Chapter 11
Disposal of Pharmaceutical Waste in Households – A European Survey

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11.1 Pharmaceutical Waste – Reducing the Environmental Burden

Pharmaceutically active compounds are created to have specific physicochemical and biological properties. While such characteristics are necessary to deliver the desired therapeutic effect, many pharmaceutical products have an impact on the aquatic environment (comprehensive information on sources, fates and effects in K Kümmerer Pharmaceuticals in the Environment 2008). In an EEA report (European Environment Agency 2010) on "Pharmaceuticals in the Environment" the results on a workshop including proposals for action are summarised.

Not all packages of pharmaceutical products prescribed or bought as over the counter (OTC) are actually taken for therapy. Instead, a considerable number of them are wasted because the therapy succeeds before all tablets are taken, the product's expiry date passes, the expected effect does not occur, or the patient stops the therapy due to side effects and other reasons for insufficient compliance.

The disposal of unused or expired pharmaceuticals is worthy of particular interest. Pouring them into the sink or toilet has a direct impact on the water environment. Some active ingredients cannot be completely removed during waste water treatment and so could appear in drinking water.

The use of methods of "green pharmacy" to create active ingredients that deliver the desired therapeutic effect but have less environmental impact has started but is not yet very common. The priority remains to ensure safe disposal methods for expired and unused pharmaceuticals as this is currently the easiest way to reduce their environmental burden. Combustion in modern waste incinerators should be

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Disclaimer: The results of the questionnaire described here are compiled on the basis of the responses from the national authorities in charge of pharmaceutical waste. Used data are their responsibility.

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the preferred treatment of pharmaceutical waste (as for other aspects see Castensson and Ekedahl, Chap. 12, this book).

Previous studies have used a variety of questionnaires to assess consumer behaviour on the disposal of pharmaceuticals. However, a comprehensive overview of consumer behaviour, amounts of collected pharmaceuticals, and participation of pharmacies or municipal collection centres in separate collection of waste pharmaceuticals, has been missing. The European Environment Agency (EEA) therefore launched such a Europe-wide questionnaire in 2008 and assessed the results, which are summarized in the rest of this chapter.

11.2 Legislation

Several pieces of EU legislation refer to pharmaceutical waste:

- Commission Decision (2000)/532 (EC) part 2 distinguishes between "pharmaceuticals" and "medicines". Medicines are categorised under waste from health care or as part of the municipal waste (household and similar). For municipal waste, under category 20 01 31 cytotoxic and cytostatic medicines are listed, whereas category 20 01 32 lists all other medicines. Unused or expired cytotoxic and cytostatic medicines are defined as hazardous waste, other medicines not.
- Article 54 (j) of Directive 2004/27/EC (2004) amending Directive 2001/83/EC on the Community code relating to medicinal products for human use requires that "the following particulars shall appear on the outer packaging ... specific precautions relating to the disposal of unused medicinal products ... as well as a reference to any appropriate collection system in place". Article 127b of this Directive refers to collection systems: "Member States shall ensure that appropriate collection systems are in place for medicinal products that are unused or have expired".
- Directive 2008/98/EC on waste and repealing certain other Directives states in the consideration No. 17 that "Waste collection schemes which are not conducted on a professional basis should not be subject to registration as they present a lower risk and contribute to the separate collection of waste. Examples of such schemes are waste medicines collected by pharmacies ...".
- The Basel Convention on the Control of Movements of Hazardous Waste (1989) lists in Annex I "categories of wastes to be controlled" under Y3: Waste pharmaceuticals, drugs and medicines.

11.3 The EEA Questionnaire on Disposal of Unused Pharmaceuticals in Households

EEA created a questionnaire which was sent to all national focal points (NFPs) within the European Environment Information and Observation Network (Eionet) of the European Environment Agency. Whereas other questionnaires interviewed

single citizens or contacted associations, this was the first comprehensive survey of human pharmaceuticals waste based on responses from the authorities in Europe responsible for pharmaceutical waste.

