Unused Pharmaceuticals Where Do They End Up?

A Snapshot of European Collection Schemes

Health Care Without Harm

ACKNOWLEDGEMENTS

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EXECUTIVE SUMMARY

Hundreds of different active pharmaceutical compounds are being discovered in waterways around the world. Concern is increasing about the harm these might be doing to human health and the environment. Whilst pharmaceutical residues can enter the environment during the production, consumption and disposal, incorrect disposal of household pharmaceutical waste is considered the second major pathway into the environment. Proper collection and disposal of household pharmaceutical waste can contribute to reducing the impact of pharmaceuticals in the environment. Effective collection schemes would divert unused medicines from mixed waste streams that are not designed to deal specifically with pharmaceutical products.

Directive 2004/27/EC (relating to medicinal products for human use) introduces an obligation for Member States to implement appropriate collection schemes for unused pharmaceutical products. However, it does not provide any guidelines on implementation of schemes and a number of studies have pointed to significant differences between Member States.

Detailed information regarding the implementation and efficiency of collection schemes for unused pharmaceuticals throughout Europe is highly scattered and deficient, preventing comparisons between countries and type of scheme implemented. Moreover, it is not clear that all EU countries have implemented their obligations. In particular, for Bulgaria, Cyprus and Malta we could not find any evidence that a system is implemented.

This snapshot report discusses the results of a survey carried out by HCWH Europe in the capital cities of six European countries (Belgium, Hungary, Italy, Lithuania, Portugal and the United Kingdom) to understand the general public's approach to disposal of unwanted medicines and to help assess the efficiency of existing pharmaceutical collection schemes in these countries. We interviewed total of 600 respondents, 100 in each city.

A major issue is the very existence of unused medicines. The main reason that respondents gave for having unused medicines at home were lack of adherence to the prescribed treatment, followed by storing for future use and reaching the expiry date. Better prescribing practices and an improved communication between doctors and patients can contribute to a reduction in the amount of unused medicines.

With the exception of United Kingdom, more than half of the respondents were aware that there was a collection scheme for unused medicines in their country. However, only a percentage of our interviewees disposed of medicines at the appropriate collection sites. Despite the high number of respondents that disposed of unused medicines into the rubbish bin, only a very small percentage flushed them down into the toilet or sink, the method of most concern for the environment.

Educational campaigns can have a big impact in educating the general public on how to dispose of unused medicines and on the risks of pharmaceuticals in the environment. Lack of information on how to proceed was one of the main reasons why respondents to our survey did not use the collection schemes. Moreover, the majority of them believed that more public awareness campaigns were needed. In our view, effective educational campaigns must go hand in hand with the (well-functioning) collection schemes.

Health Care Without Harm Europe proposes a number of specific recommendations to improve collection schemes and communication campaigns in the Member States. This must start with a strong regulatory framework, which could make a major contribution to environmental protection given the potential effects of pharmaceuticals. The limitations of the EU regulatory frameworks need to be addressed. Specific recommendations include:

- Harmonisation of collection schemes in EU Member States.
- Increasing the accountability of the pharmaceutical industry and associated actors.
- Better reporting and transparency on the implementation of collection schemes and collected data.
- Consideration of the environmental risks of pharmaceuticals in the cost-benefit analysis performed to grant new market authorisations for human medicines; revision of cost-benefit-analysis for old pharmaceuticals.
- Classification of pharmaceuticals as hazardous waste and promotion of environmentally sound disposal techniques.
- Introduction of quality standards for pharmaceuticals throughout relevant EU legislation.
- Support for upstream and downstream measures that avoid emissions of pharmaceuticals into the environment and increase the efficiency of removal of pharmaceuticals from the waste stream.

HCWH Europe is an organisation whose mission is to transform the healthcare sector, without compromising patient safety or care, so that it is ecologically sustainable and no longer a source of harm to public health and the environment. This report is part of HCWH Europe's work to raise awareness on the impacts of pharmaceuticals in the environment and of upstream and downstream measures available to reduce that impact.

Throughout the EU, collection schemes for unused pharmaceuticals are not effective enough, and too many pharmaceuticals end up unnecessarily in the environment. European citizens do not know how to dispose of unwanted medicines safely. EU legislators and Member States need to act urgently to address this environmental challenge!

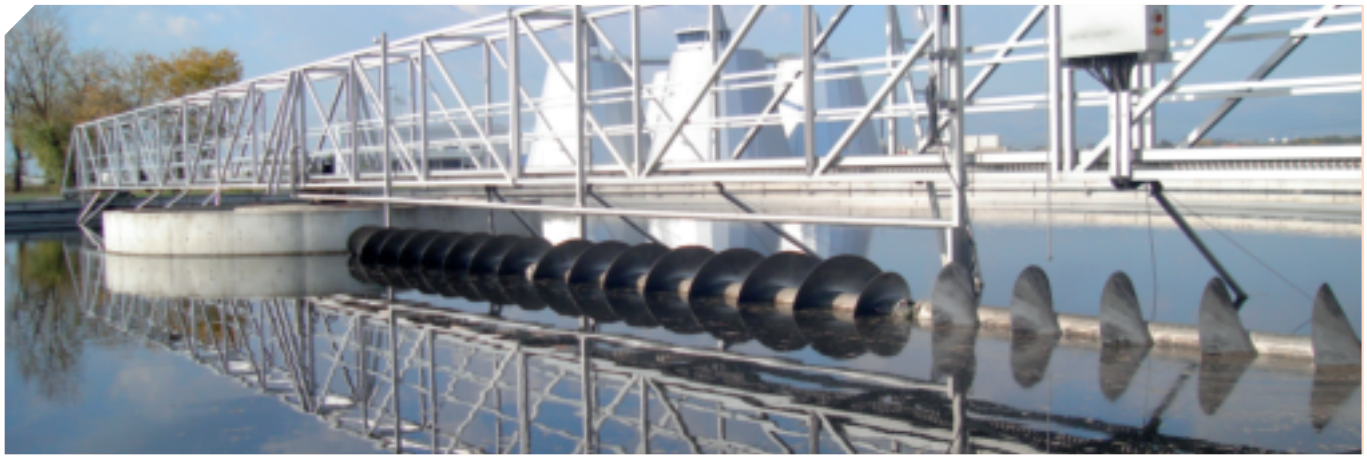
Pharmaceutical residues in the environment

Pharmaceutical residues, from prescription and over-the-counter medicines for human and veterinary use, are now ubiquitous in surface water, groundwater and seawater worldwide. This constitutes a major health and environmental concern that is very likely to worsen in the future given the expected increase in the use of pharmaceuticals due to higher standards of living worldwide, a growing and aging world population, and the correlated increase in animal farming[1]. So far, more than 150 different pharmaceutical substances and metabolites have been found in various water bodies in Europe, including in drinking water supplies[1,2,3]. Clofibric acid, a metabolite of a blood lipid regulator medicine, was the first pharmaceutical residue found in sewage effluent more than 20 years ago[4]. Other classes of therapeutic pharmaceuticals that have been found include analgesics, antidiabetics, tranquillisers, beta-blockers, diagnostic contrast agents, anti-inflammatory drugs, antipyretics, hormones (both synthetic and naturally occurring) and antibiotics.

Pathways into the environment

The environmental consequences of pharmaceutical residues are dominated by the risks associated with their release into the environment. Residues can enter the environment during pharmaceutical production, consumption and disposal[5]. One of the major pathways into the environment is excretion by humans and animals (runoff from agricultural areas and discharges from aquaculture). While some pharmaceuticals are processed easily in the body and/or degrade quickly in the environment, others do not. For human medicines, excretion rates range from 0 to 100%, meaning that a large proportion of medicine is not assimilated by the body and is excreted either as the original compound or as a metabolite. The second major pathway is incorrect disposal, usually by flushing household pharmaceutical waste into sewers from the toilet or sink or by throwing them into waste bins destined for landfill sites.

Pharmaceutical residues which are excreted or disposed of into sewers can reach wastewater treatment plants (WWTPs). Most studies have found that WWTPs are not able to remove efficiently many



pharmaceutical residues, dependent on the standard of the local WWTP and climatic variables[6]. When residues are not degraded in WWTPs they can flow into surface waters and reach seawater and/or end up in sludge. Any sludge generated may be landfilled or spread on agricultural land, further increasing contamination. Finally, for pharmaceuticals disposed of in household rubbish, their final destination may be landfill. In this case, leachate contaminated with pharmaceuticals can form and pollute groundwater[2].

Reasons for concern

The active ingredients of pharmaceuticals are designed to stimulate a response in humans and animals at low concentrations. Moreover, pharmaceutical substances are often engineered so that they remain unchanged during their passage through the body. Unfortunately, this stability means that they may also persist outside the body and, as a consequence, can build up in the environment. The potential for such substances to have impacts on the environment and in non-target organisms is therefore considerable[7]. Of particular concern are those pharmaceuticals that are designed to interfere with our hormone system and are active in very low concentrations such as endocrine active pharmaceuticals, anti-cancer treatment drugs because of their ability to cause cancer themselves, and antibiotics because of the potential for promotion of resistance[1]. Despite several studies in recent years, the potential risk associated with the presence of pharmaceuticals in the environment is largely unknown. Detecting effects in the environment is difficult and, given the occurrence of pharmaceutical residues in complex mixtures of unrelated substances with a wide range of pharmacological activities, there may be additive and synergistic effects.

