Reports of the Finnish Environment Institute 34 | 2020

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Clear Waters from Pharmaceuticals (CWPharma) Activity 4.1 Report

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Centre for Sustainable Consumption and Production

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Subject Editor: Ari Nissinen

Financier: European Union, Interreg Baltic Sea Region,
European Regional Development Fund
Publisher of publication: Finnish Environment Institute (SYKE)
Latokartanonkaari 11, 00790 Helsinki, Phone +358 295 251 000, syke.fi

Layout: Päivi Fjäder
Cover photo: Halacious Aypa / Unsplash

The publication is available in the internet (pdf): syke.fi/publications | helda.helsinki.fi/syke and in print: syke.omapumu.com

ISBN 978-952-11-5201-6 (PDF)
ISBN 978-952-11-5200-9 (pub.)
ISSN 1796-1726 (online)
ISSN 1796-1718 (print)

Year of issue: 2020

Abstract

Good practices for take-back and disposal of unused pharmaceuticals in the Baltic Sea region

Appropriate collection and disposal of medicine-related waste has been identified as one of the main ways to decrease the emission of active pharmaceutical ingredients (APIs) into the environment. Improvement to the take-back and treatment of collected pharmaceutical waste may be considered low-hanging fruit when one is considering measures to reduce API emissions. However, comparable information that would enable estimating the potential impact of these efforts has not been available.

Directive 2004/27/EC, related to medicinal products for human use, mandates that EU member states implement appropriate collection schemes for unused or expired human-use medicinal products. However, it does not provide any guidelines on practical implementation of these schemes. Several studies have pointed out significant differences among Member States in this regard.

In March 2019, the European Commission published the European Union Strategic Approach to Pharmaceuticals in the Environment. The actions specified therein cover all stages of the pharmaceutical life cycle, from design and production to disposal and waste management. It emphasizes such elements as sharing good practices, co-operating at international level, and improving understanding of the risks.

This report is aimed at filling knowledge gaps and proposing good practices for take-back and disposal of unused human and veterinary medicines and other pharmaceutical waste. The report is targeted to e.g. ministries, environment and medicines agencies, supervisory authorities, municipalities, hospitals, NGOs, pharmacists, doctors, and veterinarians.

For the report, current national practices for take-back and disposal of unused medicines and other pharmaceutical waste in Denmark, Estonia, Finland, Germany, Latvia, Lithuania, Poland, Russia, and Sweden were evaluated. The pharmaceutical waste originating from households, hospitals and other health care institutions, the pharmaceutical industry, and veterinary use was considered.

The proportion of citizens who return unused pharmaceuticals via designated collection points varies greatly between Baltic Sea countries, from about 10% to 70%, with 16–80% disposing of them of as mixed household waste and 3–30% flushing them down the drain. The most commonly cited reason for improper disposal of medicines on households' part is lack of information about their environmental impacts and how to get rid of them in an environmentally sound manner. Separate collection of unused household pharmaceuticals does not exist in Russia, and the collection mechanism functions poorly in Latvia, Lithuania and Poland. Information on the take-back schemes for unused human medicines is more readily available than is corresponding information on veterinary medicines.

We identified, all told, 21 good practices and recommendations for take-back and disposal of unused pharmaceuticals and other pharmaceutical waste and for promoting the rational use of pharmaceuticals in the Baltic Sea region. Nevertheless, implementing them at national level requires particular consideration due to differences in national legislation and other characteristics of the EU Baltic Sea countries and Russia. The good practices identified in this report answer the call issued in the EU strategic approach for an efficient risk-reduction strategy.

Keywords: good practices, unused pharmaceuticals, active pharmaceutical ingredients (APIs), pharmaceutical waste, take-back and disposal of pharmaceutical waste, Baltic Sea region, households, pharmaceutical industry, hospitals, health care institutions, veterinarians

Tiivistelmä

Hyviä käytäntöjä käyttämättömien ihmis- ja eläinlääkkeiden sekä muun lääkejätteen keräämiselle ja hävittämiselle Itämeren alueella

Lääkejätteen asianmukaisen keräämisen ja hävittämisen on osoitettu olevan merkittävä keino ympäristöön päätyvän lääkeainekuormituksen vähentämiseksi. Lääkejätteen keräyksen ja hävittämisen kehittämistä voidaan pitää helposti toteutettavana keinona vähentää lääkeainekuormitusta, vaikka näiden toimien tehokkuuden arvioimiseksi ei vielä ole olemassa riittävästi tietoa.

Ihmiskäyttöön tarkoitettujen lääkkeiden käyttöä koskeva direktiivi 2004/27/EC velvoittaa EU:n jäsenvaltioita toteuttamaan asianmukaisesti käyttämättömien ja vanhentuneiden lääkkeiden keräyksen. Direktiivi ei kuitenkaan anna käytännön ohjeita toteutukseen, ja jäsenvaltioiden välillä onkin useissa tutkimuksissa havaittu olevan merkittäviä eroja.

