (from now on referred to as the HCWH report) that reviews collection schemes across Europe[86], which showed that take-back schemes are implemented in almost every country of the EU and only Bulgaria, Cyprus and Malta did not have information on any collection schemes.

Regarding the level of organization, the HCWH report found that in five Member States the scheme is organized at pharmacy level, in nine countries at local level, in one country at regional level and in nine countries it is organized at national level.

Collection sites

In relation to collection sites, the HCWH report indicated that in all countries for which information on collection schemes is available, pharmacies are the collection sites of unused pharmaceuticals. In eight countries, in addition to pharmacies, unused pharmaceuticals can be disposed of in specific household disposal sites (e.g., for small chemical waste) and in two countries unused pharmaceuticals can also be disposed of in health clinics.

Fate of the collected waste

According to the EU survey, in many countries the wholesale distributors act as mediator for the destruction of pharmaceutical waste. Even though the EU survey did not include any specific question related to the final fate of the waste some countries provided that information. FI, FR and SE stated that incineration was the method used. The HCWH report did not provide information on the fate of pharmaceutical waste.

[86] Unused Pharmaceuticals. Where do they end up? Health Care Without Harm (HCWH), 2013. https://noharm-europe.org/sites/default/files/documents-files/4646/2013-12%20Unused%20pharmaceuticals.pdf

Level of success of the systems

Out of the 16 countries responding to the EU survey, three countries provided information regarding the effectiveness of the system. For these three countries 50-90 percent of the respondents disposed of their unused medicines using the take-back scheme. No specific conclusion can be drawn concerning the effectiveness of the different collection schemes due to the lack of information.

According to a review of take-back schemes in Baltic countries (From now on "The Baltic Sea Report") published in 2020[87] , the proportion of citizens who return unused pharmaceuticals via designated collection points varies greatly across Baltic Sea countries, from about 10 to 70 percent. 16–80 percent of the citizens dispose of unused pharmaceuticals via regular household waste and 3–30 percent by flushing them down the drain. The most cited reason for improper disposal of medicines is a lack of information about their environmental impacts and a lack of knowledge on how to dispose them in an environmentally sound manner. According to the report, collection systems work poorly in Latvia, Lithuania, and Poland.

Public awareness

With respect to public awareness, the results of the EU survey demonstrate that communication tools for raising awareness are in place in most respondent Member States. From some Member States no information is available on patients access to information on proper disposal of unused medicines. Information is mainly available via the internet through specific websites and/or at pharmacies and collection sites. Additionally, in some Member States, campaigns have been performed sporadically, but it is not always clear what kind of information that has been presented, who is responsible for the initiation of such a campaign or whether campaigns are repeated periodically. Only a limited number of Member States have recurring awareness campaigns. The questionnaire did not ask for further details regarding which kind of information/media is used.

A survey performed by HCWH among the users of medicines revealed that lack of adequate information is one of the main reasons why existing take-back schemes are not used. In some Member States the population is not aware of existing take-back schemes or what consumers should do with unused pharmaceuticals. According to this survey, the majority of respondents are willing to use collection schemes if suitable information is provided on what to do with unused or expired medicines.

The German example (Götz et al. 2014) demonstrates that even when take-back schemes are in place, communication to patients and health care professionals needs to be clear. This is supported by the HCWH report which emphasizes that planned campaigns should not only focus on how to inform about and on how to use existing take-back systems for unused pharmaceuticals, but also on general information on potential adverse effects/impacts of

[87] Finnish Environmental Institute (2020), Good practices for take-back and disposal of unused pharmaceuticals in the Baltic Sea region.

pharmaceuticals to the environment. HCWH proposes a number of elements for educational campaigns[88]:

- Clear information on the adverse environmental effects of pharmaceutical residues, with particular emphasis on avoiding water pollution via the sink or toilet.
- Clear message to return unused pharmaceuticals using the official collection scheme.
- Identification of locations of collection points in the area.
- Information on the types of pharmaceutical residues that are accepted.
- Reminders to check regularly (at least once a year) the household's medicine cabinet to identify expired or unneeded medicines.
- Information on separating (where necessary) and recycling empty packages and leaflets.
- Where to get further information – doctors, nurses, pharmacists, etc.

Possible options for raising awareness

In order to raise awareness, each target group, e.g., different healthcare professionals (physicians, nurses, pharmacists) and the public, should be addressed accurately and adequately. Furthermore, information programs/campaigns should be periodically repeated so that awareness of this topic is continuously strengthened. Information materials should be made easily available, using different communication tools, also aimed at illiterate citizens, continuously updated and communication should be user-friendly. Proposals on how awareness could be raised are given in Table 4.

[88] Unused Pharmaceuticals. Where do they end up? Health Care Without Harm (HCWH), 2013. https://noharm-europe.org/sites/default/files/documents-files/4646/2013-12%20Unused%20pharmaceuticals.pdf

Table 4: Possible options for raising awareness.

Target audience	Media	Information on	Raising awareness	Distributor/ supply source
Public	Flyers Brochures/posters Post cards	Proper disposal/ take-back systems	Unused pharmaceuticals should be disposed of via take-back systems, if available, and NOT via sink or toilet (e.g. pictogram with crossed-out toilet/sink)	Pharmacies/ collection points website
	Campaigns			Institutions, NGOs, medicines' Marketing Autorisation Holder (MAH), radio and/or TV spots
	Outer packages of pharmaceuticals and package leaflets	Incorrect disposal (e.g. pictogram with crossed-out toilet/sink)		National Competent Authorities (NCA)
-Public -Health-care professionals	Internet (proactive search) Press (analog and digital)	• Proper disposal/ take-back system • Pharmaceuticals in the environment	• Pharmaceuticals in the environment • proper disposal/ take-back system • strengthen of the advisory function (multiplier)	Website: multiple sources (professional associations, specialized media/press, institutions, EC, etc)

Extended producer responsibility (EPR)

Introduction

The way the collection schemes for unused pharmaceuticals are organized differs across the Member States. In some Member States, Marketing Authorization Holders play a role in waste collection schemes from an Extended Producer Responsibility (EPR) perspective which springs from the Polluter Pays Principle. In this section, we will explore the concept of the polluter pays principle, the EPR, and how this is applied to the waste collection system in some Member States.

The polluter pays principle

The polluter pays principle, as first mentioned in 1972 by OECD, is laid down in the Treaty on the Functioning of the European Union (TFEU) law Article 191(2). The main goal of this principle is to allocate the costs of pollution prevention and control measures to encourage rational use of scarce environmental resources and to avoid distortions in international trade

and investment. This means that the polluter should pay for the costs generated to make sure that the environment quality standards set by the government are met. It can be seen as an overarching principle of environmental responsibility, including pollution prevention and control measures, covering liability and clean-up costs. The field of application of this principle has been extended in recent years from pollution control at the source towards control of product impacts during their whole life cycle[89].

Regarding the issue of pharmaceuticals in the environment, the question is often asked who the polluter is (the pharmaceutical industry, the pharmacist, the prescriber, or the patient). Depending on the answer, the costs should be allocated to producers, individual patients, or to the society. So, the valid question arises if pharmaceutical companies should pay for the waste collection systems and upgrading sewage treatment plants, or if it would be simpler to divide these costs evenly over all inhabitants. This discussion is currently held in many countries on different levels.

Extended Producer Responsibility in practice

EPR is a widely used environmental policy in which the producer's responsibility for a product is extended to the postconsumer stage of a product's life cycle. EPR policy can also create incentives to prevent waste at the source and to promote better product design to minimize waste and optimize material recycling. In the EU, EPR is implemented in directives regulating management of end-of-life vehicles, waste from electrical and electronic equipment, batteries, and packaging[90]. The aim of these directives is to harmonize national measures to tackle the end-of-life management of these product groups. This helps to reduce the environmental impact of these products as well as to ensure the functioning of the EU's internal market. In some EU countries, such as Sweden, additional product groups are legally covered by the EPR, pharmaceuticals being one of them.

In addition to legally enforced (formal EPR) initiatives, several voluntary initiatives (informal EPR) have been identified that could potentially reduce and minimize pharmaceutical waste including packaging as well as improve collection and treatment of pharmaceutical waste and medical residues. For example, in some EU countries there are voluntary initiatives that are similar to an EPR in how they are organized and financed. These voluntary initiatives are often mainly driven by the market value of the waste that is collected and treated.

Examples on initiatives to prevent and minimize pharmaceutical waste and pharmaceutical packaging include:

- Funding R&D projects aimed at minimizing impacts of pharmaceuticals on the environment. E.g., the IMI PREMIER project, which is working on understanding the feasibility of "green pharmacy" (i.e., devising human medicinal products less harmful to

[89] European Commission, 2012. Principles of EU Environmental Law – the Polluter Pays principle. https://ec.europa.eu/environment/legal/law/pdf/principles/2%20Polluter%20Pays%20Principle_revised.pdf

[90] Directive 2000/53/EC on end-of life vehicles; DIRECTIVE 2012/19/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 4 July 2012 on waste electrical and electronic equipment (WEEE); DIRECTIVE 2006/66/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 September 2006 on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157/EEC; Directive 94/62/EC on packaging and packaging waste.

the environment and including environmental considerations early in the drug development process). This could also include research on optimized delivery methods of pharmaceuticals, personalized diagnostics, or personalized medicines.

- Promoting personalized prescription and use of medicine to reduce packaging and the usage of pharmaceuticals through advertisements, packaging size, awareness raising campaigns.
- Initiatives aiming to establish collection and treatment of pharmaceutical waste and treatment of pharmaceutical residues include:
  - Financial and organizational responsibility to collect and treat pharmaceutical waste.
  - Sewage treatment funds to ensure financial support to sewage treatment plants in treating pharmaceutical residuals in wastewater, also asked for by the European federation of national associations of water services (EUREAU) in their opinion paper.

Recommendations

Implementation of collection schemes

Most of the EU Member States have a collection scheme in place. Implementation of these schemes differs across Member States, e.g., regarding legal obligation or voluntary basis, the level of organization (local, regional, or national) and application of the EPR principle. In some countries the responsibility of the disposal lays on the individual pharmacies; in these cases, there is a risk that pharmacies might not encourage the disposal due to the costs of destruction.

The provision of having a take-back scheme (in accordance with article 127b of the Directive 2001/83) should still be an obligation under the upcoming reviewed Pharmaceutical Directive. The implementation of this legal obligation should be periodically monitored. However, given that many take-back schemes are already in place and that health care systems differ greatly across Member States, harmonization of the design of the take-back schemes via EU legislation might be difficult. Public awareness (see below) should be part of this.

To start with, all citizens should have easy and constant access to collection points to ensure that they are able to dispose of pharmaceutical residues in a correct way.

We recommend an EU-wide survey on user adherence to the take-back schemes and other ways to dispose of pharmaceutical residues, to evaluate the effectiveness of the measures put in place and identify best practices.

Communication between NCAs and stakeholders (pharmacies, industry, wholesalers, and health professionals) should be reinforced in order to raise awareness of the issue, stimulate cooperation and identify gaps. It must be noted that in most cases the communication routes between NCAs and stakeholders already exist, but the issue of disposal should be raised in these fora.

Recommendation 6.1

a. The EU should provide guidelines to help the National Competent Authorities (NCAs) and stakeholders to design their own take-back schemes, where possible including the Extended Producer Responsibility concept.

b. Ensuring easy access to collection points.
c. Conducting an EU-wide survey on user adherence to the take-back schemes and other ways to dispose of pharmaceutical residues.

Public awareness

Public awareness of risks and concrete consequences of pharmaceuticals in the environment regarding ecosystems in general and human beings in particular, the necessity to dispose of pharmaceutical in a correct way and how/where to do so, is fundamental for the success of any take-back scheme.