The questionnaire focussed on:

- Means of informing citizens
- Classification of pharmaceutical waste
- Take back schemes
- Estimation – as far as available – of the annual amount of collected pharmaceuticals wasted in households

The questionnaire did not include the evaluation of pharmaceutical waste from hospitals for the following reasons. First, the amount of pharmaceutical products purchased by a hospital is close to the real needs – there is little leftover to be wasted. Second, hospitals' pharmaceutical waste usually does not pose an environmental burden as it will be regularly incinerated with other hospital waste.

The questionnaire was sent to the National Focal Points of all EU Member States, as well as to Albania, Croatia, Iceland, Liechtenstein, Norway, Serbia and Switzerland. Out of 34 countries 28 responded, while for the UK replies were received from Northern Ireland, Scotland and Wales only.

11.4 Educating and Informing Citizens

Consumer behaviour regarding the disposal of pharmaceutical waste determines the impact on the water environment. Although all authorities are convinced that unused pharmaceuticals should never be discharged through the sink or toilet, this behaviour is still common.

The means to inform citizens about the best way of disposal varies widely in Europe. Due to cultural differences and national authorities' previous experience of how best to communicate information to citizen, different approaches are used. Very often, cities, counties and regions use their websites to disseminate information. Brochures and leaflets addressed to the consumer are also common. To reach all citizens, the leaflet in Luxembourg for example is issued in five languages.

In some countries there is information on the collection containers placed in a pharmacy or at other places. Other countries rely on direct oral information given by pharmacists or doctors to patients.

Information is also given by associations of pharmacists and by the take back systems for unused or expired pharmaceuticals, e.g. Cyclamed in France.

Because a special collection system for unused pharmaceuticals exists in nearly all EU Member States, the recommendation to return unused or expired pharmaceuticals to a pharmacy or to a special collection centre is a key message.

In the EEA questionnaire we did not focus on differences in type and style of consumer information. In fact, the results presented in Fig. 11.1 show the total effort undertaken to inform the consumer about the correct way of disposal and indicate the number of information sources used.

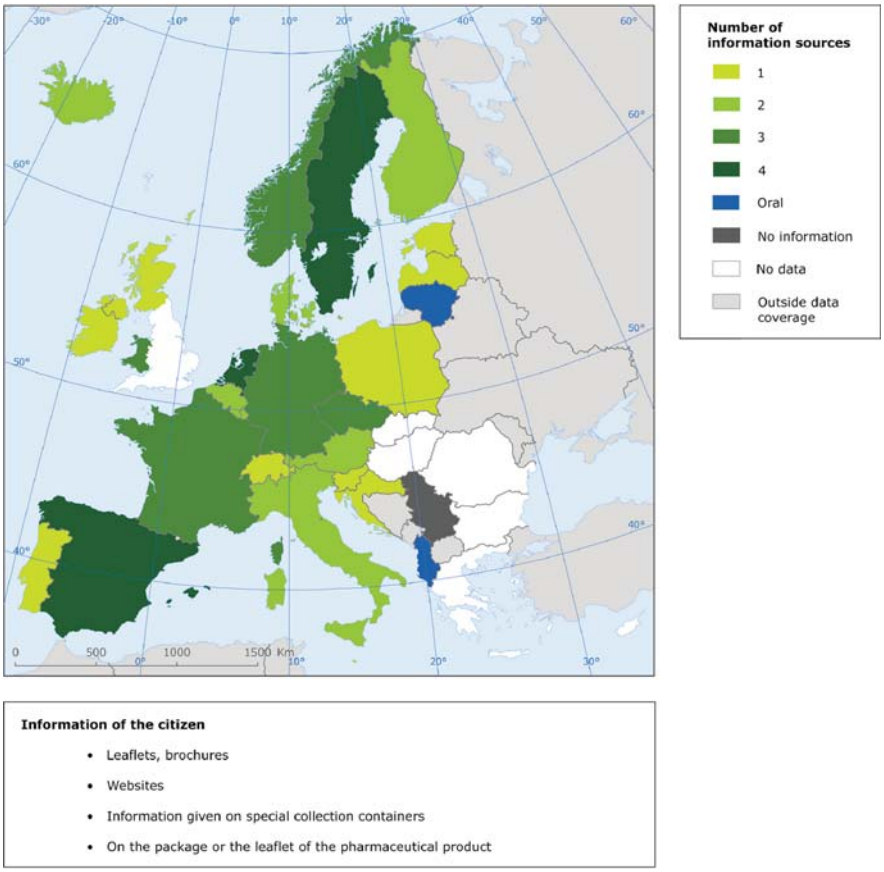

Fig. 11.1 Information provided to citizens on disposal of pharmaceuticals as waste (number of Information sources)

The effort undertaken differs widely. The Netherlands, Spain and Sweden use all means of information provision considered in the questionnaire.