Aquatic organisms are particularly vulnerable to the effects of pharmaceutical residues. For instance, chronic exposure to environmental concentrations of 17-ethynylestradiol (an oestrogen found in contraceptive pills) led to the feminisation of fathead minnow males, causing a significant reduction in the sustainability of the population[8]. Antibiotics have been shown to lead to the presence of new antibiotic-resistant strains of bacteria[9] and to induce genetic alterations and mutations in a number of aquatic species[10].

With regards to human health, the concerns are rather less, because the quantities to which one can be exposed from drinking water are below the dosages used during therapy[7]. However, the risks have usually been calculated for exposure to a high dosage of a single substance over a short period of time, and further research that considers the effects of exposure to a mixture of substances and to low concentrations in different age groups over a long-term period is needed. Moreover, other routes of exposure, such as uptake from soils and biomagnification through the food chain, are also poorly understood and the risks cannot be assumed to be negligible.

Environmental risks of medicines in European legislation

Before being placed on the European market, pharmaceuticals have to undergo an authorisation process. The application must contain *"an indication of any potential risks presented by the medicinal product for the environment"*, and *"specific*

arrangements to limit it [the environmental impact] shall be envisaged" (Directives 2001/83/EC and 2004/27/EC). However, Directive 2004/27/EC states *"in any event this impact should not constitute a criterion for refusal of a marketing authorisation"*. In practice, this means that environmental risks are not part of the risk-benefit analysis for human medicines.

Collection schemes for unused pharmaceuticals

Collection and disposal of household pharmaceutical waste could represent an important measure to protect the environment, while also protecting human health from unintended exposure and inappropriate use. An effective collection scheme for human medicines would divert unused pharmaceuticals from waste streams, leaving only the pharmaceutical residues (unaltered or as metabolites) that pass through the body to contaminate the sewage systems.

The Waste Framework Directive (Directive 2008/98/EC) establishes the basic principles and provisions on re-use, recycling, recovery and disposal of waste to avoid dangers to human health and harm to the environment. The Directive clarifies that collection schemes for medicines from household waste are not to be subject to registration, as the schemes present a low risk and contribute to the separate collection of waste. Further to that, Directive 2004/27/EC (relating to medicinal products for human use) introduces the obligation of Member States to have *"specific precautions relating to the disposal of unused medicinal products"* as well as the obligation to implement appropriate collection systems (Article 127). However, several surveys have noted that the implementation of these systems and their efficiency varies widely across Member States[11,12].

For example, in the Netherlands, where collection schemes have been implemented for several years, a study from 2013 found that almost 70% of the respondents returned their unused medicines to the pharmacy or a hazardous waste collection point, 11% threw them in the bin and 2% flushed them down the toilet[13]. A previous study in the UK found that, of those interviewed, two thirds discarded unused medicines in household waste, with the remainder either returning them to a pharmacist (21.8%) or emptying them into the sink or toilet (11.5%)[6]. As a last example, a survey in Latvia found that 41% of the respondents discarded

Figure 1- Examples of communication activities in different European Member States
(Spain - website; France - social media; Luxembourg - leaflet; Croatia - poster; News piece - Ireland)

unused medicines in the rubbish, while 12% flushed them down the toilet and only 6% returned them to pharmacies or hazardous waste collection sites[14]. In many Member States, citizens seem to be uninformed about what they should do with expired or unused medicines and are not aware that they can take unused medicines to collection facilities.

The awareness of citizens seems to influence the quantities of medicines put into collection schemes in Europe[11]. But generally the overall message for European citizens is patchy, unclear and lacking in many countries. Currently, it is not always clear for consumers how they should and could dispose of unused pharmaceuticals appropriately and there is lack of knowledge on the environmental implications of incorrect disposal. Additional measures are needed to influence and change behaviour amongst the population. Consistent guidelines and messages across Europe could contribute to a decrease in pharmaceutical residues in the environment.

Different tools have been used at national level to promote awareness of proper disposal schemes for unused pharmaceuticals and to raise the problems of pharmaceuticals in the environment (Figure 1). Most of the tools are based on communication activities towards the general public, such as ads or media inserts, websites, brochures and posters, but have also involved training activities for doctors and pharmacists who can then provide information to patients.

The Health Care Without Harm (HCWH) Europe Unused Pharmaceuticals Survey

The implementation of collection strategies for unused medicines is one of the measures HCWH Europe endorses to reduce the impact of pharmaceuticals in the environment, together with promoting "green pharmacy", improving prescribing practices, and supporting the adoption of innovative wastewater treatment methods. For this report, HCWH Europe has carried out a survey of the general public's approach to disposal of unwanted medicines, in selected EU countries, to help assess the efficiency of pharmaceutical collection schemes. This snapshot tries to understand consumer behaviour in handling household pharmaceutical waste (expired and unused medicines) and assesses the environmental

awareness on the issue in six European countries with different types of collection schemes. This report begins with an overview of the systems that have been implemented in the EU countries (Table 1), and is followed by the results of our interviews. A number of policy recommendations are proposed in order to encourage better consumer behaviour regarding the disposal of pharmaceuticals and to improve the current collection strategies in EU Member States.

Table 1 – Overview of implemented collection schemes for unused pharmaceuticals in EU Member State

Information is provided on how the systems are organised ("Level of Organisation"); on the geographical level of coverage within the country ("Coverage"); on who finances the system ("Financial Support"); and on the types of locations where unused pharmaceuticals can be returned ("Collection Sites"). For Bulgaria, Cyprus and Malta we could not find any information that indicates that collection schemes have been implemented in these countries. The national legislation of Ireland is currently under revision. In the table and elsewhere in the report the expression "Pharmaceutical Industry Groups" is used to indicate manufacturers and distributors of pharmaceuticals and pharmacies.

COUNTRIES	LEVEL OF ORGANISATION	COVERAGE	FINANCIAL SUPPORT	COLLECTION SITES
Austria	Local	National	Local Government, Pharmacies	Pharmacies,Household Waste Disposal Sites
Belgium	Regional	National	Pharmaceutical Industry Groups	Pharmacies
Croatia	Local	National	Pharmaceutical Industry Groups	Pharmacies, Health Clinics, Events
Czech Republic	Local	National	Local Government	Pharmacies
Denmark	Local	National	Local Government	Pharmacies
Estonia	Pharmacies	National	Pharmacies	Pharmacies
Finland	Local	National	Local Government	Pharmacies
France	National	National	Pharmaceutical Industry Groups	Pharmacies
Germany	Local + Pharmacies	Only certain areas	Local Government	Pharmacies
Greece	National	National	Government, Pharmaceutical Industry Groups	Pharmacies
Hungary	National	National	Pharmaceutical Industry Groups	Pharmacies and other selling points, Household Waste Disposal Sites
Ireland	National/ Pharmacies	National	Health Safety Executive/Pharmacies	Pharmacies
Italy	Local	National	Local Government	Pharmacies, Health Clinics, Household Waste Disposal Sites, Street Containers
Latvia	Pharmacies	National	Pharmacies	Pharmacies, Household Waste Disposal Sites
Lithuania	Pharmacies	National	Pharmacies	Pharmacies
Luxembourg	National	National	National Government	Pharmacies, Household Waste Disposal Sites
Netherlands	Local	National	Local Government, Pharmacies	Pharmacies, Household Waste Disposal Sites and Vehicles
Poland	Pharmacies	National	Local Government, Pharmacies	Pharmacies, Household Waste Disposal Sites
Portugal	National	National	Pharmaceutical Industry Groups	Pharmacies
Romania	Pharmacies	National	Pharmacies	Pharmacies
Slovakia	National	National	National Government	Pharmacies
Slovenia	Local	National	Local Government	Pharmacies, Containers, Household Waste Disposal Sites and Vehicles
Spain	National	National	Pharmaceutical Industry Groups	Pharmacies
Sweden	National	National	National Government	Pharmacies
United Kingdom	Local	National	Local Government	Pharmacies, Health Clinics, Events

Semi-structured one-to-one interviews were conducted in the city centres of the capital cities of six European countries: Belgium, Hungary, Italy, Lithuania, Portugal and the United Kingdom (Table 2). The countries were selected taking into consideration the diverse types of collection systems for unused pharmaceuticals implemented at national, regional or local level. Given that the interviews were confined to the capital cities and a limited number of interviews were performed, the data presented in this report should not be considered as representative of the entire population of the country.

For each country, one surveyor was selected to conduct the interviews. All interviewers participated in a training session that focused on how to perform and document the interviews. The interviews took place during the first week of September 2013; in each city 100 people were interviewed. The target group of the survey was native speakers who were residents in the country where the interviews took place and aged 18 years or older. The interviewees were spread evenly across different age groups.

Table 2 – Percentage of respondents by gender

COUNTRY	CITY	%M	%F
Belgium	Brussels	42	58
Hungary	Budapest	47	53
Italy	Rome	54	46
Lithuania	Vilnius	52	48
Portugal	Lisbon	51	49
United Kingdom	London	51	49

Surveyors approached people directly on the street in their own language. At the beginning of each interview, the surveyors explained the goal of the project. Each interviewee was given a study code and the surveyor completed the interview form. No personal data were collected.

The respondents were asked several questions that covered demographic characteristics (age group and sex), behaviour and opinions in relation to the disposal of unused medicines, the collection system implemented in their country and the level of awareness of the problem of pharmaceuticals in the environment (see Box 1 for a list of questions). Closed and open-ended questions were used. The open-ended questions were used to try to obtain truthful answers and avoid people feeling pressed to give answers that they thought the surveyor might want to hear.