For those citizens already concerned about the topic, passive information (leaflets, posters in health-care premises or information on the internet) will be sufficient. However, it is also necessary to carry out active campaigns targeted at the public to encourage citizens to return their unused, expired, or discontinued medications to take-back sites. These campaigns should be carried out periodically and take geographical, cultural, and social factors into consideration. They should contain information on why (risks of pharmaceuticals in surface waters), how, and where. Additionally, avoiding disposal via sink or toilet should be part of any campaign, to reduce this practice. The success of the campaigns should be measured through periodic (e.g., every three years) surveys.

Currently, the Package Leaflet of the medicine serves as the first and main source of information to the user on the safe use of a medicine and already contains a general sentence on disposal. Nevertheless, this sentence is a general statement that does not provide useful information to the users on the collection scheme in their country; country-specific information should be included in the leaflet. Inclusion of a pictogram on the outer packaging or leaflet (e.g., crossed toilet) could help improve communication and reduce improper disposal. Nevertheless, it must be considered that in multilingual packages/leaflets it might be difficult to accommodate more information. In addition, care must be taken that any pictogram used is not misunderstood by the final user and that it is accepted by the QRD group at European Medicinal Agency (EMA) level.

Recommendation 6.2

a. Carry out active campaigns targeted at the public to encourage citizens to return their unused, expired, or discontinued medications to take-back sites.
b. Inclusion of a pictogram on the outer packaging or leaflet (e.g., crossed toilet) could help to improve communication and to reduce improper disposal.

Recommendation 6.3

Extended Producer Responsibility (EPR) could be used by the Member States to finance take-back schemes and awareness campaigns to encourage citizens to return their unused or expired medicines to designated collection points.

7. Improve the level of environmental expertise in the Committees and networks – Action 7

Environmental Training for Assessors

A survey among the members of subgroup 7 of the Ad-hoc working group on Pharmaceuticals in the Environment on national responsibilities in environmental assessment showed that in most cases the environmental assessment of marketing authorization applications (MAAs) for human pharmaceuticals is carried out by non-clinical assessors. However, often they are not sufficiently familiar with environmental sciences and are lacking hands-on experience to the environmental risk assessment (ERA) data. Consequently, the environmental expertise of the assessors reviewing the ERA in the different Member States varies considerably and may be insufficient. Therefore, initiatives and training tools/programs coordinated at EU-level are needed to meet the national ERA training requirements of all Member State and improve ERA expertise across the regulatory EU network and human pharmaceutical committees.

Experiences with ERA training in the past

Previously, informal ERA assessors' meetings were organized as voluntary initiatives by single national agencies. So far, these meetings have been hosted by France, Germany, Netherlands, Portugal, and Italy. The agenda of these informal meetings included selected training aspects and topics for human pharmaceuticals, e.g., PBT assessment or tailored risk assessment. Costs related to the organization of the meetings (e.g., catering, meeting rooms etc.) were covered by the host agency in addition to the logistical time-cost associated, while travel costs were covered by the national agencies of the attendees. Due to the lack of systematic financial support, training opportunities were limited regarding time, attendance, organization, and frequency. It is not financially or logistically feasible for single national agencies to organize an adequate and sufficiently frequent training (e.g., on an annual basis) to meet the ERA training requirements of the network.

In 2014 and 2017, a more comprehensive training was given by the German Environment Agency (UBA) and the National Institute for Public Health and the Environment (RIVM, Netherlands), respectively. In 2017, reimbursement of the participants' costs (one participant per Member State; travel costs and accommodation for the duration of the training) was provided by the EU Network Training Centre (EU NTC) of the European Medicines Agency (EMA). The feedback collected from participants of the 2017 training showed high appreciation for the input provided, in particular for its practical sessions involving case studies.

Training modules on the ERA for human pharmaceuticals are available for assessors of national competent authorities of the Member State online on the EU NTC platform. Currently, 5 training modules are available. However, these training modules, by their nature, can only provide basic theoretical education but do not allow discussion and exchange on more complex practical aspects of data evaluation on a case-by-case basis.

Experience from previous informal ERA assessors' meetings demonstrates that development and preparation of suitable training tools and formats, as well as the organisation and delivery of the training sessions, requires considerable human resources. Moreover, the variety of complex issues to be considered during the evaluation of the environmental risk of human pharmaceuticals, which requires practical training exercises, suggests further resources and a systematic approach are needed. The current reimbursement mechanisms of EU NTC allow for the participation of one assessor per Member State. However, given the workload and the currently limited ERA expertise in some member states, training is urgently needed for a number of assessors and in numerous aspects (exposure assessment, fate and effects assessment, tailored risk assessment, assessment of specific effects, etc). This is only possible with financial support for participants and presenters.

Ideas to improve knowledge, communication and exchange

Regular training opportunities in person and/or online

One way to fill knowledge gaps and improve expertise in the Member States is to provide a comprehensive training program. The program should include annual training meetings to facilitate use of practical exercises (e.g., case studies), allowing Member State to systematically build their capacities and expertise in ERA. In addition, recorded webinars would be helpful, especially as an introduction for new assessors, as well as for non-clinical assessors whose core expertise lies in areas other than ERA. The organization of such an annual ERA training could for example be in the remit of the Non-clinical Working Party (NcWP) under the umbrella of EMA, and not solely dependent on the initiative of individual Member States. This should be offered in addition to the training modules provided by NTC.

Funding is required for regular training meetings which exceeds the current financial possibilities of NTC. A budget at EC level is proposed to address ERA training requirements, in particular with a new ERA guideline version and/or new legislative framework coming into force. Reimbursement of travel costs should be available for all ERA assessors interested in attending training in person. In addition, the setup of hybrid meetings should be supported to allow additional assessors to attend virtually. If EMA hosts these training meetings, this will facilitate their regular occurrence as this would remove the logistical burden from individual Member States, as well as the costs associated with hosting. The planning of the scientific content of the annual training could be led by an ERA Operational Expert Group (OEG) of the NcWP (see below).

Online Communication Platform

Simple and informal ways of exchanging information, e.g., in case of questions arising during the evaluation of an ERA in a single application or related to the interpretation of the ERA guideline, would be desirable. One possibility would be the creation of a chat platform for ERA assessors of all Member States, where questions can be raised and answered by assessors

more experienced in that matter. The platform could be hosted by e.g., EMA. However, it must be noted that questions and answers exchanged via this platform would be intended as informal technical discussions and should not substitute regulatory discussions during the marketing authorisation procedure.

Designation of contact persons for ERA issues

Furthermore, it would be helpful to designate well-experienced regulatory ERA experts who could be consulted for ERA issues in general as well as in on-going procedures and provide their contact information in a database for example under the lead of an ERA OEG or an ERA related “European Specialised Expert Community (ESEC)” (please see new structure of non-clinical domain on EMA website: https://www.ema.europa.eu/en/committees/working-parties-domains" \l "overview-and-domain-concept-section).

The availability of ERA senior experts in addition to building up an online platform connecting senior and junior ERA experts to discuss issues ad-hoc could, at least temporarily, compensate the lack of specialized ERA assessors in some agencies. This might be particularly needed when the RMS/Rapporteur is inexperienced in ERA.

Funding by EC to buy in environmental expertise at National Competent Authorities (NCAs)

The need for regular training of non-clinical assessors, who are responsible for the ERA assessment of MAAs, to fill knowledge gaps and improve expertise, is obvious. However, there are limitations to what can be achieved with the proposed training of non-clinical assessors. A thorough technical background covering all environmental study types cannot be achieved even within an annual two day in-person training course. Therefore, regular ERA assessor training together with the other measures proposed, such as online platforms for informally exchanging information or twinning between ERA experts and less experienced assessors will represent an ongoing EC funding and resource requirement.

EC funding should also be provided for ecotoxicological training of non-clinical assessors at academic institutions to achieve a more relevant qualification to perform an ERA.

An additional supporting approach for EC would be to provide funding directly to the National Competent Authorities (NCAs) to contract external environmental experts. Currently, many European NCAs do not hire ERA specialists as this expense is not considered warranted given the ERA is not part of the benefit/risk assessment and currently does not constitute a criterion for refusal of marketing authorization. However, this approach has previously been used by the Commission, for example to support safety assessment of multinational clinical trials (CTs). EU funded a CT Safety Assessor role via joint action 12 of the EU4health program “Safety Assessment Cooperation and Facilitated Conduct of Clinical Trials (SAFE CT)”, providing up to 80 percent EU/ 20 percent NCA funding for an assessor to conduct the work imposed as part of the new implementing regulation on safety cooperation.

A similar approach could be taken to improve the level of environmental expertise quickly and efficiently across the network and to achieve the goal of action 5.3 “Improve the level of environmental expertise in the Committees and networks" of the EC strategy on Pharmaceuticals in the environment. This enhanced ERA expertise will be essential if any of the proposed solutions to strengthen the ERA, as outlined in the concept paper on environmental challenges, are to be implemented in the revision of the pharmaceutical legislation. If ERA becomes a criterion for refusal of a MAA, expert judgement regarding environmental risk will be required to inform a MAA assessment that must weigh potential environmental risk against the benefit/ risk of a product to a patient.

Mandate and objectives for an ERA Working Party (human) or an ERA Working Group (human) at EMA

General considerations

Currently, there is no central ERA Working Party or an ERA Working Group for human pharmaceuticals at EMA. The responsible working party for ERA issues is the Non-clinical Working Party (NcWP), a working party of the Committee for Medicinal Products for Human Use (CHMP), which is mainly focused on patient safety issues. Under the remit of the NcWP (formerly Safety Working Party = SWP) an ERA drafting group was convened to review and prepare the current ERA guideline (Doc. Ref. EMEA/CHMP/SWP/4447/00 corr 21*) for revision. However, there is no suitable group available to discuss ERA issues in on-going procedures or e.g., new scientific approaches in environmental risk assessment in a European harmonized way. The need for such a group has been identified by subgroup 7 of the ad hoc working group and is outlined below in more detail.

There are two possible scenarios for the format of such a new ERA advisory group at EMA:

1. A new, permanent ERA working Party (human) established as a new working party of the non-clinical domain, under the responsibility of the CHMP (as foreseen in the current draft of the revised legislation).
2. A new ERA operational expert group (OEG) established under the responsibility of the NcWP. The restructuring of the non-clinical domain at EMA is in force since May 2022. It allows for the possibility to create so called “operational expert groups”, if the NcWP lacks adequate expertise. Experts for an OEG are drawn from working parties as well as from the scientific network, including academic institutions. The intention for any OEG is to form a temporary group for specific tasks defined by a specific project scope within the domain, or to provide product support. However, an OEG could be set up in the short term to support ERA issues until the new legislation is enacted, at which time an ERA Working Party could replace the OEG on a more permanent basis.

For either scenario, it is recommended to install a permanent ERA advisory group in the non-clinical domain. The structure selected should facilitate both conceptional work and the high-volume workload that is expected following the finalization of guideline revision and changes

to ERA foreseen in the revised legislation. Support will be needed from EMA as well as HMA and the group will need regular face-to-face meetings at EMA every year.

Training and assessment support should be an important task of an ERA OEG or an ERA WP and included in its mandate. Also, questions arising from implementation of the revised ERA guideline should be covered by such a group. However, the newly installed European Specialised Expert Community (ESEC) group could also cover the goals related to a better ERA training and providing ERA expert contact data. The membership of this group could also comprise experts from academic or public institutions on a national level.

Meanwhile, before such an ERA WP, ERA-OEG or ERA-ESEC can be set up, information on existing or newly offered ERA training possibilities could be sent to national non-clinical contact points of the NCAs. Such an information channel could be built under the responsibility of the NcWP at EMA.