Recommendations from the United States, where a nationwide take-back scheme does not exist, show the efforts needed to reduce the risks for small children. The Missouri Department of Natural Resources (2008) instructs putting liquid or solid medications into a hard plastic container and adding thickening material like cat litter, charcoal or coffee grounds. The riverside county waste management department, California (2008), states that liquid medications must be emptied into paper towels; pills must be crushed and mixed with cat litter or coffee grounds.

Smarxt Disposal, a joint public awareness campaign of the USA Fish and Wildlife Service, the American Pharmacists Association and the Pharmaceutical Research and Manufacturers of America created a video on the complex procedure

of crushing medication and sealing the package which is required before a pharmaceutical can be disposed of in a household bin.

11.5 Amounts of Pharmaceutical Waste

An Europe-wide overview of amounts of unused pharmaceuticals and their return rate does not exist. Data available before the present study was conducted were as follows.

The Government of the Austrian Land Styria (Steiermark) publishes data on unused pharmaceuticals as hazardous waste. For 2004 up to 2007, the amounts vary between 80.4 and 98.9 t/million capita.

In a collection programme using special collection containers in 60 out of 216 pharmacies in the city of Krakow, Poland in 2007, 4,928 kg of unused and expired pharmaceuticals were collected (Krakow Ekocentrum 2008). On that basis one the city of Krakow's pharmaceutical waste can be estimated at 25 t/capita/year. Liquid pharmaceuticals and aerosols were excluded.

The altmedikamente initiative estimated that in Germany the Vfw-REMEDICA and of MEDIrecycling take back schemes dispose of 1,400 of the 4,000−7,000 t of pharmaceuticals not used each year. The amount of unused pharmaceuticals collected in France annually by the CYCLAMED system increased from 6,900 t in 1995 to 10,300 t in 1998 per year (Macarthur 2000). For 2007, 13,000 t of unused pharmaceuticals collected in France were reported (Taylor and Poulmaire 2008). The same authors estimate the effectiveness of different return systems for five countries ranging from 1 to 80%.

Isacson and Olofsson (1999) found in the County of Malmöhus, Sweden that 3% of the sold pharmaceuticals were returned for disposal to Pharmacies. Eurostat (2009) provides information on household waste evaluated in 2004 and 2006. Category ewc_02 covers without specification hazardous and non-hazardous "chemicals preparation waste" including pharmaceuticals.

Within the EEA evaluation, the responsible authorities were asked for an estimation of the annual amounts of unused pharmaceuticals returned via special waste collection systems. Twenty state authorities responded (see Table 11.1).

The amounts calculated per capita differ widely. It should be noted that some of the figures are based on exact counting, whereas other figures are estimates (e.g. Germany and Ireland). Some figures are probably based on pharmaceutical waste collected in municipal collections centres without counting the amount from pharmacies and the share given to household waste without further notice.

As the amount of disposed pharmaceuticals depends, among other factors, on the amount distributed, Table 11.1 includes information on packages marketed (data from Ipf report 2008). Following Ipf (2009), the data for Austria can be taken for Styria. Figures for France show a high amount of distributed packages. The return rate in Switzerland seems to be higher as in all other countries. However, Fig. 11.2

Table 11.1 Annual pharmaceutical sales and waste per capita (total waste including packages)