The first question was designed to establish the relevance of the survey to the interviewee, by asking if he/she ever had unused medicines at home. If the respondent replied negatively to question 1, the interview would be stopped. If the interview stopped, another person was approached until 100 respondents in each country replied yes to question 1.

For certain questions (i.e., Q 2, 7 and 8), multiple answers were accepted since more than one option or reason was feasible.

In questions 3 and 4 on how the interviewees disposed of medicines, the replies were unprompted but the surveyor categorised the answers given by the respondents into one or more of the following groupings: 1. Return to

pharmacy; 2. Throw in specific container for pharmaceuticals outside pharmacy; 3. Discard in rubbish bin; 4. Flush down the toilet or down the sink; 5. Give away to family, friends or charitable institution; 6. Take to hazardous waste collection site; 7. Don't know; 8. Other.

The data were quantified and analysed by HCWH Europe's Pharmaceuticals Officer and Coordinator of the Project.

Box 1 - The survey questions (for the multiple choice questions, respondents could choose more than one answer)

	TEXT OF QUESTION	OPTIONS FOR RESPONDING
Q1	Do you usually have expired, left over or untaken medicines at home?	Yes –No
Q2	Why do you have unused medicines at home?	Improved and stopped the treatment before end - Storing for future use – Expired – Unclear instructions from doctor/pharmacist – Person taking medicines passed away – Doctor prescribed too many medicines – Excessive number of pills in package – Unsure why medicine was prescribed – Other
Q3	How do you dispose of liquid or cream medicines that you are not going to use in the future or are out of date?	Open answer, then categorised by surveyor into one or more of eight categories (see text)
Q4	How do you dispose of solid or semi-solid medicines (pills or capsules) that you are not going to use in the future or are out of date?	Open answer, then categorised by surveyor into one or more of eight categories (see text)
Q5	I am now going to read you three statements about medicines and the environment, please state how much you agree with them or if you don't know: a) Medicines disposed of incorrectly can contaminate the environment; b) The amount of medicines that reach the environment is low, therefore their effects are negligible; c) In practice, there is no way to reduce the presence of medicines in the environment.	Don't know – Strongly Disagree – Disagree – Neither Disagree nor Agree – Agree – Strongly Agree
Q6	Are you aware if in your country you can return unused medicines to a collection system?	Yes – No
Q7	Which reasons prevent or would prevent you from using such a collection system?	Lack of disposal locations – Lack of information on how to proceed – Lack of time – Distance to disposal location – Don't know – Other
Q8	Have you ever received any information on how to dispose of expired or unused medicines?	No – Don't know – Family/Acquaintance –Oral info via pharmacist –Social Media – Marketing material - Medicine leaflet – Newspaper – Radio – TV – School – Internet – Event organised by local authority – Oral information via doctor – Poster in pharmacy or health clinic – Other
Q9	If you received further information on how to dispose correctly of unused medicines would you follow this?	Very Likely – Likely – Don't Know – Unlikely – Very Unlikely
Q10	How do you think the awareness of citizens could be improved on the issue of pharmaceuticals in the environment?	Open answer

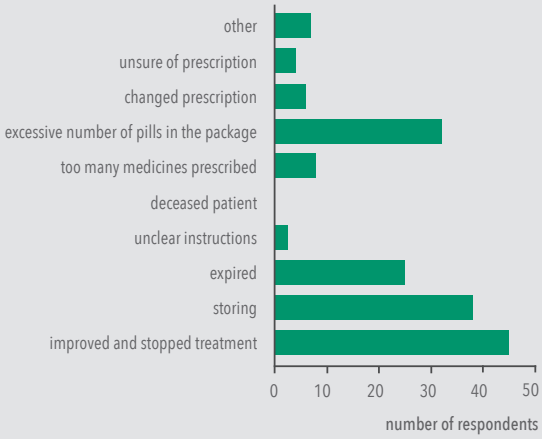
BELGIUM

HOW THE COLLECTION SYSTEM WORKS

Belgium has had a national system for the collection and disposal of household pharmaceutical waste since 2000 (www.bonusage.be), implemented in the Brussels region in 2002 (Arrêté du Gouvernement de la Région de Bruxelles Capitale 2002/31400). The system is organised through a partnership of the pharmaceutical wholesalers, the pharmaceutical industry and the pharmacies in collaboration with the regional environmental agencies[15]. Pharmaceutical wholesalers collect the pharmaceuticals in containers from the pharmacies and are responsible for all the costs of removal, storage and transport from the pharmacies to disposal sites. The pharmaceutical industry is responsible for the costs of incinerating the pharmaceutical residues, each company paying a percentage dependent on market representation. Since September 2005, the pharmacies also pay a fee for each waste container ordered from the wholesalers[16].

Since 2005, medicines have to be returned exclusively to the pharmacies. Before 2005, medicines could be disposed of in hazardous waste collection sites and specific drop-off locations. Pharmacies are obliged to participate in the system; if they do not comply citizens can file a complaint with their regional environmental agency. Pharmacists are responsible for receiving returned medicines, and have to ensure that the products received fall within the legislation, namely that only pharmaceutical residues of human and (since 2010) veterinary medicines are collected. If plastic or aluminum blisters or glass or plastic jars and flacons are empty the consumer must sort them according to the more general rules for this type of waste. Paper packaging and leaflets also have to be recycled by the consumer and cannot be disposed of in the containers[15].

ACCUMULATING UNUSED MEDICINES AT HOME



Reasons for accumulating unused medicines at home

SYSTEM SUCCESS

In 2011, Belgium pharmacies collected around 572 tonnes of unused medicines, an average of 111 kg per pharmacy or 208 grams per household. These values include medicine residues but also the inner packaging if not empty. From 2000 to 2011, the amount of recovered residues increased by 33%, an average of 2.5% per year[17]. In 2011, in the region of Wallonia, 15,776 containers were recovered from pharmacies, with a total weight of collected residues of 186,908 kg, accounting for 53 g per inhabitant. This disposal cost EUR 90,000, including the price of the containers, transport and incineration, or around EUR 0.50 per kg of pharmaceutical residues[16].

In our survey in Brussels, 62% of the respondents stated that they were aware that they could return unused medicines to a pharmacy. However, in spite of a number of information campaigns carried out by pharmaceutical stakeholders in recent years, 78 out of the 100 respondents pointed to a lack of information on how to proceed as one of the reasons why they did not use the system. The other main reason was the lack of disposal locations (51 respondents). Nonetheless, an overwhelming 96% said that they would be very likely or likely to use the system if they received further information on how to dispose of pharmaceuticals correctly.

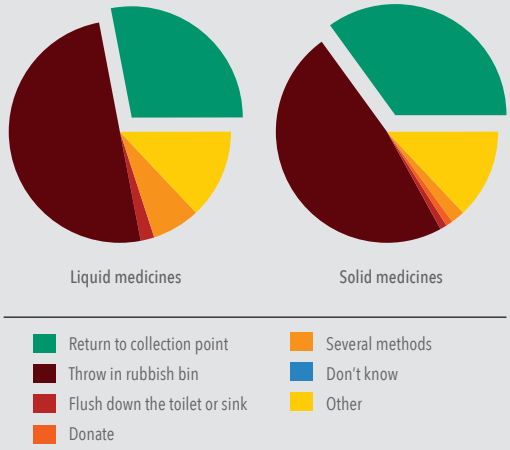
COMMUNICATION ACTIVITIES

In 2011, a national awareness campaign organised by the Belgium Pharmacies Association (Association Pharmaceutique Belge – Algemene Pharmaceutische Bond) spent under EUR 10,000 to distribute 150,000 practical guides to pharmacies and the general public on how to dispose of unused and expired medicines correctly[15]. Nevertheless, 71% of the respondents did not remember having received information on how to dispose of expired and unused medicines. And, only 12 respondents pointed to the pharmacist as their source of information on how to proceed.

Sorting leaflet from the Belgium Pharmacies Association

USE OF THE COLLECTION SYSTEM

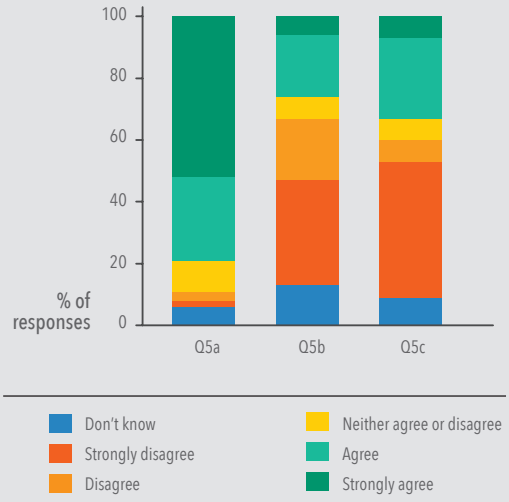
Half of the respondents disposed of liquid and solid medicines by throwing them into the rubbish bin (50 for liquid and 48 for solid medicines). The good news was that almost no one disposed of medicines by flushing them down the toilet or the sink - only one respondent for solid medicines and five for liquid medicines, of whom four also used other practices including returning them – on some occasions – to the pharmacy. Only about one third of the respondents returned unused medicines to the pharmacy (28 for liquid medicines and 35 for solid medicines).