Possible Mandate and objectives of an ERA advisory group

The ERA-advisory group, ERA-WP or ERA-OEG, should be responsible for:

- Harmonization/consistency of ERA in procedures in the Member States. This should be reached on an EU/EEA level for all procedure types. Therefore, the ERA group opinion should be available not only on the request of CHMP but also of NcWP, CMDh, and individual member states or their experts. Thus, the ERA group could also support the assessment of complex ERAs on request, although this would not be intended to substitute regulatory discussions within individual marketing authorisation procedures.
- Harmonization of scientific and technical (experimental) aspects of performing the ERA methodology between substance frameworks as far as possible.
- Scientific advice on the interpretation of the EMA ERA guideline for HMPs, for instance through scientific advice procedures where applicants can ask advice regarding proposed ERA strategies for marketing authorization applications.
- The ERA advisory group should also provide a forum for discussing ERA issues with National Competent Authorities and Member States experts, upon request.
- Scientific input for the training of assessors from all EU/EEA Member States and the training itself.
- Necessary revisions and implementation of the EMA ERA guideline for HMPs and associated documents, considering the scientific state of the art.
- Expression of general scientific and technical views on ERA topics in new guidelines or reflection papers (e.g., on environmental risk mitigation measures, antimicrobial resistance, etc.) or by commenting on ERA related documents from other organizations.
- Liaising with the ERA WP (veterinary), as well as with other working groups (through EMA) at e.g., the European Commission, ECHA, EFSA, ECVAM, etc.

- Evaluation of developments regarding new exposure models, qualification of new testing systems / testing strategies, and 3Rs related methods about pharmaceuticals in the environment.

Regular training opportunities should be made available by providing a comprehensive training program including annual training meetings and recorded webinars in addition to the offered training modules provided by the European Network Training Center (NTC) at EMA.

Recommendations

7.1 Regular training opportunities should be installed by providing a comprehensive training program including annual training meetings and recorded webinars in addition to the offered training modules provided by the European Network Training Center (NTC) at EMA.

7.2 A budget at EC level is proposed to address environmental risk assessment (ERA) training requirements, in particular with a new ERA guideline version and/or new legislative framework coming into force. Reimbursement of travel costs should be available for all ERA- assessors interested in attending the training in person or remotely (hybrid meetings).

The organization and content of ERA-trainings with the possibility to attend in person could be in the remit of for example an ERA Operational Expert Group (OEG) to be established under the umbrella of the non-clinical working party (NcWP) at EMA and should not be dependent on the initiative of individual Member States (see also 7.6).

7.3 Creation of an online communication platform for ERA assessors from all Member States where questions can be raised and answered by assessors more experienced in that matter should be considered. The platform should be hosted by e.g., EMA.

7.4 Well-experienced regulatory ERA experts, who could be consulted on ERA issues in general as well as on on-going procedures, should be appointed and provide their contacts in a database for example under the lead of an ERA-OEG or an ERA related European Specialised Expert Community (ESEC).

7.5 EC funding should be provided directly to the National Competent Authorities (NCAs) to contract external environmental experts and for further qualification of non-clinical assessors.

7.6 A new ERA advisory group should be established at EMA. This could be a permanent ERA Working Party (human) inside the non-clinical domain under the responsibility of the CHMP or alternatively, a new ERA-OEG under the responsibility of the NcWP (a proposal for a mandate is given under Action 7).

V. Annexes

Annex 1: Questions and answers of the questionnaire – Action 1

Questions and answers

1. Do you develop guidelines for healthcare practitioners within your Member State or do you use guidelines from other countries? If you develop guidelines yourself: who develops these guidelines?

   About 70 percent develops their own guidelines for healthcare practitioners at least to some extent.
   - *National guidelines developed by e.g., chambers of experts, expert associations/ medical societies, national authorities, regional healthcare, social insurance institutions, Ministry of health.*

2. Do you have guidelines on reducing the use of antibiotics that could also be useful for general pharmaceutical use?

   It was difficult to interpret if/how guidelines could be useful for general pharmaceutical use.

3. Do you have guidelines on how to deal with environmental issues in daily practice for healthcare professionals? If so, how are healthcare professionals informed or educated about existing and new guidelines?

   About 35 percent responded that they have guidelines on how to deal with environmental aspects in daily practice for healthcare professionals, handling of waste is mentioned specifically. An additional 18 percent responded that they have guidelines on this for antibiotics.
   - *Instructions, websites, or training are mentioned for education and information about existing and new guidelines.*

4. Are appropriate tools for diagnosis easily available to prescribing physicians, to facilitate therapy choice (e.g., in case of viral versus bacterial infections)? Do you have any guidelines on when and how to use those tools?
   About 70 percent responded that appropriate tools for diagnosis are easily available to prescribing physicians, to facilitate therapy choice, ca 6 percent responded to that the tools are available to some extent.
   - *Guidelines on proper diagnosis of infections (viral or bacterial) are mentioned.*
   - *Tools mentioned include blood tests, swabs, Point of Care tests (CRP, streptococcus A antigen, urine dipsticks).*
   - *Reimbursement issues are mentioned e.g., tools for diagnosis of infectious diseases may be available but not always used due to reimbursement issues.*

5. Which guidelines that include environmental considerations are in place regarding prudent use of medicinal products/choice of therapy (i.e., use in the correct way, only for the right indication) in general or on specific patient/pharmaceutical groups such as:
   a) Reducing polypharmacy (e.g., in elderly)
   b) Patients with dementia
   c) Patients with depression and anxiety syndrome/psychotropic conditions
   d) Hormonal treatment
   e) Cytostatic
   f) Antibiotics
   g) Other pharmaceutical groups (exemplify)
   h) Specific patient groups (exemplify)
   i) Reducing spillage

   Most Member states have guidelines on prudent use for medicinal products/choice of therapy, mainly for antibiotics (about 90 percent) and reducing polypharmacy (about 55 percent*). Fewer mention other guidelines such as for cytostatic and treatment of depression/ anxiety syndrome/ psychotropic conditions or other guidelines. Few mentions specific environmental considerations in these guidelines.*

6. Are these guidelines (Question 5) only for general practitioners, or also for specialists and other healthcare professionals like pharmacists, midwives, physiotherapists, dentists, nurses?

   These guidelines (see Question 5) are mainly for general practitioners and specialist doctors (about 65 percent). Fewer (ca 30 percent) mention pharmacists, midwives, physiotherapists, dentists, and nurses.

7. Do you have (additional) guidelines or tools to consider environmental aspects in the choice of therapy? If so, which?

   The overall majority responded that they do not have this or that they were not aware of additional guidelines or tools to consider environmental aspects in the choice of therapy.

Summary of the results

Most of the countries that responded developed their own guidelines for healthcare professionals. An overall impression from the questionnaire is that many guidelines focus on diagnosis of infections and on prudent use of antibiotics. For instance, most of the Member States responded that tools for diagnoses are available, and the tools mentioned are mainly for diagnosis of infections. However, some Member States mentioned that tools for diagnosis for infectious diseases may be available but not always used due to reimbursement issues. Regarding guidelines on environmental aspects in daily practice, guidelines on antibiotics are mentioned but also handling of waste.

Guidelines on prudent use for medicinal products/choice of therapy are mainly for general practitioners and specialist doctors and these guidelines mainly concern prudent use of antibiotic and reduction of polypharmacy. Fewer Member States mention other guidelines such as for cytostatic and treatment of depression/anxiety syndrome/psychotropic conditions. Few mentions specific environmental considerations in these guidelines.

Annex 2: Questions and answers of the questionnaire – Action 2

Questionnaire

1. Are environmental aspects related to the drug development, manufacturing, distribution, use, and end-of-life of pharmaceuticals included in pharmacy and medical university studies?
2. Idem to the question 1, but for training programs and continuous professional development programs (on the job) for healthcare professionals.
3. Are there any national initiatives exploring how environmental aspects can be included in the training of pharmacy and medical students, or healthcare professionals? Are there any relevant documents (e.g., national guidelines/publications) specifying/directing towards how environmental aspects can be included in the education of pharmacy/medical students?
4. What would be needed to include environmental aspects in pharmaceutical and medical studies?

Summary of the results

Few Member States have developed initiatives exploring the ways for inclusion of the environmental aspects in pharmacy and medical studies/training programs and continuous professional development programs for healthcare professionals. Some countries provide or will provide supporting guidelines, although it is unclear how they are taken up in training. However, while the Italian guidelines focus on health in the environmental and proper pharmaceutical waste management to better protect the environment, most of the French guidelines deal with exposure to toxicants (due to accident, occupational exposure) and the treatment, not with the impact of pharmaceuticals on the environment.

In the other Member States, the initiatives are regional (Sweden, Italy), limited to specific actions initiated by universities (Germany, Finland, Sweden) or training of healthcare professionals (Italy).

Member states are aware of the lack of systematic incorporation of the environmental aspects in the education/professional training and suggests that Ministries of Education could play an important role in improving the situation and leading the responsible institutions to support anchoring of environmental aspects on pharmaceuticals in the environment in official curriculum. As exemplified by Italy, also the Ministry of the Environment can be involved by issuing guidelines for environmental education and sustainable development of pharmaceuticals for students. A suggestion for a joint EU-wide initiative has also been mentioned.

Annex 3: Questions and answers of the questionnaire – Action 3

1. **Does the national legislation allow for the inclusion of environmental information in the advertising of over the counter (OTC) and/or prescription medicines?**
    - No legal restrictions for the inclusion of information as long as information is also reflected in Summary of product characteristics: AT.
    - The company proposes the type of packaging/the pack sizes for the medicinal product. The competent authorities assess user-friendliness and suitability to protect the medicine during the shelf life.
    - The company that applies for a marketing authorisation proposes the type of packaging and the pack sizes for the medicinal product. Regarding the type of packaging, the competent authorities assess user friendliness and suitability to protect the medicine during the shelf life. For the pack size, the competent authorities mainly verify whether is in line with the posology. When the marketing authorisation is obtained, it is the company that decides which of the approved packaging types and pack sizes are commercialised. This may also depend on the reimbursement rules in the country where it is commercialised. Advertising of medicines is strictly regulated in Belgium by the Royal Decree of 1995/04/07.Inclusion of environmental related information might be allowed if exact, up-to-date, and verifiable: BE.
    - There is no objection by the legislation. This is not a requirement at the time. The legislation on the advertising of medicinal products transposes the provisions of Directive 2001/83/EC: CY.
    - This is not mentioned in national legislation (either not allowed or restricted): CZ.
    - The national legislation does not contain any specific provisions dealing with the inclusion of environmental information in the advertising of medicinal products. As long as all requirements of the national legislation in respect of the advertising of medicinal products are met, the inclusion of environmental information is possible: DE.
    - All parts of the advertising of a medicinal product must comply with the particulars listed in the summary of product characteristics, cf. Article 87(2) of Directive 2001/83 and section 63 of the Danish Medicines Act. For example, information about special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product. The judgment of the ECJ in case C-249/09 contains information about the interpretation of Article 87(2) of the Directive and the use of claims in advertising of medicinal products. Advertising of a medicinal product (over-the-counter) to the general public shall not contain any material which suggests that the safety or efficacy of the medicinal product is due to the fact that it is natural, cf. point (h) of Article 90 of Directive 2001/83/EC and section 10(1)(ix) of the Danish executive order on advertising of medicinal products: DK

- The advertising of medicines for human use, including over the counter and prescription medicines, is based upon the product information. Information not included in this document cannot be displayed in the advertisement: ES.
- Information on advertising should be based on information in the approved SPC, which rarely includes information on environment. The legislation does not specifically mention environmental aspects in the advertising of medicines: FI.
- TV ads and billboards about the French Cyclamed network[91] that recycles expired drugs (both over-the-counter and prescription medicines): FR.
- Yes - there are no provisions that forbidden it: HR, LU.
- There is no specific national legislation explicitly forbidding the inclusion of environmental information in advertising: IT.
- Only information included in the approved product information can be used in advertising. Advertising for prescription medicines can only be directed to health care professionals/prescribers: NO.
- Yes, usually on products' insert and Summary of product characteristics: PL.
- The legislation seems to allow it, but we have not seen yet such information in the advertising: RO.
- Yes, albeit not explicitly. And even though Article 87 of Directive 2001/83/EC states that all parts of the advertising must comply with the Summary of product characteristics, our interpretation is that this regulation does not preclude environmental information: SE.
- There are no explicit provisions relating to environmental information, but neither is the addition of such information excluded. For example, the National Competent Authorities has the authority to prescribe the use of any other markings to be included on the label: SI.