Country	Sold packages (per capita annually)	Waste (g per capita annually)
Croatia	-	0.19
Estonia	19.46	3.4
Slovenia	16.91	4.5
Lithuania	27.12	10
Finland	16.64	11
Iceland	-	19
The Netherlands	14.34	30
Czech Republic	25.75	36
Liechtenstein	-	39
Belgium	21.83	46
Italy	28.87	54
Denmark	14.84	55
Spain	26.99	57
Portugal	25.12	58
Germany	18.34	73
Sweden	16.91	119
Ireland	22.86	142
Luxembourg	27.72	174
France	51.79	231
Switzerland	19.78	237
Styria	22.71 (Austria)	99

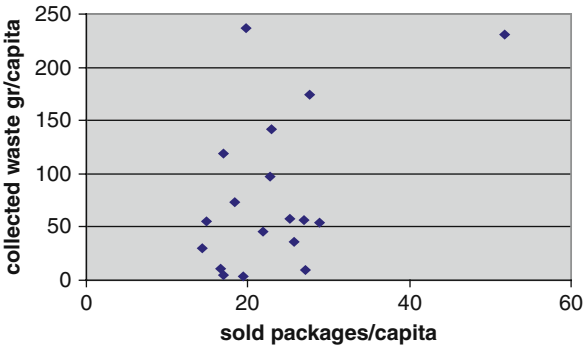

Fig. 11.2 Pairs of values pharmaceuticals sold vs. amount of waste collected

shows that the return rate depends obviously on various elements beyond the amount of pharmaceuticals marketed.

11.6 Classification of Pharmaceutical Waste

How is pharmaceutical waste being categorized: as "normal household waste" or as waste to be collected separately?

Despite its possible effect on wildlife and potentially on small children, pharmaceutical waste is currently not defined as dangerous waste within EU legislation. It should be noted that a study on hazardous household waste (DG Environment 2002) concluded that leather products and pharmaceuticals were household products that cannot be labelled as hazardous but could still potentially pose a risk to health and environment during disposal.

Figures are not available for intoxications of small children by disposed pharmaceuticals. However, the data from tox information centres on consultations give some basic information. The Giftinformationszentrum Nord Göttingen (2007) records in its annual report for 2007, 10,779 cases mainly from northern Germany of consultation after uptake of pharmaceuticals. Out of those, 2,784 (25.8%) are cases concerning small children (aged 1−4). These figures include uptake from all types of sources in the household including waste bins.

The given classification is not valid for cytotoxic and cytostatic medicines, which are defined as dangerous. However, because they are primarily used in hospitals and cancer treatment centres, the EEA evaluation did not target those pharmaceuticals. It should be noted that the trend is more and more out patient treatment, i.e. after 1–2 days in the hospital at the beginning of the therapy patients return home and take their pharmaceuticals there.

Defining waste as "not dangerous" does not necessarily mean that it is preferable to dispose it as normal household waste; e.g. glass bottles are often subject to special collections systems.

Figure 11.3 shows that, with the exception of Malta and Serbia, all countries that responded to the questionnaire classify pharmaceutical waste as subject to special collection systems. Some allow also collection within normal household waste. However, the enormous success of the Cyclamed system in France suggests that the amount of pharmaceutical waste in household waste must be very limited.

Concerning Serbia, the responsible desk officer reported that a new law on waste that is being enacted will contain articles on pharmaceuticals. The Environment Ministry of North Rhine Westphalia issued a leaflet on pharmaceutical waste (NRW 2007) stating "putting old and no longer used pharmaceuticals into the grey bin [i.e. household waste] is not only the simplest and most comfortable way to dispose them but also the most environmentally friendly". This leaflet does not mention the potential risks for small children posed by this disposal procedure. It should be noted that this statement is not supported by the German federal authorities, any of the other 15 German Länder or all communities in North Rhine Westphalia.