Disposal of unused pharmaceuticals (solid and liquid medicines)

KNOWLEDGE OF THE IMPACTS OF PHARMACEUTICALS IN THE ENVIRONMENT

Regarding the awareness levels for medicines and the environment, almost 80% agreed that medicines disposed of incorrectly contaminate the environment, with more than 50% strongly agreeing with the statement. But only half of the respondents (54%) believed that the effects of these products in the environment are not negligible and only 51% of the respondents considered that there are measures to reduce the presence of pharmaceuticals in the environment.



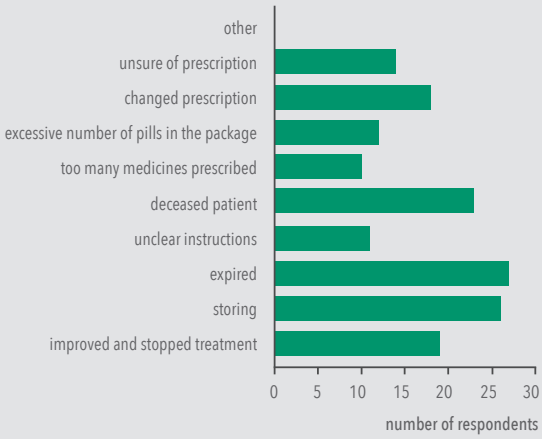
Knowledge of the impacts of pharmaceuticals in the environment

HOW THE COLLECTION SYSTEM WORKS

Hungary has implemented a national system for the collection and disposal of household pharmaceuticals since 2005 (20/2005. (VI.10) EüM rendelet a humán gyógyszerek és csomagolásuk hulladékainak kezeléséről). According to Hungarian legislation (currently under revision), the pharmaceutical industry is responsible for the establishment and operation of the disposal system (its organisation and financing). However, the pharmaceutical industry is allowed to give this duty to pharmaceutical distributors or a coordinating organisation. Since its beginnings the system has been coordinated by Recyclomed (www.recyclomed.hu), a non-profit organisation founded in 2003 by the pharmaceutical industry (Magyar Gyógyszergyártók Országos Szövetsége) to organise, collect, treat and recycle packaging waste generated by the industry. In 2005, the organisation started dealing with the collection and disposal of household pharmaceutical waste, including packaging and medicinal residues.

The cost of the collection system is fully supported by the pharmaceutical industry, as a percentage of their sales proportion in the previous year. In 2012, costs amounted to EUR 580,000. Pharmaceutical waste, including packaging and medicines, is collected in sealed containers that are sent for incineration once they are full. In theory, anything could be thrown into the containers, but the practical experience of Recyclomed shows that people only dispose of pharmaceutical waste into them. Participation of pharmacies in the system is obligatory. Recyclomed is responsible for collecting household pharmaceutical waste from pharmacies, distributors and other selling points. Sites selling non-prescribed medicines are also obliged to participate. Pharmacies and other outlets provide space for the containers, which should be easily accessible to the public, whilst pharmacists provide assistance when needed. Currently, there are about 4064 collection points[19].

ACCUMULATING UNUSED MEDICINES AT HOME



Reasons for accumulating unused medicines at home

SYSTEM SUCCESS

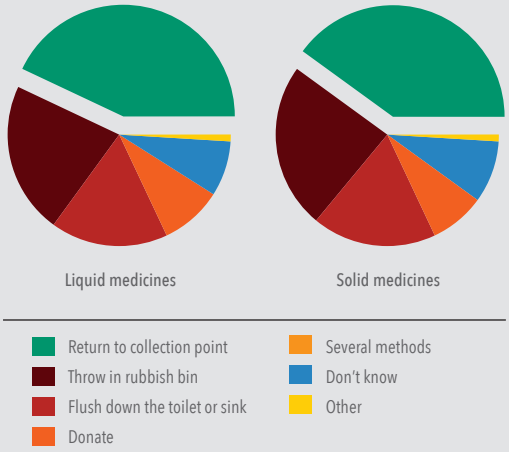
The initial goal of Recyclomed was to recycle 300-500 tonnes of waste per year[18], but between 2005 and 2009 the average was only 200 tonnes per year. In recent years, the amount has been increasing continuously, 6-7% per year see Table 3. The largest amount of household pharmaceutical waste comes from pharmacies.

Table 3 – Amount of household pharmaceutical waste collected in Hungary from 2007 to 2012[19]

	COLLECTED VOLUME (TONNES)	AVERAGE MONTHLY (TONNES)
2007	176.7	14.7
2008	173.9	14.5
2009	175.3	14,6
2010	196.2	16.4
2011	205.7	17.1
2012	222.7	18.6

Of the 100 people interviewed in Budapest, more than half (63) were aware of the existence of a collection scheme for unused pharmaceuticals in Hungary. However, only one third of the respondents disposed of unused pharmaceuticals by taking them to a collection point (43 and 40 respondents for liquid and solid medicines respectively). The number of respondents that incorrectly disposed pharmaceutical waste was similar both for liquid (39) and for solid medicines (42),

with a number flushing medicines down the toilet or sink (17 for liquids, 18 for solids). Lack of time was the reason most commonly stated by respondents for not using a collection scheme (40), followed by distance to disposal location and lack of information on how to proceed (both listed by 28 respondents each).



Disposal of unused pharmaceuticals (solid and liquid medicines)

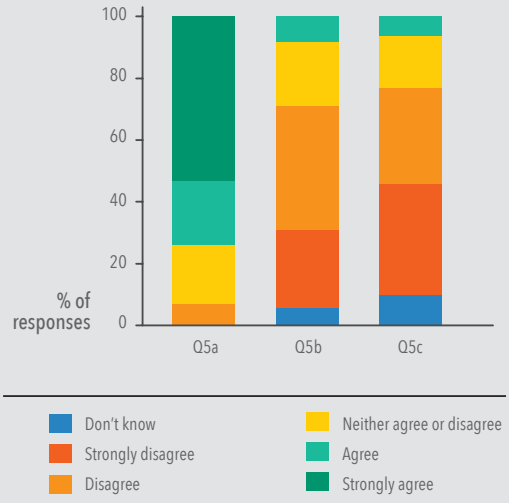
COMMUNICATION ACTIVITIES

The majority of the respondents (78) recalled having received information about the collection system. The main sources of information were pharmacies and doctors' surgeries (49 of the 100 respondents). This accords with Recyclomed's practices. In 2005, when the system was first implemented, Recyclomed received communication and financial support from the Hungarian Government for communication activities, but later on the resources for these activities were reduced (Recyclomed personal communication). This has influenced the types of campaigns that could be developed. The main campaign is now carried out in pharmacies with the support of posters, leaflets and articles in magazines produced by the pharmacies. The collection containers are also placed in a visible area and carry information about the disposal system, so acting as a communication tool. Other ad hoc events include press articles, invited conference talks, etc. According to our survey, family and acquaintances were also one of the main sources of information, which highlights the importance of oral communication for the respondents in this survey.

Information poster from Recyclomed

KNOWLEDGE OF THE IMPACTS OF PHARMACEUTICALS IN THE ENVIRONMENT

With regards to the awareness level of the respondents to our survey in Budapest, 65% of the respondents would be very likely or likely to dispose of unused pharmaceuticals in the correct way if provided guidance on the issue. Moreover, more than 70% of the respondents were aware that medicines disposed incorrectly could contaminate the environment and 65% believed that the effects on the environment were not negligible. Two thirds (67%) of the respondents also believed that in practice it is possible to reduce the presence of pharmaceuticals in the environment.



Knowledge of the impacts of pharmaceuticals in the environment

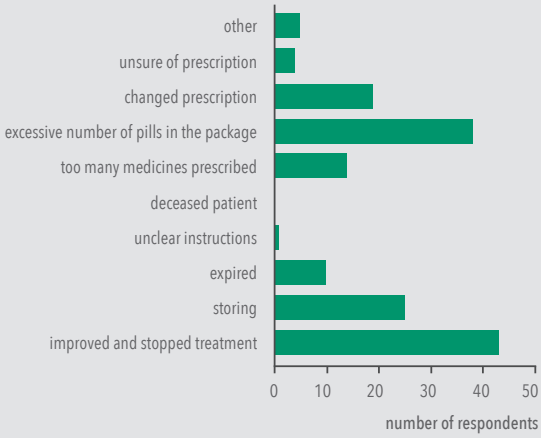
HOW THE COLLECTION SYSTEM WORKS

The collection and disposal of pharmaceutical household waste in Italy has been managed at local level since 2005. Each municipality has its own set of regulations following the national legislation (Decreto Legislativo 6 aprile 2006, n. 193). The collection system is a public utility linked with the collection of recyclable material. Each municipality, together with one or more public or private partners, manages its own system and pays for all the costs involved in the collection, transport and disposal. The entire waste service is covered by a waste tax paid by the citizens - TARES (Tributo comunale sui rifiuti e sui servizi).

Unused medicines can be brought to specific collection bins in pharmacies, healthcare centres or on the streets and/or to hazardous waste collection sites, depending on the municipality. Again depending on the municipality, users may be able to dispose of blister packs, tubes and sachets and sometimes packaging. In both cases empty recyclable packaging needs to be separated before disposal. The difference in disposal locations and methodology might create an unclear message to the general public, since, for example, in some places citizens can bring packaging while in others they must separate blisters and medicines themselves from the rest of the packaging.