2. Do you have guidelines or practices on how to take into account environmental considerations when advertising medicines and the choice of therapy? If so, please give more information about these guidelines or practices.

- No: BE, CY, CZ, DE, DK, ES, FR, HR, IT, LU, NO, PL, SE.
- No guidelines on this, when we do not have enough scientific information to support these guidelines, or facts to be based on: FI.
- Not yet, but we can include them as we are currently considering revising the advertising regulations in the field of medicinal products: RO.
- We do not have guidelines nor experience in assessing environmental aspects in the advertising of medicines. The Agency encourages an open and constructive dialogue with stakeholders, taking environmental and public health aspects into account: SI.
- None determined: AT.

[91] CYKLAMED. https://www.cyclamed.org/

3. **Do you have guidelines or practices on how to take into account environmental considerations in the prescription of medicines and the choice of therapy? If so, please give more information about these guidelines or practices.**

- No: BE, CY, CZ, HR, LU, NO, RO.
- No, apart from antimicrobial resistance: DK.
- No guidelines can be given, when we have not enough scientific information on which these guidelines can be based on (relates e.g., different materials, packages, recycling of various materials etc.): FI.
- No. In any case it should also be important to know whether environmental considerations affect the cost of the medicinal product for national health systems/patients: IT.
- No stringent considerations. Some national/regional therapeutic guidelines include environmental aspects, but limited areas and limited extent. Projects in progress on environmental aspects on pricing and criteria for sales of medicines outside pharmacies: SE.
- None directly addressing environmental considerations, however there is a recommendation by the Health Insurance Institute of Slovenia to prescribe larger pack sizes instead of an equivalent in small packs, which in effect reduces packaging waste: SI.
- Anti-infectives GL recommends caution when prescribing antibiotics in the context with evolving resistance: AT.
- There is no knowledge about such guidelines or practices: DE.
- These guidelines are only available for antibiotic prescribing and, as mentioned above, they are developed by the Spanish action plan on antimicrobial resistance: ES.
- Yes: usually on products' insert and Summary of product characteristics: PL.

Annex 4: Questions and answers of the questionnaire – Action 4

1. **Do you have guidance on reducing pharmaceuticals pack sizes/packaging and on how to deal with environmental issues related to packaging (e.g., greener packaging)?**
   - No: AT, CY, CZ, DK, LU, PL, RO, SE, SI.
   - No, packaging will be different between pharmacy and hospital pharmacy (bigger one), reasons to change packaging size due to toxicity/safety reasons for patients: FR.
   - No guidance but dose-dispensing activities in pharmacies, and package sizes without the package leaflets in order to minimize unneeded waste: FI.
   - No, use of unit-dose packaging by a law (2014), environmental issues related to packaging not addressed at national regulatory level: IT.
   - No, for long term treatment smaller pack sizes used mainly by economic motivation: NO.
   - Yes: HR.
   - Yes, in some therapeutic areas: opioids and antibiotics: BE.
   - Yes, by therapeutic appropriateness in approval and variation procedures: largest packages size authorized by the competent higher federal authority cannot be reimbursed by statutory health insurance: DE.
   - Yes, by guidance developed by SIGRE and some pharmaceutical industries, FSC symbol* (forest steward ship council) is allowed to be included in the inner side of the packaging: ES.

     ** FSC symbol: When a wood product has an "FSC-certified" label, this means the wood and its manufacturer met the FSC standards for sustainable and societally beneficial forest use. More details: https://fsc.org/en/fsc-labels, FSC organisation website: https://fsc.org/en*

2. **If not, do you plan to develop such guidance?**
   - No: AT, CY, CZ, DK, NO, PL, SE, SI.
   - No, currently collaborating in the E-PIL project where paper package leaflets are replaced by electronic versions for medicines that are only used in hospitals: BE.
   - Not applicable: LU, ES.
   - No, no need to change the legal regulations on pack sizes of medicinal products: DE.
   - No, but interested in: IT.
   - No, more efficient if such guidance is developed at EU level: FR.
   - Yes, but need to see some models from more experienced countries: RO.

3. Who is deciding on the drug packaging in your country?

- National competent authorities: AT, CY, CZ, ES, FI, FR, HR, IT, NO, RO, SE, SI.
- National competent authorities can impose certain pack sizes that are appropriate to areas of application and intended duration of use during approval process: DE.
- National competent authorities after proposal of MA (compatibility package/shelf-life, in line with posology): BE.
- Rely on packages that are manufactured in countries that supply the national market: LU.
- Marketing Authorization Holder: CY, DK, PL.
- Pharmacists for compounded medicines (magistral formula): IT.
- Pharmacy-produced products (few) according to prescription (magistral formula): NO.

Figure 4. Map that visualizes the differences between the answered member states in who that deciding on the drug packaging.

4. Optimizing the package size, how do you deal with the following items?

<u>Tighten prescription rules</u>

- Prescription recommendations for antibiotics: AT.
- The MA that we deliver can restrict prescription and/or delivery, prescription can for example be limited to specialised physicians/delivery can for example be limited to hospital pharmacies: BE.
- Imposed by Health Insurance Organisation, pharmacists advised to dispense only the quantity needed by the patients: CY.
- According to law, the prescribing medical person decides on the amount of the (human) medicinal product to be prescribed: DE.

- Prescribers are instructed to start new medicines with smaller packages, especially for long-term treatment: FI.
- Focus on patients and physician in order to reduce waste. Tighten prescription rules is more a matter of safety or economic impact: FR.
- Yes, but not detailed: HR.

Dispensing only the prescribed quantity

- When dispensing only the prescribed quantity, it should be taken into account that this is not suitable for all dosage forms and that there is an expense and resource consumption for the management of opened packs, and it's dispensed: DE.
- Prescribed quantity corresponds always with the marketed pack sizes except in in hospital setting, where the quantity of medicine is dispended based on the individual need of the patient: BE.
- By dose-dispensing for individual patients needs in pharmacies, unnecessary quantities (package waste) of medicines can be avoided: FI.
- Usually, and in accordance with the Public Health Code, the pharmacist cannot dispense, at one time, medication prescribed on a prescription for more than one month (4 weeks) of treatment, especially for certain classes of drugs such as anxiolytics, hypnotics..., The Shared Medical Record (DMP)*, Dispensing at the unit (DAU)*: FR.
- Yes, but not detailed: HR.
- At a licensed pharmacy, drugs can be automatically dispensed and delivered according to a patient's prescription; marked with name, date, and timing of administration: SE.

*DMP: digital health record that stores and secures health information: treatments, test results, allergies, etc. Additional information could be integrated to alert on pharmaceuticals posing a risk to or via the environment and on the different packages size that could be delivered to better match need.

*DAU: into force since 10th February 2022 introduced in the public health code. The pharmacist will receive the serialized box and will have to decommission it at the first opening of the box. The remaining units will be kept by the pharmacist in the pharmacy for later dispensing. Thus, storage in the pharmacy ensures that the remaining units will not be replaced by falsified units.

Smaller pack size good waste dispensing practices?

- Pharmacies have the legal obligation to collect unused medicines, brought to specialised companies for destruction. Quantities of collected medicines demonstrate that this system works well: BE.
- Initiatives looking into using smaller pack size have been implemented: ES.
- Perhaps but not necessarily: the solution of less packaging does not mean less waste. There is a major safety objective in packaging, but it would be wise to consider it in the environmental risk: FR.

- Smaller pack sizes should be considered for medicinal products used for the treatment of acute disease which resolve in a few days (e.g., semi-solid or liquid preparations for topical use which expire within a few months after opening): IT.
- Gains: smaller pack size, exact dispensing, reduced secondary packaging with dispensing only the prescribed quantity: SE.
- The pack size (number of dosage units, e.g., tablets) should be adapted to the posology- the packs are approved during the marketing authorisation procedure: SI.

Adapt/personalize the Dispensing posology

- System under development to personalize the dispensing quantity for opioid pain medication and antibiotics, in retirement homes a system is in place that permits the preparation of the medication for individual patients from a bulk packaging: BE.

Reducing secondary packaging

- There are not specific steps to optimize package size, which is not easy to manage in small market: CZ.
- There is currently no national/regional initiative in this direction: IT.
- There is no national framework aiming to optimizing pack size: LU.
- This is very complex issue, not easy to judge: PL.
- See Q1 and Q3 on Action 4, NO.
- We will have to reflect on these aspects, we have yet not implemented specific measures in this respect: RO.
- Not easy: mechanical protection or protection of the medicine from light, secondary packaging contains information for the patient that can not by printed on the primary pack, allows the placement of an anti-tampering device (ATD), as requested by the Falsified Medicines Directive, package leaflet placed in the secondary packaging: BE.
- The pharmaceutical company himself determines the type of packaging basing on DIN standards of the packaging industry: DE.
- According to the rules on labelling, the package size should be balanced with the therapeutic purpose, the adequate dosing and stability: DK.
- Leem (National syndicate of the pharmaceutical companies) emphasizes that the main cause of wastage does not come from packaging but from inappropriate prescriptions and poor monitoring of the treatment prescribed by patients: FR*.
- Reduced secondary packaging or personalized posology is not applied: SI.
- Initiatives looking into reducing secondary packaging have been implemented (ES)

**According to the latest figures from the Cyclamed eco-organization in charge of collecting unused medicines (MNU), the quantity of medicines recycled per French person was 162 grams in 2018. This is far, very far from the "1.5 kg of medicines thrown away each year by French people" cited in parliamentary debates.*

5. Are there any prescriber and pharmacist initiatives in your country to increase public awareness on the impact of pack size/packaging on environment?

- No: CY, FR, HR, NO.

- Nothing identified: AT, DK.
- Not informed: BE, CZ.
- Not available: DE, PL, RO.
- Pharmacist initiatives exist (https://www.pharmacie.lu/medicaments-perimes-comment-les-recycler/) but not specifically targeting pack size: LU.
- Pharmacy initiative: shelf labelling "Välvald"[92]. The Välvald label guides pharmacy customers to pharma companies that are more transparent about their sustainability work. At the moment not focusing on packaging. SE.
- Recommendation issued by the Health Insurance Institute of Slovenia to prescribe larger pack sizes (e.g., 90 tablets) instead of an equivalent in small packs (e.g., 3 boxes of 30 tablets each), which in effect reduces packaging waste: SI.
- Yes, some initiatives have been promoted by the SIGRE system and some pharmaceutical industries: ES.
- Yes, Helsinki University - "Generation green"[93] project: FI.
- Yes, some hospital pharmacies have implemented a personalised dose program for some drugs: IT.

6. Is there a possibility to re-think or optimize the way how the expiry date is currently set to safely extend it if allowed by existing stability data?

- The expiry date is based on the production date of a batch and the shelf life of the medicinal product. Pharmaceutical companies foresee that a batch of medicines is sold long before the expiry date. The expiry date for a batch of medicines is based on the production date of the batch and the shelf life of the medicinal product. That principle should be maintained. Although requestion the longest shelf life that can be justified by the stability data could be an option, it is not sure that this will have a significant impact on the situation on the market: BE.
- This issue has already been optimised by the stability data studies: ES.
- Today, the pharmaceutical companies (responsible for the test of the shelf life) have no incentives to extend the tests for longer than required, usually two years: SE.
- Yes, but currently this is company driven. Stability data could be made at least in part, publicly available: CY.
- It is not allowed by law to beyond shelf-life usage of medicines, however there are some plans to tackle this in future legislation: CZ.
- Basically, the German pharmaceutical law does not provide extended expiry dates. It is conceivable that expiry dates may be extended if, on the basis of further stability tests carried out by the marketing authorization holder, these have been approved by the regulatory authority: DE.
- Expiry date is linked to the approved stability data and extension would require support from such studies: NO.