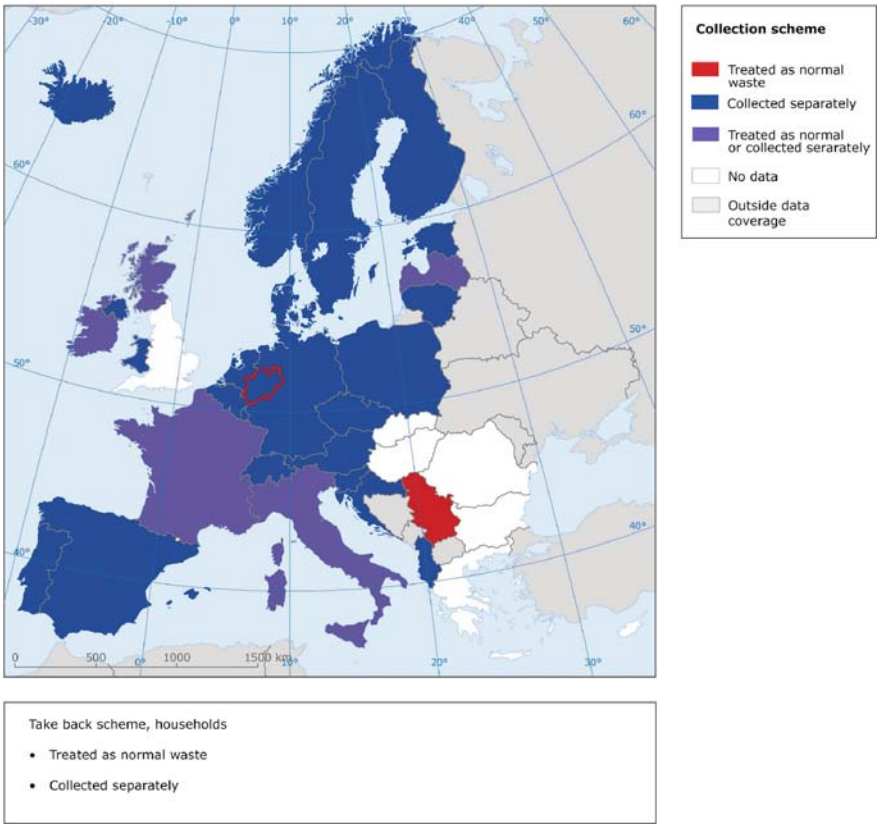

Fig. 11.3 Pharmaceutical waste to be collected as normal household waste or as special waste

11.7 Collection Points for Pharmaceutical Waste

The EEA questionnaire asked those countries where pharmaceutical waste has to be collected separately to identify who was responsible for collecting this special waste.

Figure 11.4 shows that nearly all countries responded that this waste must be given to a pharmacy; some also provided for public collection centres. Only Slovenia excludes pharmacies from its collection programme.

In fact, the majority of European countries have a return scheme for unused and expired pharmaceuticals. Those systems cooperate with pharmacies and take back collected unused or expired pharmaceuticals from there.

In 2007, eight European countries were without a specific unused or expired pharmaceutical return system (Taylor and Poulmaire 2008). This does not mean that those countries do not treat unused pharmaceuticals in a special way. Luxembourg has the "Superdreckskëscht" collection system for dangerous waste which includes pharmaceutical waste. This is taken back in cooperation with the pharmacies. Latvia