Street container in Rome

ACCUMULATING UNUSED MEDICINES AT HOME



Reasons for accumulating unused medicines at home

SYSTEM SUCCESS

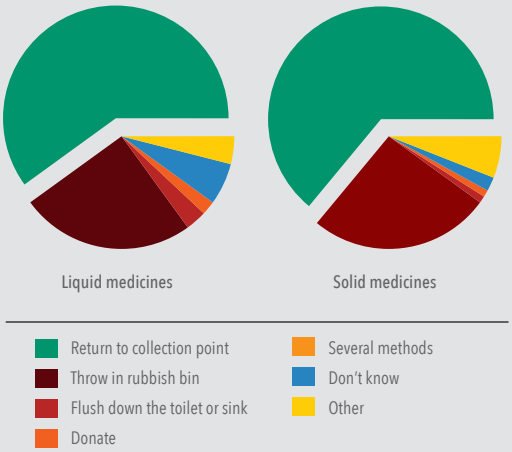
Data on household waste, including pharmaceuticals, is collated on a yearly basis by the governmental environment institute, ISPRA (Istituo Superiore per la Protezione e la Ricerca Ambientale) (see Table 4)[20].

Table 4 – Amount of household pharmaceutical waste collected at national and regional level per person in Italy in 2009, 2011, and 2013

	2009 (g/person)	2011 (g/Person)	2012 (g/Person)
Italy	85	78	88
North	99	89	101
Centre	73	67	70
South	48	42	55

The majority of the respondents to our survey (82%) were aware of the existence of a collection system for unused pharmaceuticals in the municipality of Rome, and more than 60% of the respondents used the containers to dispose of liquid medicines (60) or solid medicines (64). The number of people that flushed medicines down the toilet was much reduced - only one for liquid medicines, and three for solid. However, one quarter of the respondents still disposed of pharmaceuticals incorrectly by throwing them into the household waste. The main reason stated by the respondents for not using the available collection system was the lack of information on how to proceed

(37 respondents), followed by lack of disposal locations (19) and distance to disposal location (18). Nevertheless, 91% of the respondents stated they were very likely or likely to dispose appropriately of pharmaceuticals if they were given information.



Disposal of unused pharmaceuticals (solid and liquid medicines)

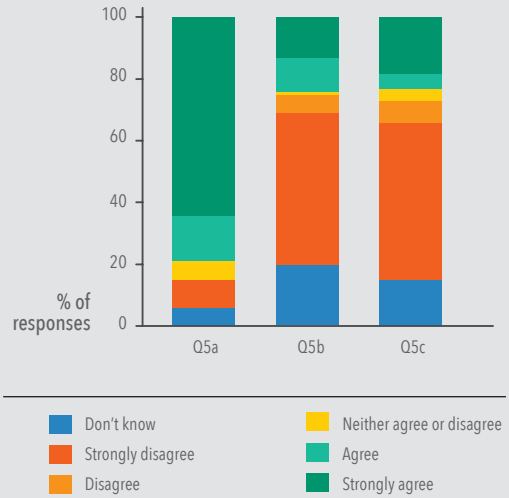
COMMUNICATION ACTIVITIES

Almost one third of the respondents did not remember having received information on how to correctly dispose of unused pharmaceuticals. More than half of those that had received information had seen a poster in the pharmacy or information on the disposal container. Very few people remembered having received information through media, either in newspapers, television, radio or Internet. Older respondents remembered a particular TV campaign from the nineties, while for younger respondents the main source of information was a member of the family or an acquaintance.

There have been no specific communication campaigns to raise awareness of the issue of pharmaceuticals in the environment or how to dispose of unused pharmaceuticals in recent years. Municipalities promote generic awareness campaigns on household waste, which also include information on how to dispose of pharmaceuticals. For example, when a house is newly occupied, the municipality sends an information brochure on correct waste disposal practices. Many municipalities also have online information, listing sites for disposal of pharmaceutical waste, including the location of containers or of hazardous waste sites that accept pharmaceuticals. Legambiente, an Italian environmental non-governmental organisation, promotes a nation-wide verification and communication initiative that rewards local communities, administrators and citizens who have obtained the best results in waste management projects (www.ricicloni.it). This project is funded by the Italian Government and is one of the most recognised environmental projects in Italy. Its scope also includes the management of pharmaceutical waste.

KNOWLEDGE OF THE IMPACTS OF PHARMACEUTICALS IN THE ENVIRONMENT

Almost 80% of the respondents agree or strongly agree that medicines disposed of incorrectly can contaminate the environment, while 55% believe that the effects in the environment are not negligible. A further 58% believe that there are practical measures that can be implemented to reduce the presence of pharmaceutical residues in the environment.

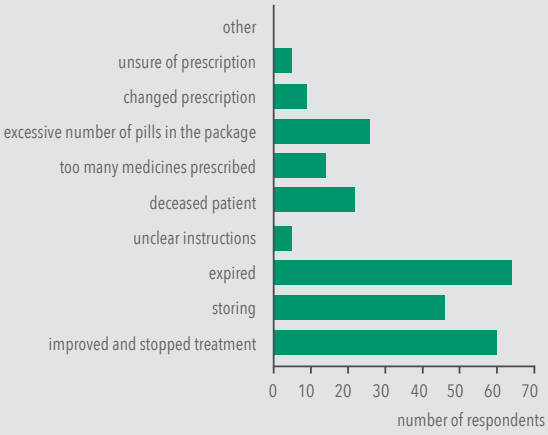


Knowledge of the impacts of pharmaceuticals in the environment

HOW THE COLLECTION SYSTEM WORKS

According to Lithuanian national legislation, pharmaceutical waste must be collected separately and treated in accordance with the waste management regulation. However, the current regulation does not cover household pharmaceutical waste and it is not clear who is legally responsible. At the same time, all community pharmacies are obliged by law to accept unused and expired medicines and transfer them to a licensed pharmaceutical waste management company every three months (Farmacijos įstatymas nustato 2006/6/22 d. No. X-709, Official Gazette, 2006, Number: 78-3056). The legislation states that the government is responsible for the financing of the system but the role of the different institutions is not clearly defined. This means that pharmacies are currently responsible for paying for the disposal of collected medicines and for any communication campaigns on the topic. In practice, this means that pharmacies do not communicate widely about their obligation to take back unused pharmaceuticals and sometimes refuse to accept them because of the costs of communication and disposal[21].

ACCUMULATING UNUSED MEDICINES AT HOME



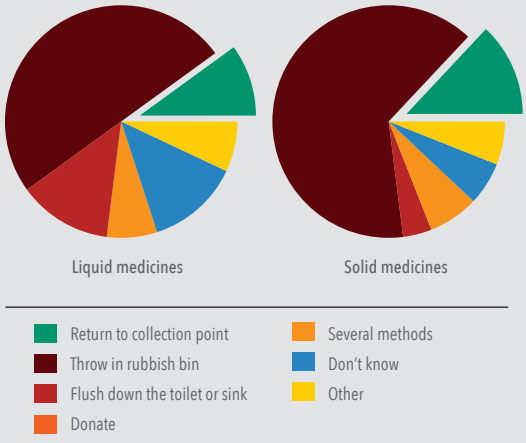
Reasons for accumulating unused medicines at home

In Lithuania, the survey's respondents pointed to a number of reasons for having unused medicines at home. These were mainly unclear instructions from the doctor on how to proceed with treatment, stopping treatment because of improvement, and storing medicines for future use.

SYSTEM SUCCESS

In 2009, only one company had a license to manage pharmaceutical waste in Lithuania[22]. In 2009, 31 tonnes of pharmaceutical waste were collected although it is not clear if this value refers exclusively to household pharmaceutical waste or includes other types of pharmaceutical waste. Since then, this company has ceased its activities[23].

Despite the lack of a well-coordinated system, 54% of the respondents were aware that they could take unused and expired medicines to pharmacies or hazardous waste collection sites. The main reasons noted by respondents in Vilnius for not using the collection points were lack of information (63 out of 100), followed by lack of disposal locations (34). Very few respondents disposed of pharmaceuticals by returning them to the pharmacy, only 10 and 13 respondents for liquid and solid medicines respectively. The majority of the respondents threw unused medicines into the rubbish bin, 50 for liquid and 64 for solid medicines. Several respondents also mentioned burning unused medicines.



Disposal of unused pharmaceuticals (solid and liquid medicines)

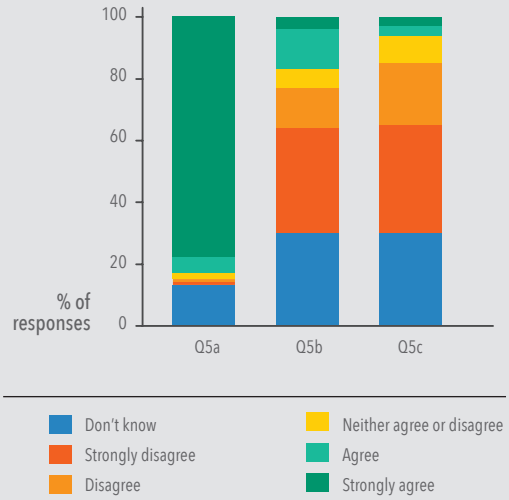
COMMUNICATION ACTIVITIES

More than 60% of the respondents did not remember having received information about how to dispose safely of pharmaceuticals. Those who remembered information recalled TV or newspapers as the main source of information.