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[92] Välvald. Swedish Pharmacy Association (Sveriges Apoteksförening) requirements for responsible pharmaceutical manufacturing. https://www.sverigesapoteksforening.se/wp-content/uploads/2021/04/2101-QA-eng.pdf

[93] Generation Green. https://blogs.helsinki.fi/generationgreen

- Collection of substance specific stability data to help to extend expiry date, has to be a centralized process: AT.
- Yes, this cannot be excluded. To be looked at EC-level: DK.
- Currently, many companies submit variations to reduce the shelf life for commercial purposes. This situation will not only lead to higher expenses for national health systems but also result to higher packaging wastes. EU stability and variation guidelines may be amended to prevent such situation: FR.
- We are open to proposals, but we are aware that this would probably need to be addressed at EU level: LU.
- Before 1990 Romania used to have such a system and we believe that a modern system in this respect is possible and should be developed at EU level: RO.
- Monitoring of stockpiled medicines: There is a technical guideline developed for monitoring of tablets with potassium iodide. The tablets I can be used up to 10 years after expiry if sufficient quality is demonstrated during monitoring by OMCL: SI.

Logotypes

French logotype

The Triman logo has been introduced in France by the Decree 2014-15733 and, since January 1, 2022, it will have to be mandatorily displayed on the labels of recyclable products – including medicinal products.[94] The symbol aims to inform the consumer that the product must be recycled appropriately: at the end of its life cycle, the item has to be thrown away in the correct collection bin.

Figure 5. Structure of the Triman logo.

[94] Structure of the Triman logo. https://deutsche-recycling.com/blog/triman-logo-in-france-2/

Swedish logotype

Figure 6. The logo of Välvald that contains the Swedish Pharmacy Association requirements for responsible pharmaceutical manufacturing.[95]

International logotypes

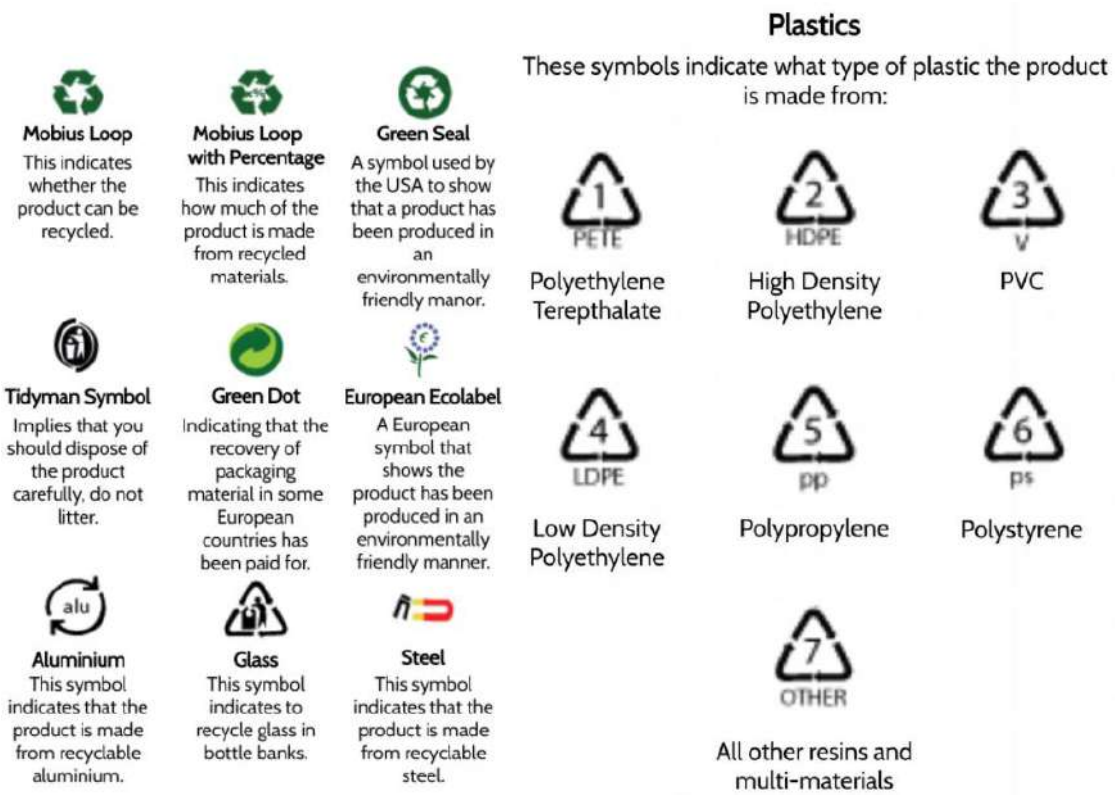

Figure 7. Different international logos.

[95] Välvald. Swedish Pharmacy Association (Sveriges Apoteksförening) requirements for responsible pharmaceutical manufacturing. https://sverigesapoteksforening.se/valvald/

Annex 5: Questions and answers of the questionnaire – Action 5

1. **Are there any guidelines for Health Care Professionals (HCP) and future HCP (i.e., pharmacy/medical /dental students) which tackle the environmental aspects? - Link with Action 2.**

   8 Countries answered with Yes and 9 with No. CY and ES have mainly for cytostatic drugs, while DK have GL for antibiotics. RO answered positively, but the bill of Law didn't pass.

   A handful of countries have training for future HCP but not guidelines in place at present for established HCP.

2. **Do you have a legislative framework to manage medicinal product waste disposal to tackle the environment issues? How is the system working (i.e., related to organization and management)? What current initiatives/best practices you could share with the other Member States?**

   The majority of MS, i.e., 14 answered Yes. In most of the MS, the pharmacies collect the unused or expired medicines, and the pharmacy must ensure safe disposal. Some states have variations in the collection procedure based on local authorities.

   Germany advice on the disposal in the grey waste, probably because 80 percent of it is incinerated and does not reach the water network.

3. **What current initiative or best practice your country has that could help Member States cooperate more to formulate a common goal (reducing and managing the waste in an effective way) and address the environmental challenges of medicines? Please share them with the other Member States.**

   59 percent of the responding Member States have initiative/best practices to reduce and manage the waste in an effective way and address the environmental challenges of medicines.

   AT, DE and ES have guidelines that can be shared and be integrated into a common framework for all MS. FR has a specific system where the producer is rendered responsible for the full lifecycle of the pharmaceutical product.

   To decrease the number of expired medicines, IT has a special pharmaceutical bank that enables unexpired medicines to be redistributed to persons in need through affiliated charities.

   SL can advise on reduction of poly medication and on reasonable usage of antibiotics. SE encourages the general population to bring unused medicines back to pharmacies. These two Member States provide upstream initiatives to reduce consumption of pharmaceuticals and hence decrease the volume of waste.

4. **Do you have guidelines or collection schemes for healthcare professionals on how to deal with unused or expired pharmaceuticals? E.g., guidance not to flush away any leftover pharmaceuticals.**

   Most of the states (77 percent) have guidelines on how to safely dispose pharmaceuticals directed towards healthcare professionals as well as patients. It is also considered that health care personnel should be involved in raising public awareness.

5. **For products with active substances that impact the environment, are measures in place that would guide the patient during the use of the medicinal products to minimize this environmental impact (e. g. handling of topical products)?**

   RO answered that pharmacies should collect such products from patients, but the system is not always working in practice. There is a ministry order in place on proper collection of pharmaceutical waste but there are no repercussions in place for not observing the rules.

   10 countries answered that there are no specific measures in place, other that the information available in the package leaflet/ Summary of product characteristics (SmPC). 24 percent of responding Member States have measures in addition to SmPC to reduce the environmental impact.

   IT responded that some specific instructions addressed to professionals for inactivating active substances are in place (e.g., metabolites/anti-metabolites) usually by strong oxidation or protein denaturating procedures to limit sewer contamination.

Table 5. Question 1 and the answers of the responding countries.

	Q1: Are there any guidelines for Health Care Professionals (HCP) and future HCP (i.e. pharmacy/medical /dental students) which tackle the environmental aspects? - Link with Action 2.	
	ANSWER	**COMMENTS**
AT - Austria	YES	General Austrian standard (ÖNORM) on waste from medical institutions
BE - Belgium	NO	We are not informed of such guidelines
BE2 - Belgium		We are not informed of such guidelines
CY - Cyprus	YES	Mainly for cytotoxic
CY2 - Cyprus		The Department of Environment of the Ministry of Agriculture is preparing Regulations for the disposal of unused/expired medicinal products.
CZ - Czechia		See Action 1, answer to Q1
DE - Germany	NO	The environment is part of medical training. Medical training provides knowledge about the influences of the environment on health. Further, the subject of clinical environmental medicine is a part of medical education.
DE2 - Germany		The environment is part of medical training. Medical training provides knowledge about the influences of the environment on health. Further, the subject of clinical environmental medicine is a part of medical education.

DK - Denmark	YES	List – not exhaustive: Order for handling of pharmaceuticals in institutions (in Danish): https://www.retsinformation.dk/eli/lta/2005/1222 Guidelines for handling of pharmaceuticals in the primary sector (in Danish): https://stps.dk/da/ansvar-og-retningslinjer/vejledning/haandtering-afmedicin/~/media/0E30EDB960FA47DBA41FDA577A0AB979 National action plan on antibiotics in human healthcare (not updated since 2017): https://sum.dk/publikationer/2017/juli/national-handlingsplan-for-antibiotika-tilmennesker
ES - Spain	YES	Guidelines for antibiotics and for the correct disposal of cytotoxic products at hospitals. Also, different autonomous communities have their own guidelines in respect of different medicinal products.
FI - Finland	YES	There are strict instructions in every hospital pharmacy on how to deal with drug waste. Hospitals have closed loops with medicines meaning that drug waste from every clinic and department returns to pharmacy which arranges the safe disposal.
FR - France	NO	No comments
HR - Croatia	YES/NO	Yes for HCP and no for future HCP
IT- Italy	NO	No comments
LU - Luxembourg	NO	No; please refer to answers provided for Action 2
NO - Norway	NO	No GLs that we are aware of. Pharmacy students have a training period in pharmacies and learn about the take back scheme there. Some general information in online sources, see action 2.
PL - Poland	NO	No comments
RO - Romania	YES	There is currently a bill of law in the Romanian Parliament tackling this topic.
SE - Sweden	YES	Yes. Environmental aspect (compulsory course) is part of the education for pharmacy, medical and dental students in Sweden.
SI - Slovenia	NO	Answer delayed.

Table 6. Question 2 and the answers of the responding countries.