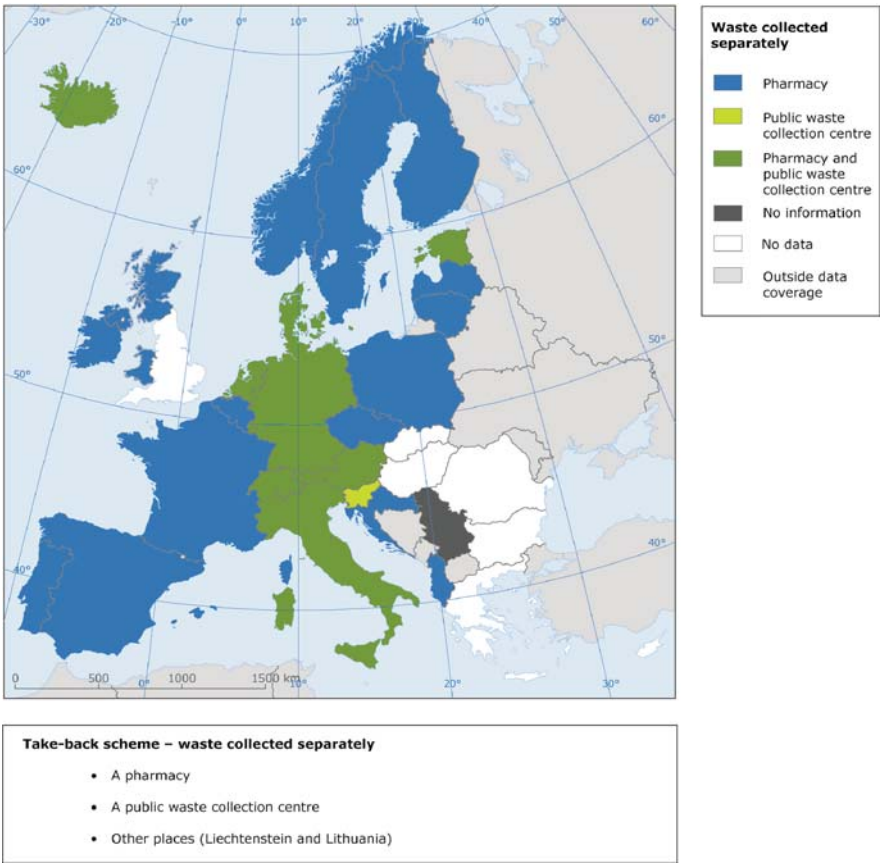

Fig. 11.4 Collections points for pharmaceutical waste provided it is classified as waste to be collected separately

and Slovenia, although lacking a special collection system for unused pharmaceuticals, ask citizens to bring the pharmaceutical waste to public waste collection centres or (in Latvia) to a pharmacy. In Malta, the civic amenity sites collect medicines amongst other waste (WasteServe Malta Ltd). In the United Kingdom unused pharmaceuticals must be given back to a pharmacy. Municipal collection centres are not allowed to collect them.

11.8 Consumer Behaviour and Return Rate

Due to lack of awareness of the environmental consequences or unwillingness to use the collection scheme available, some consumers flush unused pharmaceuticals through the sink or toilet. Götz and Keil (2007) found in a survey in Germany that 16% of people always or at least occasionally dispose of unused or expired tablets

via the toilet. For liquid pharmaceuticals, the authors found that the behaviour is different; 43% of unused or expired drops and syrups are always or at least occasionally discharged through the sink or toilet.

Liquids are an important part of the pharmaceutical market. Sigre (2006), the Spanish return system, reported for Spain that 20% of the pharmaceutical therapeutic units are liquids (solutions, suspensions or similar). Some of those consumers who pour liquid pharmaceuticals down the drain rinse – with best intentions – the emptied syrup bottles with tap water and give them to the glass recycling system.

Persson et al. (2008) reported the results of three surveys (conducted in 2001, 2004 and 2007) among Swedish people. With respect to the question "how would you handle unused prescription drugs?" the response "I would flush it down the drain" declined from 2% in 2001 to zero in 2007. The return rate to the pharmacy increased from 70% in 2001 to 73% in 2007. There is an increasing awareness of the effects of pharmaceuticals on the environment. In 2007, 42% said they were worried, 33% in 2001. During the same period of time, the group which did not worry decreased by 10%.

Bound and Voulvoulis (2005) carried out a survey in south-east England and found that 12% of the population emptied unwanted pharmaceuticals into the sink or toilet. Kruopienė and Dvarionienė (2007) report that in Lithuania 8% of town residents and 6% of those in the suburbs and settlements flush medicines with the sewage. Ruthoy and Daughton (2007) used data collected from the Clark County Coroner's Office, Nevada (USA) and calculated that more than 92% of the medications found at decedent sites were flushed into the sewage system.

A guess of the Umweltbundesamt, Berlin, is that in total about 30% of sold amounts are not used and thrown away. A survey within the START project (2008) based on 1,306 interviews in Germany found that 34% never return their unused pharmaceuticals to a pharmacy; the others return always or at least occasionally unused or expired pharmaceuticals to a pharmacy. Less than one-third of those interviewed always return their unused pharmaceuticals to a pharmacy. Bound et al. (2006) assessed the link between people's attitudes to the environment in general and their attitude to the disposal of drugs based on a survey carried out in South-East England. Only 21% of the people who strongly agreed with the statement: "I live an environmentally friendly life" disposed of pharmaceuticals in the bin, whereas approximately 57% of those people returned them to a pharmacy. Those who neither agree nor disagree with this statement disposed in the bin 75%, and to a pharmacy approximately 22%, of their unused pharmaceuticals. See also Sect. 1.1.6 and Chap. 29 in Kümmerer, Pharmaceuticals in the Environment (2008).