News piece on the problem of pharmaceuticals in the environment

KNOWLEDGE OF THE IMPACTS OF PHARMACEUTICALS IN THE ENVIRONMENT

Regarding environmental knowledge, more than 80% of the respondents believed that medicines can contaminate the environment but only 47% believed their effects are not negligible. Thirty percent of the respondents did not know if the effects of pharmaceutical residues were negligible to the environment, a similar number to those that did not know if there were measures that could be put in place to reduce the presence of pharmaceutical residues in the environment. However, more than half of the respondents believed such measures exist.



Knowledge of the impacts of pharmaceuticals in the environment

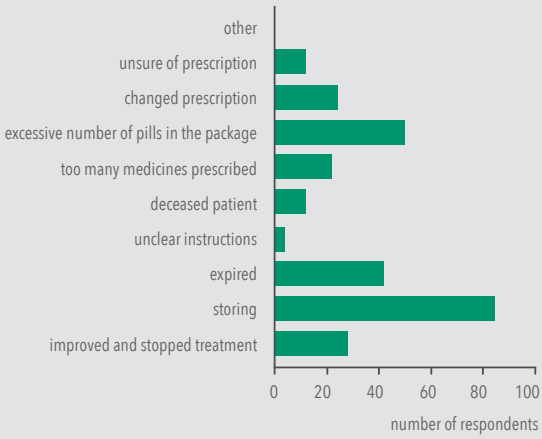
HOW THE COLLECTION SYSTEM WORKS

Portugal has a national collection system for unused pharmaceuticals (human and veterinary medicines) called SIGREM – Sistema Integrado de Recolha de Embalagens e Medicamentos fora de uso. This system was implemented by the Portuguese Government in 2001 (Decreto Lei n.o 366-A/97, changed by Decreto-Lei n.o 162/2000, and by Decreto-Lei n.o 92/2006 and by Portaria n.o 29-B/98, de 15 de Janeiro), and is managed by Valormed (www.valormed.pt), a not-for-profit society created by the pharmaceutical industry (APIFARMA – Associação Portuguesa da Indústria Farmacêutica), pharmaceutical distributors (Associação de Grossistas de Produtos Químicos e Farmacêuticos) and the national pharmacies association (ANF – Associação Nacional das Farmácias). The system covers household pharmaceutical waste, and since 2007 has been extended to veterinary pharmaceuticals, pharmaceutical packaging produced during industrial or distributor activity, and packaging from hospital pharmacies and other health providers.

The system is mostly funded by a levy supported by the pharmaceutical industry according to the number of primary packages put on the market. In 2011, the levy was set at EUR 0.005 per package. Since 2009, all recyclable material is separated for recycling while non-recyclable materials and medicine residues are incinerated. More than 95% of the materials were collected in pharmacies. Although participation of pharmacies is voluntary, in 2011, 99% had adhered to the system. Pharmacies provide space for collection and pharmacists advise citizens on disposal of pharmaceuticals. Outlets selling non-prescribed medicines are not included in the system[24].

Valormed's facebook webpage

ACCUMULATING UNUSED MEDICINES AT HOME

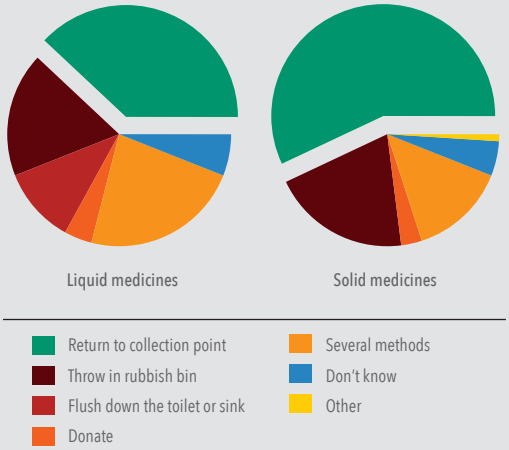


Reasons for accumulating unused medicines at home

SYSTEM SUCCESS

In 2011, the system collected 854 tonnes of material covering packaging and medicine residues, 214 tonnes of which were recyclable residues. This value represented an increase of 2% regarding 2010, when 838 tonnes of residues were collected.

The majority of the respondents in Lisbon (85%) were aware of the existence of a collection system for unused pharmaceuticals in Portugal. However, less than half of these usually took their liquid medicines to be disposed of in pharmacies (38 out of 100 respondents) and many still discarded them down the toilet or sink (13). An additional 19 also disposed occasionally of their liquid medicines by flushing them down to the sewers, including two respondents that on other occasions had taken them to the pharmacy. The picture is slightly better for solid medicines, with 57 respondents usually taking them to be disposed of in pharmacies, and some others (7) that occasionally take them to the pharmacy. Nonetheless, 30 respondents still disposed of regularly or occasionally of solid medicines in the rubbish bin. The good news is that only one respondent stated that they occasionally flushed unused solid medicines down the toilet or sink, in other occasions they were returned to the pharmacy.



Disposal of unused pharmaceuticals (solid and liquid medicines)

The main reasons cited for not using the system were distance (57) or lack of disposal locations (34), lack of time (37) and lack of information on how to proceed (39). However, taking into consideration the high level of participation of pharmacies in Portugal, the high number of pharmacies in Lisbon and the high level of general awareness about the system, we can surmise that the reason for not using the system is more related to the unwillingness of the respondents. This also seems likely because the majority of respondents (81%) stated that they would be very likely or likely to dispose of pharmaceuticals correctly if provided guidance, which 81% also admitted having received.

COMMUNICATION ACTIVITIES

Valormed invests part of its financial resources in communication activities (30% in 2011). The media campaigns usually have a general recycling motto, and in 2011, included, for example, 1886 radio spots and 650 TV spots. The campaign was covered in more than 180 news items in several newspapers, online media and TV shows on national television[24].

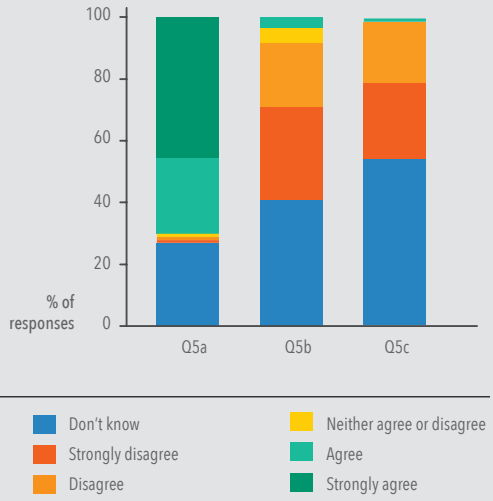
Valormed's communication activities include:

- Partnerships with schools, non-governmental and local governmental organisations
- Media campaigns
- Organisation of events
- Awards for scientific research
- Training and merchandising for pharmacists and pharmacies.

The investment of Valormed in awareness campaigns was well recognised by the respondents, and more than 80% remembered having received information on how to dispose of pharmaceuticals, predominantly through general media, in particular television (60 respondents). A significant percentage of the respondents had also received information via pharmacists (32) or through communication materials in pharmacies and healthcare facilities (41). The survey also showed that family and schools act as important information providers (25).

KNOWLEDGE OF THE IMPACTS OF PHARMACEUTICALS IN THE ENVIRONMENT

Of the respondents, 70% agreed or strongly agreed that if medicines are disposed of incorrectly they can contaminate the environment, but were less sure about the magnitude of the effects (51% thought they are not negligible) and 54% thought that in practice it is possible to reduce their presence in the environment. However, a high percentage of respondents felt they did not know enough to evaluate the questions and options (from 27% to 54%).



Knowledge of the impacts of pharmaceuticals in the environment

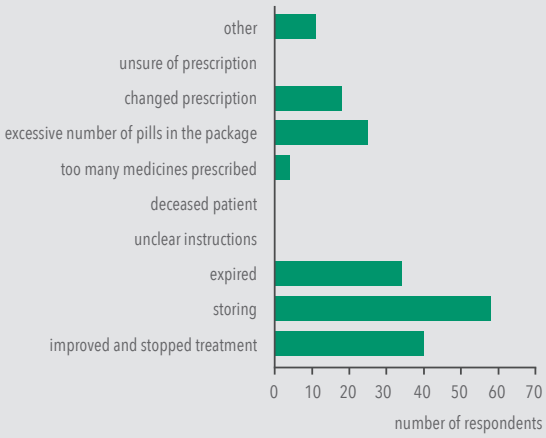
UNITED KINGDOM

HOW THE COLLECTION SYSTEM WORKS

Pharmacies in the United Kingdom are obliged to take back and sort unwanted and/or unused medicines brought by patients and return these to the National Health Service SI 2014/349: The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013. The system only covers household waste. Medicines from care homes cannot be accepted by pharmacies since 2005, unless pharmacies have a Waste Management Licence. On certain occasions, besides the collections in pharmacies, local collection events are also organised by the NHS. The main aims of the system are to provide an easy method for disposal of unwanted human medicines, while reducing environmental risk and accidental poisoning.

Local authorities, without the participation of the pharmaceutical industry, finance the disposal system and promote awareness campaigns. All local Primary Care Trusts in England and Local Health Boards in Wales have a scheme in place to collect and dispose of unused medicines through pharmacies.