	Q2: Do you have a legislative framework to manage medicinal product waste disposal to tackle the environment issues? How is the system working (i.e. related to organization and management)? What current initiatives/best practices you could share with the other Member States?	
	ANSWER	**COMMENTS**
AT - Austria	YES	Hygiene regulation regulates disposal especially of disinfectants, cytostatics and pharmaceuticals containing heavy metals
BE - Belgium	Yes	Yes, Royal decree 2009-01-21. Expired or unused med. returned by the patient are collected by the pharmacist in a separate place, then collected by the wholesaler for destruction (art. 13, RD 21.1.2009). He has to keep a proof of the destroyed medicines
BE - Belgium	Yes	"Expired medicinal products have to be stored in a clearly separated place (clearly marked 'NOT TO BE DELIVERED') waiting for destruction. The pharmacist himself is responsible for the destruction of these products in accordance with the applicable regulations (in Flandres for example, there is the OVAM legislation with separation of naesthetics><nonanaesthetics). He has to keep proof of the destroyed medicines (mentioning at least the name and quantity) (art. 13, RD 21.1.2009*). In practice, this destruction is often organised by the local pharmaceutical associations. * Koninklijk besluit van 21 januari 2009 houdende onderrichtingen voor de apothekers : http://www.ejustice.just.fgov.be/cgi_loi/change_lg.pl?language=fr&la=F&cn=2009012132&table_name=loi

		The expired or unused medicines returned by the patient are collected by the pharmacist and collected by the wholesaler-distributor (wholesaler) for destruction (art. 13, RD 21.1.2009). In this case, the pharmacist may not refuse to also collect the liquid remnants of medicines (e.g. syrups). The obligation of wholesaler-distributors to collect and pay for the latter is an obligation imposed by the regional governments, i.e. the Flemish Government, Brussels Capital Region and the Walloon Region. * Koninklijk besluit van 21 januari 2009 houdende onderrichtingen voor de apothekers : http://www.ejustice.just.fgov.be/cgi_loi/change_lg.pl?language=fr&la=F&cn=2009012132&table_name=loi"
CY - Cyprus	no	Legislation currently under implementation
CY2 - Cyprus	No	The Department of Environment of the Ministry of Agriculture is preparing Regulations for the disposal of unused/expired medicinal product
CZ - Czechia	Yes	Yes, each Health Care Provider must have SOP. Act No. 378/2007 Coll.on Medicinal Products states unusable medicine falls under "hazardous" waste treated as Act 541/2020 Coll.on Waste collected via pharmacy/collection yard managed by authorized entity
DE - Germany	Yes	"In Germany, the legal basis is the Recycling Management Act (KrWG). According to this, waste must be properly disposed and without causing damage. Central aspects are the protection of people, the environment and natural resources. For the area of waste from health care facilities, in particular hospitals, medical and veterinary practices, and pharmacies, Note 18 of the Federal/State Working Group on Waste (LAGA-M18) serves as an enforcement aid for the concretization of the above-mentioned proper and harmless disposal. The aim of this guideline is to ensure safe and proper waste disposal for this sector. Further information on applicable legal regulations that go beyond this can be found in Appendix 2 of the LAGA-M18 enforcement guideline. These Guidelines only apply pharmaceuticals waste of the healthcare sector, the private sector and schools are excluded. Medication waste or the like should be disposed of according to the links below.There does not exist a specific legislative framework to manage the disposal of medicinal product waste of private households. In general waste management is regulated at the municipal level. Therefore, different recommendations on how to dispose unused pharmaceuticals exists in Germany. Approx. 80 percent of private household waste is incinerated in Germany. Therefore, disposal of unused or expired pharmaceuticals via household waste is the safest and recommended route in most regions. However, certain pharmaceuticals like cytostatics have to be disposed under special conditions and not via household waste. For getting the information on how to dispose unused pharmaceuticals in a certain region, a website is available describing the various preferred disposal recommendations in the districts (https://arzneimittelentsorgung.de/home/)."
DE2 - Germany	yes	Legal basis is the Recycling Management Act (KrWG), for the waste from health care facilities it is Note 18 of the Federal/State Working Group on Waste (LAGA-M18). Website for information on disposal: (https://arzneimittelentsorgung.de/home/).
DK - Denmark	yes	Pharmacies: Waste collection; users can drop unused medicines at pharmacies. Hospitals: SUM/MST (ifht produktionssteder).
ES - Spain	YES	SIGRE system manages the medicinal products household waste disposal and unused pharmaceuticals. The system is a non-for-profit entity. Autonomous communities have other frameworks for managing waste disposal from hospitals and GP practices.
FI - Finland	yes	"Medicines are hazardous waste. Collection is organised by municipalities through pharmacies and all medical waste is high-temperature incinerated in one location. See publication https://helda.helsinki.fi/handle /10138/319009."

Relevant international conventions which have implications for Health Care Waste

Table 7. Texts that should be taken into account for healthcare waste disposal.

Texts	Reference
Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (Recast)	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02010L0075-20110106
Council Directive 96/59/EC of 16 September 1996 on the disposal of polychlorinated biphenyls and polychlorinated terphenyls (PCB/PCT)	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A31991L0156
Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (recast)	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02011L0065-20240201
Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A31991L0156
Council Decision (EU) 2019/638 of 15 April 2019 on the position to be taken on behalf of the European Union at the fourteenth meeting of the Conference of the Parties with regard to certain amendments to Annexes II, VIII and IX to the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32019D0638&qid=1709556115007
Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02008L0098-20240218&qid=1709556338511
Council Directive 1999/31/EC of 26 April 1999 on the landfill of waste	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:01999L0031-20180704&qid=1709556459109
Directive (EU) 2018/850 of the European Parliament and of the Council of 30 May 2018 amending Directive 1999/31/EC on the landfill of waste	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32018L0850&qid=1709561753865
European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:01994L0062-20180704&qid=1709557394235
Directive (EU) 2018/852 of the European Parliament and of the Council of 30 May 2018 amending Directive 94/62/EC on packaging and packaging waste	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32018L0852&qid=1709561753865
Directive (EU) 2018/851 of the European Parliament and of the Council of 30 May 2018 amending Directive 2008/98/EC on waste	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32018L0851&qid=1709561753865
Regulation (EC) No 1013/2006 of the European Parliament and of the Council of 14 June 2006 on shipments of waste	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02006R1013-20210111
Commission Decision of 3 May 2000 replacing Decision 94/3/EC establishing a list of wastes pursuant to Article 1(a) of Council Directive 75/442/EEC on waste and Council Decision 94/904/EC establishing a list of hazardous waste pursuant to Article 1(4) of Council Directive 91/689/EEC on hazardous waste (notified under document number C(2000) 1147)	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02000D0532-20231206&qid=1709562608603

Table 8. National guides, some examples.

Country	Guide
France	Guide pratique 2016 Ministère des Affaires sociales et de la Santé. Pour une bonne gestion des déchets produits par les établissements de santé et médico-sociaux. Déchets issus de médicaments/ Déchets liquides. https://sante.gouv.fr/IMG/pdf/pour_une_bonne_gestion_des_dechets_produits_par_les_etablissements_de_sante_et_medico-sociaux.pdf
France	Haut Conseil de la santé publique 2023. Avis relatif aux nouvelles recommandations de tri des déchets d'activités de soins en lien avec la révision du guide national sur l'élimination des déchets d'activités de soins à risques infectieux et assimilés (DASRIA) https://www.hcsp.fr/Explore.cgi/AvisRapportsDomaine?clefr=1316
England	England NHS: Health Technical Memorandum 07-01: Safe and sustainable management of healthcare waste 2022. NHS clinical waste strategy. Version 1, 31 January 2023 https://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-htm-07-01/
Switzerland	Technical Brief: Sustainable Health Care Waste Management. 17 FEBRUARY 2020 GENEVA https://greenhealthcarewaste.org/wp-content/uploads/2020/12/The-Global-Fund-Technical-Brief-Sustainable-HCWM.pdf
Scotland	Guidance for the storage and treatment of healthcare waste Storage and treatment of healthcare waste: Appropriate measures and supporting guidance. In Scotland, the storage or treatment of healthcare waste is regulated by the Scottish Environment Protection Agency (SEPA). https://www.sepa.org.uk/media/w0qdaa1l/guidance-for-the-storage-and-treatment-of-healthcare-waste.pdf

Annex 6: Results of the questionnaire – Action 6

Results of the questionnaire and inventory

As a response to the questionnaire, 11 out of 17 Member States replied that no Extended Producer Responsibility (EPR) was in place in their Member States. In some Member States (Belgium, Norway, Sweden, Slovenia), some form of EPR is in place, where the pharmacies and/or the wholesalers are responsible for the collection and destruction of patient's pharmaceutical waste. In Belgium, Slovenia, and Sweden this is regulated by law. In Romania, a polluter pays principle is applied, which was not further defined in the questionnaire results. Only in France, it is specified that not the pharmacies, but the pharmaceutical industry contribute to financing destruction of unused medication, which is regulated by law.

In the responses to the survey provided by Spain it was shown that there is no regulated EPR, although there is a voluntary EPR initiative set up by the pharmaceutical industry. According to the inventory that was made to prepare the questionnaire, also the Netherlands, who did not fill in the questionnaire, has an informal EPR initiative in place.

Some examples and best practices of EPR in some Member States are discussed below.

France

In France a regulation obliges dispensing pharmacists to collect drugs brought back by patients. These drugs are transported to the logistics centers of wholesaler's from where an eco-organization collects them and ensures the destruction by incineration. According to the producer pays principle, drug manufacturers contribute to financing of the eco-organization.

Directive 94/62/EC requires that the Member States of the EU must ensure the establishment of an Extended Producer Responsibility (EPR) scheme for packaging by 31 December 2024, in accordance with the provisions set out by Directive 2008/98/EC. The purpose of this requirement is to facilitate the re-use, recycling, and recovery of waste in the EU.

The legislative measures include encouraging the development and production of multiple-use materials, and recovery and recycling of the materials. Some countries such as France and Germany have taken legislative actions to implement the EPR starting on 1 July 2022.

In France, starting December 7th, 2023, all packaging, papers, and medicines subject to EPR on the French market, unless exempted by law, must carry the new recycling labelling, the Triman logo. The symbol aims to inform the consumer that the product must be recycled appropriately: at the end of its life cycle, the item must be thrown away in the correct collection bin.

In Sweden, the Välvald label guides pharmacy customers to MAHs that are more transparent about their sustainability. In addition, brief information about how to handle unused products and packaging is presented on the package of Over-The-Counter medicines.

Spain

SIGRE Medicine and Environment is a non-profit organization set up in 2001 on the initiative of pharmaceutical laboratories with the purpose to prevent waste at source as well as the build-

up of medicines in Spanish households and to ensure correct environmental treatment of the waste generated. The key-stakeholders are the laboratories, the pharmacies, and the distributors. Pharmacies receive unused medicines left by members of the public at the special SIGRE-collection points located within most pharmacies. The waste deposited in the pharmacies is then picked up and taken to the treatment plant.

This is an informal type of EPR-system; set up, organized, and funded by the pharmaceutical industry on their own initiative, but in close collaboration with the pharmacies and distributors. Actions to reduce pharmaceutical waste are performed in several stages of the pharmaceutical life cycle. The collection system is not regulated in Spanish law, but it is implemented throughout Spain, and it is recommended and promoted by Spanish and EU health institutions, pharmacies, and distributors. Actions to reduce pharmaceutical waste are performed in several stages of the pharmaceutical life cycle. The collection system is not regulated in Spanish law, but it is implemented throughout Spain, and it is recommended and promoted by Spanish and EU health institutions.

Sweden

In Sweden there is a formal type of EPR-system regulated by law through the ordinance of Producer Responsibility for Pharmaceuticals (SFS 2009:1031), in which the producer is defined as someone who holds a permit to sell medicines through a community pharmacy. This means that the pharmacies are obliged by law to take care of any pharmaceutical waste from households, without any cost to the user, and to dispose of it in the appropriate way. However, the pharmacies are only obliged to take back pharmaceuticals in proportion to the number of pharmaceuticals that they sell and there is no obligation to receive any pharmaceuticals that are classified as hazardous waste (this waste is the responsibility of the municipalities). The above-mentioned regulation also obliges the pharmacies to provide their customers with information of the importance of disposing of any pharmaceutical waste from households in the appropriate manner. The system is funded by a central government agency (TLV), who determine retail margins for all pharmacies in Sweden. In setting this margin, all costs of the pharmacy business including that of the collection system are taken into account.

In 2021, a symbol to help guide customers, was launched by the Swedish Pharmacy Association. The pharmaceutical companies that meet the pharmacy's criteria for transparent sustainability work will get the symbol displayed next to their Over-the-Counter product. The symbol is branded “Välvald”, meaning “Well-chosen”[96]. This is an example of an informal EPR-approach where the pharmacy branch organization on a voluntary basis have taken actions to make it easier for customers to make a more well-informed choice when it comes to buying Over-The-Counter-products.