In some countries, home-burning of household waste is a common procedure. Kruopienė and Dvarionienė (2007) found in a survey that 50% of countryside residents in Lithuania dispose of unused medicines by burning them.

In the United States, where a nationwide take back scheme does not exist, Glassmeyer et al. (2009) determined that 35% of unused medication is discharged via the toilet or sink. Seehusen and Edwards (2006) carried out a survey with 301

patients at an outpatient pharmacy; 54% responded that their prior practice was flushing down a toilet unused and expired pharmaceuticals. In a survey based on 500 callers to the Pittsburgh poison information center, Kuspis and Krenzelok (1996) found that 1.4% returned medications to a pharmacy, 54% disposed of them in the garbage and 35% flushed their medications down the toilet or sink.

Statistics Canada (2008) found in a survey of households that 39% disposed of leftover or expired medication using uncontrolled methods like regular household garbage, flushing it down the drain or burying it.

11.9 Participation of Pharmacies as a Legal Duty?

As part of our questionnaire, the responsible authorities were asked whether pharmacies were legally obliged to participate in take back schemes.

The following countries defined a legal obligation of pharmacies to participate in a take-back scheme:

- Belgium
- Croatia
- Denmark
- Estonia
- France
- Iceland
- Lichtenstein
- Lithuania
- Norway
- UK

For UK see also PSNC (2007).

In addition, 16 other European countries call on pharmacies to participate voluntarily:

- Albania
- Austria
- Czech Republic
- Finland
- Germany
- Ireland
- Italy
- Latvia
- Luxembourg
- Netherlands
- Poland
- Portugal

- Slovenia
- Spain
- Sweden
- Switzerland

11.10 Conclusions

Using the National Focal Points within the EIONET network to complete the questionnaire proved to be an effective means to obtain data on pharmaceutical waste that was not previously available.

Collection rates of unused or expired pharmaceuticals in Europe differ widely. They depend on the amount of pharmaceuticals distributed, variance in patients' compliance to use the prescribed pharmaceuticals for therapy and lack of knowledge of established return schemes or the environmental effects of pharmaceuticals flushed into the drain.

Return schemes via pharmacies are well established in most European countries. There seems little need to oblige pharmacies by law to participate in a take back scheme. In many countries where a considerable amount of pharmaceutical waste is taken back, pharmacies participate voluntarily.

The results of the START project (2008) and literature show that there is uncertainty among citizens about proper waste disposal of unused pharmaceuticals. The German Advisory Council on the Environment (2007) notes that: "medicines should be clearly labelled on the packaging, together with a warning that pharmaceutical residues should not be disposed of via the sewerage system, but should instead be submitted to a pharmacy for disposal". If unused pharmaceuticals are merely classified as "normal household waste", some consumers will have little understanding of why pharmaceuticals, notably syrups, suspensions or drops, should not be discharged through sink or toilet. An unambiguous policy on pharmaceutical waste disposal is required to clarify consumer uncertainties.

In addition, small children have a natural curiosity to examine things within their reach: coloured pills attract their interest. Pharmaceuticals not intended for the therapy of small children pose a potential risk for them. Return pathways should in all instances be out of the reach of small children.

There is a common understanding that pharmaceutical waste needs special care. In fact, objective 12 of the Commission Communication on Safe, Innovative and Accessible Medicines (2008) states that: Measures to reduce the potentially harmful impacts of pharmaceuticals on the European environment and public health should be proposed.

The hazardous nature of many pharmaceutical wastes is not defined in legislative texts. Nevertheless, most countries have defined unused and expired pharmaceuticals as "dangerous", "harmful", "hazardous", "special waste" or "problematic waste" in recognition of their special status.

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