ACCUMULATING UNUSED MEDICINES AT HOME



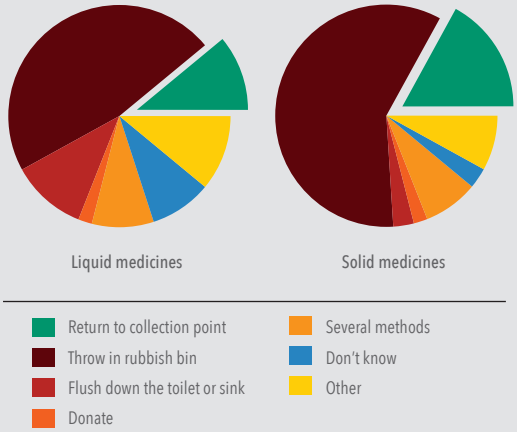
Reasons for accumulating unused medicines at home

SYSTEM SUCCESS

In 2004, the system disposed of 600 tonnes of unused medicines[25]. The Department of Health estimated that the annual cost to pay for medicine and related products to be collected, transported and incinerated was over 1 million GBP per annum[26]. For example, in just one NHS region, Brighton and Hove, the spending on disposal of unused medicines was estimated at 20,898 GBP in 2006[27].

Only 38% of the survey respondents in London were aware that they could return unused medicines to a pharmacy. However, 85% would be very likely or likely to dispose of pharmaceuticals correctly if they received further information on how to do it. The most common reasons that prevented the respondents from using the scheme were the lack of and distance to disposal locations (each pointed to by 41 respondents). These reasons were followed by a lack of information on how to proceed and a scarcity of time (33 and 26 respondents respectively).

Only 23 respondents disposed of solid medicines by returning them to a pharmacy and 6 of these also used other disposal methods. For liquid products, the number of respondents disposing correctly of medicines was even lower, with only 13 respondents taking them into the pharmacy (two of them also used other disposal methods). The majority of the respondents disposed of both solid and liquid medicines by throwing them into the rubbish bin (59 and 47 respectively). Despite the existence of a charitable recycling scheme (Inter Care), which collects unused packages of medicines (in their original packaging) with suitable expiry dates, only two respondents affirmed that they donated their medicines.



Disposal of unused pharmaceuticals (solid and liquid medicines)

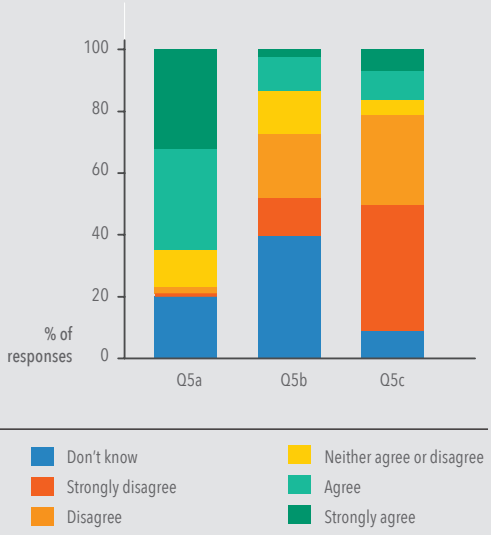
COMMUNICATION ACTIVITIES

The NHS has launched some campaigns across the UK on the topic of medicine waste that also cover issues related to collection schemes for unused pharmaceuticals. Local authorities usually promote awareness campaigns and a number of medical centres also provide information on disposal through their staff, websites and leaflets. However, almost 70% of the respondents did not remember having received information on how to dispose of unused pharmaceuticals. Of those who did remember, respondents mentioned the medicine leaflet and the pharmacist as the main sources of information.

Website of the campaign Medicine Waste UK to reduce medicine wastage

KNOWLEDGE OF THE IMPACTS OF PHARMACEUTICALS IN THE ENVIRONMENT

Of the respondents, 65% agreed that medicines disposed of incorrectly might contaminate the environment but only 33% thought that the effects were not negligible. More than 40% of the respondents did not know about the magnitude of the effects. Nevertheless, 63% believed that in practice there were measures that could be taken to reduce the impact of pharmaceutical residues in the environment.



Knowledge of the impacts of pharmaceuticals in the environment

The environmental impact of unused medicines may not be as big a contributor as other sources of pharmacologically active inputs, but their introduction into the environment should be minimised as far as possible. It is clear that when disposed of correctly, the risks of pharmaceuticals in the environment can be reduced.

Although EU legislation obliges Member States to dispose of unused medicinal products or waste derived from medicinal products, it is not clear if all EU countries have implemented these systems. This is apparently the case for Cyprus, Malta and Bulgaria, where no information was found indicating that collection systems exist.

In those countries with established collection systems, despite the coverage of the systems being nationwide in the majority of the countries, the implementation can be at national, regional, local or pharmacy level and the costs of the system are borne by a variety of different stakeholders. In most countries pharmacies are the main point of collection. More detailed information regarding the implementation and efficiency of collection schemes for unused pharmaceuticals throughout Europe is lacking. When the information exists it is scattered at national, regional or local level and comparisons between amounts recovered, costs, etc., of the different types of schemes in different countries are difficult to obtain (see also the European Environmental Agency study[11]). In many countries this information is in any case not regularly collected by any of the stakeholders involved in the schemes.

When the European Environmental Agency asked the national authorities for an estimate of the amounts of waste in 2008, it was found out that the amounts varied widely, not only because of different consumer behaviour (buying and disposal), but mainly because of the different parameters used to calculate these values for each pharmaceutical waste collection scheme[11]. Five years onwards, the scenario remains the same. For the six countries that were part of our survey, we found that the most recently reported amount of collected unused pharmaceuticals varied between the 854 tonnes for Portugal in 2011 to 31 tonnes in Lithuania in 2009. Nevertheless, even when data are available for the same year, one cannot compare the 854 tonnes collected in Portugal with the 572 tonnes of Belgium, or the 53 g per inhabitant collected in Belgium with the 78 g in Italy, because what is considered household pharmaceutical waste varies in each country. In Portugal, for example, the system collects medicine residues and all packaging (including packaging from hospital pharmacies, industry and wholesalers), while in Belgium the value refers exclusively to medicine residues and inner packaging of medicines if not empty.

Why do people accumulate medicines at home?

One of the main reasons why respondents in our survey accumulated medicines at home was stopping therapy before the end of treatment when they felt an improvement had occurred. Lack of full adherence to treatment, in particular for chronic diseases, has been identified as a major health and economic issue. A study in the UK found that one third of the returned items had pills removed from the packaging relating to less than two days of treatment[26]. These results show, on one side, a less than optimal management and control of the disease, while on the other, the lack of adherence might represent a bigger amount of medicines being unused in the long term.

Other major reasons for accumulating medicines at home in the six countries included storing for future use and/or reaching the expiry date for medicines. In five of the countries, an excessive number of pills in the package was also stated to be an issue. Accumulation of medicines because of a change in treatment was one of the main reasons in four countries.

In general, better prescribing practices and an improved communication between doctors and patients can contribute to a reduction in the amount of unused medicines accumulated. Measures that have been proposed include: unit dosing or different size packages; minimisation of the quantity dispensed; and the use of starter packs, to allow patients to try the medicine when a new treatment is started and change it in case of ineffective treatment or side effects. Incentives should also be promoted to control excessive purchasing in countries where medicine is available for free or at very low cost for some population groups[28].

What are people doing with their unused medicines?

In Portugal and Italy the majority of the respondents knew they could dispose of pharmaceuticals through a collection scheme, and in these two countries more than half of the respondents used them for disposing of solid medicines. At the other end of the scale, respondents from Lithuania and the United Kingdom were both the least aware of the existence of a collection scheme in their country and the ones that used them the least. The majority of the respondents in these two countries disposed of solid unused medicines by throwing in the rubbish bin, as so did half of the respondents in Belgium and roughly one quarter in Hungary, Italy and Portugal. In all countries, with the exception of Hungary, very few respondents flushed solid medicines down the toilet or sink. The scenario is unfortunately worse for liquid medicines, with 10% of the respondents in most countries disposing of liquids into the toilet or sink. In all countries, the number of respondents returning unused liquid medicines to collection points was smaller than for solid medicines, with the exception of Hungary. This difference was particularly high in

Table 4 - Overview of awareness of collection schemes and respondents' behaviour in the six countries surveyed. Q6 and Q8 - percentage of respondents, Q4 and Q3 – number of respondents. Numbers in brackets represent the number of respondents that used the method in combination with others.

	AWARE OF COLLECTION SCHEMES (Q6)	RETURN TO COLLECTION POINT - SOLID MEDICINES (Q4)	RETURN TO COLLECTION POINT - LIQUID MEDICINES (Q3)	REMEMBERED THAT HAD RECEIVED INFORMATION (Q8)
Belgium	62%	35 (+3)	28 (+4)	29%
Hungary	63%	40	43	78%
Italy	82%	64	60	65%
Lithuania	54%	13 (+3)	10 (+1)	39%
Portugal	85%	57 (+7)	38 (+3)	81%
United Kingdom	38%	17 (+6)	11 (+2)	31%

Portugal, with a gap of almost 20 percentage points. While a significant number of people incorrectly disposed of unused liquid medicines down the drain, an even bigger percentage of the respondents claimed they disposed of medicines in more than one way, combining both correct and incorrect disposal practices.

How can collection schemes be improved?

A majority of respondents in our survey claimed that they would be likely or very likely to dispose medicines correctly and return them to a collection point if they received information on how to proceed. Lack of information was one of the main reasons stated by respondents for not using the system, in addition to a lack of disposal locations.