The Netherlands

The collection schemes for returning unused pharmaceuticals in the Netherlands is a part of the Dutch Chain Approach[97], an ambitious project aiming at reducing the presence of

[96] Sveriges Apoteksförening, Sector Report 2022. https://www.sverigesapoteksforening.se/wp-content/uploads/2022/05/ENG_SVAP-Apoteksf%C3%B6reningen_%C3%A5rsrapport_2022_Korr1.pdf

[97] Moermond, C.T.A., de Rooy, M., The Dutch chain approach on pharmaceuticals in water: stakeholders acting together to reduce the environmental impact of pharmaceuticals. British Journal of Clinical Pharmacology, DOI 10.1111/bcp.15509.

pharmaceutical in waters. The unused pharmaceuticals are returned to pharmacies and then taken by an authorized waste manager to incinerate at high temperatures. The collection is solely carried out in pharmacies. Drugstores (that can sell Over-the-Counter medicines) do not collect unused pharmaceuticals.

The Dutch chain approach could be said to be an informal type of EPR system where the pharmaceutical company branch organizations (for innovators, generics, and self-care medicines) have created a coalition on sustainable pharmacy, together with the pharmacist's association. This coalition plays an active role in the chain approach and the Dutch Green Deal on sustainable care. They have been involved in several aspects regarding sustainable pharmacy (for more information, see their *Inspiration guide for sustainable pharmacy*):

- Organizing discussion sessions on antimicrobial resistance (AMR), sustainable production, EPR, medicinal residues in water, etc.
- Organizing Pilot waste collection week at pharmacies, including development of materials for awareness raising.
- Research consortium to reduce the amount of antibiotics in water.
- Research into the production chain for the Dutch pharmaceutical sector focused on sustainability aspects.
- Branch plan for sustainable packaging.

Detailed description of take-back schemes in different countries in the EU

Spain

There is a national take-back scheme (SIGRE) funded entirely by the pharmaceutical industry; the cost of the SIGRE is split between all the laboratories operating in Spain depending on the number of units sold by each laboratory. The system counts with the logistic collaboration of pharmacies and wholesalers. The unused pharmaceuticals are returned to the pharmacy by the consumer. The pharmacist keeps the unused pharmaceuticals until the wholesaler takes them to their stores. In the wholesaler's stores the unused pharmaceuticals from different pharmacies are kept until an authorised waste manager picks them up and takes them to a processing facility. All the unused pharmaceuticals produced in Spain end up in this single processing facility designed specifically for the separation and processing of pharmaceuticals. This plant has an automatized system that allows the separation of recyclable parts (cardboards and paper) and the non-recyclable parts (like blisters, pills, capsules, ampoules, etc.). The non-recyclable part is minced and cremated with energy recovery in cement plants. The production of cement is a process that requires high temperatures which are partially reached by using different wastes as fuel.

The SIGRE system also manages yearly communication plans that aim at raising awareness among the users of medicines in relation with the safe disposal of unused pharmaceuticals. These communication plans include campaigns in radio, TV, specialized and general press and internet.

The success of the system is measured by means of periodic surveys that give information on the awareness of the general public. In the last surveys carried out, this awareness was almost

total, but it is not possible to know numerically the fraction of unused pharmaceuticals that follow the SIGRE route.

In addition to this, SIGRE also tracks and fosters schemes for the reduction of the size of the packaging. All the laboratories provide SIGRE the ratio between the content and continent of the medicines sold yearly. Most of the laboratories are committed to reduce this ratio and to apply eco-design, where SIGRE is involved by the development of different guidelines.

The Netherlands

There is no legal obligation on the disposal of unused pharmaceuticals as they are categorized as small chemical waste produced in households. Nevertheless, as a domestic waste, it is managed by the municipalities with the collaboration of pharmacies.

The unused pharmaceuticals are returned to pharmacies and then taken by an authorised waste manager to incineration at high temperatures. The costs of the transport and incineration are covered by the municipalities (it was previously covered by pharmacies). The collection is solely carried out in pharmacies; drugstores (that can sell Over-The-Counter medicines) do not collect unused pharmaceuticals.

The separation of recyclable parts depends on the pharmacy and might face privacy issues as the outer package has private information of the patient.

The collection schemes are part of the Dutch Chain Approach[98], an ambitious project aiming at reducing the presence of pharmaceutical in waters.

Sweden

Pharmacies are obliged by law to take care of any pharmaceutical waste from households, without any cost for the user, and to dispose of it in the appropriate way. This is in accordance with the Regulation of Producer Responsibility for Pharmaceuticals, in which the producer is defined as someone who holds a permit to sell medicines through a community pharmacy.

The most common proceeding is that the collected, unused pharmaceuticals are kept in sealed, traceable boxes that are taken for incineration, by the same distributor that supplies medicines to the pharmacy. The outer packaging is sometimes included in this waste.

Over-The-Counter medicines that have been sold elsewhere must also be taken back by the user to a pharmacy. The pharmacies are not under any obligation however, to take care of any larger amounts of pharmaceutical waste than what is reasonable in proportion to the amount that the pharmacy supplies. Any hazardous material from households (e.g., methotrexate or precharged needles) are the responsibility of the municipalities, the pharmacies don't have to take these products.

The above-mentioned Regulation also obliges the pharmacies to provide information to their customers of the importance of disposing of any pharmaceutical waste from households in the

[98] Moermond and de Rooy, 2022. The Dutch chain approach on pharmaceuticals in water: Stakeholders acting together to reduce the environmental impact of pharmaceuticals. British Journal of Clinical Pharmacology, 2022.

appropriate manner. Some pharmacies have systems in place to encourage that the users dispose of the medicines; the user can get extra club-points for example.

To ensure that these obligations are followed supervisions are carried out by the Swedish Medical Products Agency. Swedish pharmacies collected a total of approximately 1,400 tons of surplus medication in 2021.

Finland

The municipalities are responsible for the disposal of human and veterinary medicines (only pets' products), but they have reached an agreement with pharmacies to use them as collection points. All the medicines collected in the country are then taken to one single incineration plant where the wastes are cremated at high temperatures.

Germany

The unused pharmaceuticals are disposed in the general waste (managed by municipalities), which is incinerated in an 80 percent of the cases. The remaining percentage is disposed in landfills, but in those cases, there is always a Mechanical Biological Treatment that allows the separation of mixed waste in different fractions (recyclable, compostable and waste for landfill), being the pharmaceuticals, presumably, in the landfill fraction. Some pharmaceuticals like cytostatic have to be disposed under special conditions.

France

There is one national scheme (CYCLAMED) in operation since 1993. It counts with the involvement of industry, wholesaler, dispatchers and pharmacies. Unused medicines are collected in pharmacies and then taken to incineration with energy recovery. Only the primary packaging to be picked in the pharmacy, the cardboard and leaflet should be separated for recycling by the consumer. The industry finances the system with a fee proportional to the total units sold by each laboratory. The system does not imply a rise in the price of the medicines. Cyclamed manages 65 percent of the total waste produced (Estimation?): 15,000 tons of waste produced (of which 11,000 are medicines in primary packaging) equal to 150 g/inhabitant/year. Cyclamed advertises in public displays and pharmacies, but the communication budget is going to be raised.

Ireland

Currently there is no national scheme[99]. The unused medicines are collected in the pharmacies and the pharmacist contracts (and pays) a waste manager to collect and dispose the unused medicines via incineration; a certificate of destruction is issued. Controlled drugs must be denatured before being disposed in the containers at the pharmacies, that process is carried out by the pharmacist and witnessed by another person and logged in the patient returns section of the "pharmacy-controlled drugs register". According to the Irish Pharmacy Union 33 percent of unused medicines are flushed or thrown to the bin. The amounts of medicines

[99] There was in the past: DUMP (Disposal of Unused Medicinal Produsts) innitiative, held by the Health Service Executive (National Health Agency). This innitiative was partially funding locallly the disposal of unused medicines.

disposed in pharmacies is not known. The system is regulated: The Regulation of Retail Pharmacy Businesses Regulations 2008 requests that all pharmacies must accept the waste. No awareness campaigns ongoing. Standard warnings are included in the package leaflet informing the patients to ask for information to the pharmacist and not to dispose through the sink or general waste.

Austria

The collection of unused medicines is a voluntary service provided by pharmacies, but patients can use other ways: disposal in waste collection centres or in domestic waste (all waste is incinerated in AT). The pharmacies deal with the costs of the disposal. The unused medicines are incinerated, and patients are recommended to separate recyclable parts. Addictive substances must be disposed via specialized pharmaceutical-chemical laboratory. The success cannot be directly measured, but according to the Austrian Chamber of Pharmacists there is a high compliance. There are no Regulations in place, the collection of the pharmacies is on a voluntary basis. The system operates well in this way. There are no communication initiatives although there is information available online on the correct disposal of medicines. It is not considered a critical issue in AT.

Czech Republic

Unused medicines are classified as “hazardous waste” in accordance with national Regulation. The unused medicines can be disposed in pharmacies or in “waste yards”; in any case they are disposed by incineration (> 1000 ºC). The costs incurred by the pharmacies due to the collection and disposal are reimbursed by the State through the Regional Governments. Pharmacies are obliged to keep and communicate records of the amount of waste; the waste is further classified as “cytostatic” and “other than cytostatic”. The total volume of unused pharmaceuticals is raising (235 tonnes in 2008, 571 tonnes in 2018). There are no communication initiatives although there is information available online on the correct disposal of medicines.

Slovenia

There is a specific legislation regulating the issue (the Regulation on the management of waste medicinal products (WMP), Ur. l. RS, št. 105/2008). The patient can dispose the unused pharmaceuticals in different ways: Disposal through a public service collector, through pharmacies and during collection campaigns. In any of these routes, the unused medicines will end up in a final collector of WPM, responsible for managing these unused pharmaceuticals. In case the unused medicines are disposed through the pharmacy, the pharmacist can take the unused medicines to the wholesaler and then to the final collector of WMP or directly can be taken from the pharmacy to the final collector of WMP. The system is funded by local authorities (in case the patient opts to dispose the unused medicines through the public service) or by the wholesalers of medicines (in any other case). The collected unused medicines are exported for destruction. The amounts of medicines disposed have been increasing since 2011 but reached a plateau in 2015. There are sporadic activities aiming at raising awareness, but it is suspected that a significant number of unused medicines are disposed inappropriately.

Romania

According to the Ministry Order no 119/2014, the unused medicines produced in households have taken to pharmacies and then disposed by incineration. The pharmacies cover the costs of the collection and disposal. The patient takes the unused medicines to the pharmacy and a form is filled specifying the following information for each medicine: The batch number, strength and the quantity. The pharmacy contracts a private service of a waste manager that will collect and take to incineration the waste. This private manager will charge a fee depending on the number of forms existing. There is no information available on how many pharmaceuticals are disposed by this way and it cannot be excluded that there is inappropriate disposal, as there is not information on the level of awareness of the patients. The level of organisation is local, but it is entirely on the pharmacy's responsibility. In relation with awareness, there have been some sporadic initiatives in the past. They were carried out by the College of Pharmacists and Community Pharmacies.

Italy

In Italy, in line with EU waste management standards, medicinal products used outside the hospitals are classified as hazardous urban waste. According to Italian law, household expired/unused medicinal product must be disposed of by returning to pharmacies, where they are handed to local waste disposal systems and incinerated. The containers of expired or unusable drugs are managed by private companies under the control of the regions.

For compiled information from the experts involved in the working group of pharmaceuticals in the environment, the EU survey, the HCWH report and the Baltic Sea report see table 9. The table provides information on how the take-back scheme is organized ('Level of org.'), how is the system funded ('Funding'), if there is some form of awareness initiative ('Awareness'), who is the entity responsible for governing the system ('Governance') and if there is a legal framework ensuring the functioning of the scheme ('Regulated'). Romania and Cyprus reported that no collections schemes exist, however, according to the responses, patients in both countries are advised to return the unused pharmaceuticals to pharmacies.

Table 9: Summary table describing the take-back schemes in the EU/EEA countries.

Country	Level org.	Funding	Collection	Awareness	Responsible of organisation	Regulated
ES	National	Industry	Pharmacies	Periodic	SIGRE (non-profit organisation)	No
NL	Local	Municipa-lities	Pharmacies or at municipal "small chemical waste" collection sites	No information	Pharmacies/ municipalities	Yes (But responsi-bilities not regulated)
SE	Local/ National	Pharma-cies	Pharmacies	Information on pharmacy website On-site	Pharmacies	Yes
FI	Local	Municipa-lities	Pharmacies	No information	Municipalities	Yes
DE	Local	Municipa-lities	General waste	Information on specific website	Municipalities	No
FR	National	Industry	Pharmacies	Periodic	Cyclamed (non-profit organisation)	No
IE	Local	Pharma-cies	Pharmacies	No (Sporadic)	Pharmacies	Yes
AT	Local	Pharma-cies	Pharmacies, general waste & waste collection centers	Information in web	Pharmacies	No
CZ	Regional	State (through Regional governmen ts)	Pharmacies & waste yards	Information in web	Pharmacies	Yes

SI	Local	Whole-salers	Pharmacies, campaigns, yards	No (Sporadic)	Pharmacies	Yes
RO	Local	Pharma-cies	Pharmacies	No (Sporadic)	Pharmacies	Yes
BE*	No information	Whole-salers	Pharmacies	Information on specific website	Pharmacies	Yes
HR*	No information	No information	Pharmacies	Information in specific website Information in pharmacies/collection sites Sporadic information campaigns	No information	No information
IT	Local/ Regional	Municipa-lities	Pharmacies	Information in pharmacies/collection sites	Municipalities	Yes
NO*	No information	Whole-salers	Pharmacies	Information in specific website Information in pharmacies/collection sites Sporadic information campaigns	No information	Yes
PL*	No information	No information	Pharmacies	No information	No information	No information
LU*	No information	No information	SuperDrecksKëscht® national waste management system and some pharmacies	Information in specific website Information in pharmacies/collection sites	No information	No information

Sources: expert in the PiE WG, the EU survey, the HCWH report and the Baltic Sea report (see "main data source" section) ***** Taken only from the responses provided in the survey

Annex 8 - Mandate of the ad hoc working group to focus on the EU strategic Approach on pharmaceuticals in the environment

The original mandate

Pharmaceutical Committee 12 March 2020[100]

Subject: Mandate of the ad-hoc working group to focus on the EU strategic Approach on pharmaceuticals in the environment.

Agenda item 10

1. General considerations

The Pharmaceutical Committee endorsed in the November and December 2019 meetings the establishment of an ad-hoc working group (WG) to focus on the EU strategic Approach on pharmaceuticals in the environment, in particular on the actions and measures that fall under the competence of the Member States.

The following Member States joined this WG: Austria, The Czech Republic, Finland, France, Germany, Ireland, The Netherlands, Slovenia, Spain, Sweden and the European Medicines Agency (EMA). The chairmanship of this WG was taken up by Sweden. A first meeting of the WG was organized on the 21st of February 2020 when the WG discussed further the mandate and the working arrangements.

This document elaborates further on the mandate and the working arrangements as discussed within the WG and it requests the endorsement of its mandate from the Pharmaceuticals Committee.

2. **The mandate of the ad-hoc working group to focus on the EU strategic Approach on pharmaceuticals in the environment**

The ad-hoc working group is set up to focus on the EU strategic Approach on pharmaceuticals in the environment, in relation to human medicines, in particular on the actions and measures of the Commission Communication (COM (2019) 128 final of 11 March 2019) that fall under the competence of the Member States. The scope of the working group is to provide recommendations for the following areas:

- Promote the development of guidelines for healthcare professionals on the prudent use of pharmaceuticals posing a risk to or via the environment.
- Explore, in cooperation with relevant stakeholders, how environmental aspects could become part of medical training and professional development programs.

[100] Mandate of the ad-hoc working group to focus on the EU strategic Approach on pharmaceuticals in the environment. https://health.ec.europa.eu/system/files/2020-03/ev_20200312_796_en_0.pdf

- Foster best-practice exchanges between Member States on how environmental considerations are taken into account in the advertising and prescription of medicinal products and the choice of therapy more generally, where appropriate.
- Explore the possibility of reducing waste by optimizing the package size of pharmaceuticals so that medicines can be dispensed in quantities better matching needs, and by safely extending use-by (expiry) dates so that fewer medicines that are still usable have to be thrown away.
- Facilitate the exchange of best practices among healthcare professionals on the environmentally safe disposal of medicinal products and clinical waste, and the collection of pharmaceutical residues as appropriate.
- Assess the implementation of collection schemes for unused pharmaceuticals and consider how their availability and functioning could be improved, how to increase public awareness of the importance of using them, and how extended producer responsibility could play a role in reducing inappropriate disposal.

The working group may also provide recommendations on the actions under section 5.3 ("Improve the environmental risk assessment and its review for the human medicines") that fall under the competence of the Member States. On this aspect, the work of the EMA on section 5.3 of the Commission Communication should be taken into account to ensure alignment and avoid duplication.

The tasks of the working group relate to human medicines. The working group will exchange views and information about the experience of Member States, examine national initiatives, share best practices and/or develop guidance or propose specific measures and/or further actions, where relevant, in relation to the above-mentioned actions in the Commissions Communication.

The mandate for the ad-hoc working group shall be three years that could be further prolonged. One of the participating Member States will chair the working group. The Secretariat of the working group will be carried out by its members. Other Member States may take the lead in relation to the different thematic strands of the above-mentioned actions. The ad-hoc working group will meet mainly via teleconference (in English) in a frequency decided by the group. The ad-hoc working group will also agree on an agenda, work plan and its working methods. The ad-hoc working group will report to the Pharmaceutical Committee.

The extended mandate

Pharmaceutical Committee Decision by written procedure[101]

Subject: Revised mandate of the ad-hoc working group to focus on the EU strategic Approach on pharmaceuticals in the environment

1. General considerations

The Pharmaceutical Committee endorsed in the March 2020 meeting the mandate of an ad-hoc working group (WG) to focus on the EU strategic Approach on pharmaceuticals in the environment, in particular on the actions and measures that fall under the competence of the Member States. Currently, the following Member States joined this WG: Austria, The Czech Republic, Finland, France, Germany, Ireland, The Netherlands, Slovenia, Spain, Sweden, Poland, Romania, Italy and the European Medicines Agency (EMA).

Following the adoption of the pharmaceutical strategy for Europe, the WG was also given the task to further work on a concept paper to address the environmental challenges and reply to certain flagship actions of the strategy, to bring the necessary support in the revision of the EU pharmaceutical legislation.

This document elaborates further on the revised mandate and the working arrangements as discussed within the WG and it requests the endorsement of its mandate from the Pharmaceuticals Committee.

2. The revised mandate of the ad-hoc working group to focus on the EU strategic Approach on pharmaceuticals in the environment

The ad-hoc WG was set up to focus on the EU strategic Approach on pharmaceuticals in the environment, in relation to human medicines, in particular on the actions and measures of the Commission Communication (COM (2019) 128 final of 11 March 2019) that fall under the competence of the Member States. The scope of the WG is to provide recommendations for the following areas:

- Promote the development of guidelines for healthcare professionals on the prudent use of pharmaceuticals posing a risk to or via the environment.
- Explore, in cooperation with relevant stakeholders, how environmental aspects could become part of medical training and professional development programs.
- Foster best-practice exchanges between Member States on how environmental considerations are taken into account in the advertising and prescription of medicinal products and the choice of therapy more generally, where appropriate.
- Explore the possibility of reducing waste by optimizing the package size of pharmaceuticals so that medicines can be dispensed in quantities better matching needs, and by safely extending use-by (expiry) dates so that fewer medicines that are

[101] Revised mandate of the ad-hoc working group to focus on the EU strategic Approach on pharmaceuticals in the environment. https://health.ec.europa.eu/system/files/2021-11/wg_pharmaceuticals-environment_mandate_en_0.pdf

still usable have to be thrown away; Facilitate the exchange of best practices among healthcare professionals on the environmentally safe disposal of medicinal products and clinical waste, and the collection of pharmaceutical residues as appropriate.

- Assess the implementation of collection schemes for unused pharmaceuticals and consider how their availability and functioning could be improved, how to increase public awareness of the importance of using them, and how extended producer responsibility could play a role in reducing inappropriate disposal.

The WG may also provide recommendations on the actions under section 5.3 ("Improve the environmental risk assessment and its review for the human medicines") that fall under the competence of the Member States. On this aspect, the work of the EMA on section 5.3 of the Commission Communication should be taken into account to ensure alignment and avoid duplication.

The tasks of the WG relate to human medicines. The WG will exchange views and information about the experience of Member States, examine national initiatives, share best practices and/or develop guidance or propose specific measures and/or further actions, where relevant, in relation to the above-mentioned actions in the Commissions Communication.

Following the adoption of the pharmaceutical Strategy for Europe that also sets flagship actions to address the environmental challenges, the ad-hoc WG is also given the task to draft a concept paper. That concept paper should outline expert views that should be solutions oriented to bring the necessary support in the revision of the EU pharmaceutical legislation (Directive 2001/83/EC) and as considerations on main elements and business processes that may need to be reflected in the regulatory framework on the following aspects:

- Strengthening the environmental risk assessment requirements and conditions of use for medicines and taking stock of the results of research under the innovative medicines initiative.
- Greener pharmaceuticals with respect to antimicrobial resistance. For this point, the ad hoc WG should also consult the EMA Good Manufacturing and Distribution Practices (GMDP) Inspectors working group on the aspect relevant to manufacturing of active pharmaceutical ingredients and finished medicinal products and GMDP and reflect their input in the finalized concept paper.

The deadline for this concept paper is March 2022 with an interim deadline for a mature draft in January 2022.

The mandate for the ad-hoc WG shall be three years that could be further prolonged. Due to the additional task, the original deadline until March 2023 is prolonged until March 2024. The duration of the mandate could be further extended, if necessary and appropriate. One of the participating Member States will chair the WG. The Secretariat of the WG will be carried out by its members. Other Member States may take the lead in relation to the different thematic strands of the above-mentioned actions. The ad-hoc WG will meet mainly via teleconference (in English) in a frequency decided by the group. The ad-hoc WG will also agree on an agenda, work plan and its working methods. The ad-hoc WG will report to the Pharmaceutical Committee.

Annex 9 – Members of the working group for pharmaceuticals in the environment

Table 10 presents a list of the members of the working group for pharmaceuticals in the environment, that worked to prepare and draft this report as of today. Moreover, there has been additional persons who has contributed during the work. A sincerely thanks to all who made this report possible.

Table 10. List of authors who led and/or participated in the worked to prepare and draft this report.

Name	Country
Alessandra Tamburella	Italy
Arne Hein	Germany
Birger Scholz	Sweden
Boris Kolar	Slovenia
Caroline Moermond	Netherlands
Cecilia Berg	Sweden
Céline Delerme	France
Christine Vaculik	Austria
Daniela Buzica	DG ENV (Commission)
Daniela Gildemeister	Germany
Eadaoin Griffin	Ireland
Felicia Ciulu-Costinescu	Romania
Francesca Tittone	Italy
Joanna Morgan-Nowak	Poland
Linnéa Larsson	Sweden
Lina Koufokotsiou	DG Sante (Commission)
Lucie Bielská	Czech Republic
Maria Grazia Evandri	Italy
Mark Montforts	Netherlands
Pauline Marck	France
Rhys Whomsley	European Medicinal Agency
Ricardo Carapeto García	Spain
Stefan Berggren	Sweden
Susanne Brendler-Schwaab	Germany
Terhi Lehtinen	Finland