The fact that respondents believed that it is acceptable and desirable to return unused household medicines to a collection point is of utter importance, indicating that the use of collection schemes could be improved. From the consumer/patient point of view it would make sense for pharmaceutical products to be disposed of in standard locations, publicly accessible and supervised, such as pharmacies. This would also be easier to communicate. Collection in a pharmacy guarantees that no one could tamper with the medicines and that children and animals could not accidentally ingest them. Furthermore, pharmacies are an easy access point for most patients. Pharmacists can provide information and ensure that the collected waste meets the system's criteria. Despite the common use of external containers for pharmaceuticals in Italy, pharmacists in Rome complain that the street containers are often mistaken for normal rubbish bins. Ideally, consumers would receive information about how to safely dispose of unused pharmaceuticals at the point of purchase, including not only pharmacies but also other authorised selling points.

The responsibility for the collection scheme should, however, not be left exclusively in the hands of pharmacies. In countries where this happens, the systems are less efficient as pharmacists and pharmacies do not feel compelled to offer a free service to customers, since the service engages them in further costs. This is the situation in Lithuania in our survey, where the costs of the pharmaceutical collection system is borne exclusively by pharmacies, even though, according to the law, part of the costs of the collection should be supported by the government. In practice, some pharmacists refuse to collect unused pharmaceuticals, in spite of their legal obligation to do this. Similar situations have been reported in Romania and Estonia. In Ireland, where up until now pharmacies are responsible for all the expenses of the collection scheme (the legislation is currently under revision), there are reports of pharmacies accepting unused medicines all year but then waiting for the national annual campaign sponsored by the Health and Safety Executive to get rid of the collected medicines, thus avoiding any costs related to the disposal.

The Waste Framework Directive (WFD) establishes that Member States can take legislative or non-legislative action to extend producer responsibility, including *"an acceptance of returned products and of the waste that remains after these products have been used, as well as the subsequent management of the waste and financial responsibility for such activities"*. In addition, the WFD details that the costs of waste

management are to be borne partly or wholly by the producer of the product from which the waste came and that the distributors of such product may share these costs. The polluter pays principle should be implemented with respect to pharmaceutical waste, and the costs associated with the collection schemes and awareness campaigns should be borne by the pharmaceutical industry and its distributors.

At the European level, the recommended disposal solution for pharmaceuticals is incineration at high temperature. This may be preferable to other disposal routes but is still a problem due to the likelihood of releasing toxic pollutantsinto the air, if best available technique is not used and high temperature is not adhered to. HCWH Europe believes that manufacturers, being familiar with the chemistry of the product, are best equipped to dispose of pharmaceuticals and that, at the European level, a chemical deactivation/destruction system would be the best option.

AN IDEAL COLLECTION SCHEME

An ideal collection scheme, as proposed by Health Care Without Harm Europe, would be:

- Easy to use and accessible
- Funded by the Pharmaceutical Industry Groups
- Free of charge for the public
- Well-communicated so that people are motivated to participate
- Able to sort and recycle packaging
- Safe for public heath, by ensuring collected residues cannot be tampered with
- Responsible for the chemical deactivation of pharmaceutical waste

How can consumers be better educated?

When asked what could be done to increase the awareness of citizens on the issue of pharmaceuticals in the environment, the majority of the interviewees claimed that more public awareness campaigns were needed and that the collection systems needed to be more accessible. HCWH Europe also believes that awareness-raising campaigns targeting the general public should be more numerous and occur regularly to achieve behavioural change. Educational campaigns providing disposal guidelines and information via different sources, including the media, schools, pharmacists and other healthcare professionals, would certainly be more successful in promoting proper disposal. Ideally, information about the safe disposal is also provided at the point of purchase.

The campaigns should focus not only on raising awareness of the existence and the functioning of collection schemes but also on the impact of pharmaceutical residues on the environment, since our survey indicates that this problem might not seem to worry EU citizens. For example, in Portugal, where the majority of respondents were aware of the collection scheme in place and had received information on how to use it, they were still not knowledgeable about the impact of pharmaceuticals on the environment. The results of our survey show that while a strong majority of the respondents believes that medicines disposed of incorrectly can contaminate the environment, a far more reduced number believed the effects to be of importance. Respondents also have a less positive outlook on the existence of measures to reduce the presence of pharmaceuticals in the environment.

It is therefore the role of governments, academia, non-governmental organisations, healthcare professionals and the pharmaceutical industry to educate the public on the environmental problems created by pharmaceutical residues in the environment and to inform them of the existing upstream and downstream measures that can improve the situation. Better public knowledge of this important issue would contribute to increased compliance of legislative measures. This would not only improve the implementation of collection schemes, but also the implementation of other upstream and downstream solutions that could successfully tackle the potential effects of pharmaceuticals in the environment. Educational campaigns would also help achieve, in the long run, the desired shift in public behaviour.

ELEMENTS FOR EDUCATIONAL CAMPAIGNS

- 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.
- Training for pharmacists and other authorised sellers so they can provide accurate advice to consumers and patients (even if pharmacies are not the main collection point).

The legislation on drug safety, or pharmacovigilance, (Directive 2010/84/EU and Regulation (EU) No 1235/2010) and the directive on priority substances for water pollution (Directive 2013/39/EU) acknowledge that the pollution of waters and soils with pharmaceutical residues is an emerging environmental problem. The pharmacovigilance legislation calls upon the European Commission, based, *inter alia*, on data received from the European Medicines Agency, the European Environment Agency and Member States, to produce a report on the scale of the problem, along with an assessment of whether amendments to legislation on medicinal products or other relevant Union legislation are required. At the time of writing the Commission's report has not been published. The new Priority Substances Directive further calls on the Commission to come up with a strategic approach to the pollution of water by pharmaceutical substances and in particular to propose measures to be taken at EU and/or Member State level to address the potential environmental impacts of pharmaceutical residues.

Health Care Without Harm believes that legislators have an important role to play in protecting the environment from the potential effects of pharmaceuticals and should devise a strong regulatory framework that reduces the risks of exposure to the environment. HCWH Europe's policy recommendations are as follows:

1. Address limitations of EU regulatory frameworks

The limitations of EU legislation for tackling the problem of pharmaceutical residues in the environment should be addressed by:

- Enforcing the correct disposal of pharmaceuticals with concrete guidance documents and a reporting mechanism at EU level, as well as harmonising EU collection schemes for expired and unused pharmaceuticals.
- Increasing the accountability of the pharmaceutical industry and associated actors by extending producer responsibility and holding them accountable for the products they place on the market and their environmental consequences. This could be, for example, through the financing of collection schemes and awareness campaigns.
- Increasing transparency regarding the results of collection schemes implemented in different Member States and enforcing compliance. While yearly reports are produced for some of the collection schemes and their activities, this is not a common practice. Reporting should be harmonised at EU level, so data is comparable between countries.
- Taking into consideration the environmental risks of pharmaceuticals in the cost-benefit analysis that is performed to grant market authorisation of human medicines and which enables consistent Environmental Risk Assessments (ERA) and monitoring across all Member States. ERA should also be required for "old" pharmaceuticals. Many of the pharmaceuticals detected in the environment are older pharmaceuticals that did not require an environmental risk assessment at the time of licensing but which are in continued use and causing environmental contamination.
- Classifying pharmaceuticals as hazardous waste and promoting chemical deactivation as a more environmentally sound option than incineration at high temperatures for the disposal of pharmaceuticals. It is also important to promote the adoption of a disposal code for pharmaceutical packaging that provides a visual explanation about the correct disposal of pharmaceuticals.
- Introducing quality standards for pharmaceuticals in relevant pieces of EU environmental legislation, specifically the Water Framework Directive, Groundwater Directive, Drinking Water Directive, Sludge Directive, Waste Framework Directive and Industrial Emissions Directive.

2. Promote awareness-raising and educational campaigns for the general public on the environmental risks of pharmaceuticals and on how to improve disposal practices

The impact of pharmaceutical residues in the environment is not well understood by EU citizens. The general public can play an important role in reducing pharmaceutical impacts by returning unused pharmaceuticals to collection schemes for proper disposal. Therefore, Pharmaceutical Industry Groups should sponsor and promote awareness-raising and educational campaigns targeting different age groups, using various communication channels.

Healthcare professionals, in particular doctors, nurses and pharmacists, should be trained and should provide information to patients on the disposal of pharmaceuticals. Campaign materials, in the form of posters and leaflets, should be displayed at pharmacies, medical offices, health centres, hospitals and other health institutions.

3. Support upstream measures to avoid the impact of pharmaceuticals in the environment

One of the key measures is to encourage the pharmaceutical industry to design and develop benign pharmaceuticals that rapidly biodegrade in the environment into harmless compounds.

Also, healthcare professionals should optimise medicine prescription behaviour so that only the necessary quantities of pharmaceuticals are prescribed, and giving priority to the least environmentally hazardous medicines. The pharmaceutical industry should also make available medicine pack sizes that are adapted to different treatments.

4. Identify, develop and promote innovative wastewater treatment technologies that increase efficient removal of pharmaceuticals

Wastewater treatment technologies are crucial components in the water management process, and the use of advance methodologies should be supported. Technologies that remove particulate matter (micro and ultra-filtration) and dissolved substances are increasingly being used in WWTPs and their use should be further promoted.

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