Euroopan komissio julkaisi maaliskuussa 2019 Euroopan unionin strategisen lähestymistavan ympäristössä oleviin lääkeaineisiin. Sen toimenpiteet kattavat lääkeaineiden elinkaaren kaikki vaiheet suunnittelusta ja tuotannosta aina hävittämiseen ja jätehuoltoon. Strategia painottaa muun muassa hyvien käytäntöjen jakamista, kansainvälistä yhteistyötä ja riskien parempaa ymmärtämistä.

Tämän raportin tarkoituksena on koota tietoa ja esittää hyviä käytäntöjä käyttämättömien ihmis- ja eläinlääkkeiden sekä muun lääkejätteen keräämiselle ja hävittämiselle. Raportti on suunnattu mm. ministeriöille, ympäristö- ja lääkevirastoille, alueellisille valvontaviranomaisille, kunnille, sairaaloille, kansalaisjärjestöille sekä apteekkareille, lääkäreille ja eläinlääkäreille.

Raportissa arvioidaan nykyiset Tanskassa, Virossa, Suomessa, Saksassa, Latviassa, Liettuassa, Puolassa, Venäjällä ja Ruotsissa esiintyvät käytännöt käyttämättömien lääkkeiden ja muun lääkejätteen keräämiselle ja hävittämiselle. Tarkastelu kattaa kotitalouksissa, sairaaloissa ja muissa terveydenhuoltolaitoksissa, lääketeollisuudessa ja eläinlääkinnässä syntyvän lääkejätteen.

Niiden kansalaisten osuus, jotka palauttavat käyttämättömät lääkkeet niille osoitettuihin keräyspisteisiin vaihtelee suuresti Itämeren valtioiden välillä ollen noin 10–70 %. Vastaavasti noin 16–80 % kansalaisista hävittää käyttämättömät lääkkeet kotitalouksien sekajätteen ja 3–30 % viemärin kautta. Yleisimmät syyt epäasianmukaiselle hävittämiselle ovat tietämättömyys lääkeaineiden ympäristövaikutuksista ja oikeasta ympäristöystävällisestä tavasta päästä eroon siitä. Venäjällä, erillistä järjestelmää kotitalouksien käyttämättömien lääkkeiden keräämiselle ei ole tai se ei toimi kunnolla, kuten Latviassa, Liettuassa ja Puolassa. Ihmislääkkeiden keräyksestä on eläinlääkkeitä enemmän tietoa saatavilla.

Tunnistimme 21 hyvää käytäntöä ja suositusta käyttämättömien lääkkeiden ja muun lääkejätteen keräämiseksi ja hävittämiseksi sekä lääkkeiden järkevän käytön edistämiseksi Itämeren alueella. Käytäntöjen hyödyntäminen kussakin Itämeren EU-maassa ja Venäjällä edellyttää kuitenkin huolellista harkintaa johtuen eroavaisuuksista lainsäädännöissä ja muissa kansallisissa piirteissä. Tässä raportissa tunnistetut hyvät käytännöt toteuttavat lääkeaineiden elinkaaren eri vaiheet huomioon ottavaa EU:n riskinvähennysstrategiaa.

Asiasanat: hyvät käytännöt, käyttämättömät lääkkeet, lääkeaineet, lääkejäte, lääkejätteen keräys ja hävitys, Itämeren alue, kotitaloudet, lääketeollisuus, sairaalat, terveydenhoitolaitokset, eläinlääkärit

Sammandrag

Goda exempel för insamling och kassation av oanvända läkemedel i Östersjöregionen

En välfungerande insamling och hantering av läkemedelsavfall är viktig för att minska utsläppen av läkemedelsrester till miljön. Att förbättra insamlingssystemen och hanteringen av insamlat läkemedelsavfall är förhållandevis enkla åtgärder för att minska utsläpp av aktiva läkemedelssubstanser. Det har dock inte funnits jämförbar information för att kunna uppskatta den potentiella effekten av dessa åtgärder, vilket påpekades av UNESCO & HELCOM (2017).

Direktiv 2004/27/EG, om gemenskapsregler för humanläkemedel, uppmanar EU:s medlemsstater att ta fram insamlingssystem för oanvända läkemedel eller läkemedel vars sista förbrukningsdag har gått ut. Direktivet ger dock inga riktlinjer för hur genomförandet av systemen ska gå till praktiskt. Flera studier har pekat på betydande skillnader i genomförandet av direktivet mellan medlemsstaterna i EU.

I mars 2019 offentliggjorde den Europeiska kommissionen Europeiska unionens Strategi för läkemedel i miljön. Åtgärderna i strategin täcker alla stadier i ett läkemedels livscykel från design och produktion till kassation och avfallshantering. Strategin lyfter fram åtgärder som exempelvis att utbyta goda exempel och erfarenheter, att samarbeta på internationell nivå och att förbättra förståelsen för risker.

Denna rapport syftar till att fylla kunskapsluckor och föreslå goda exempel för insamling och kassation av oanvända humanläkemedel, läkemedel för djur och övrigt läkemedelsavfall. Rapporten riktar sig till beslutsfattare, miljö- och läkemedelsmyndigheter, regionala tillsynsmyndigheter, kommuner, sjukhus, icke-statliga organisationer och intresseorganisationer för apotek, läkare och veterinärer.

I denna rapport utvärderades de nuvarande nationella metoderna för insamling och bortskaffande av oanvända läkemedel och övrigt läkemedelsavfall i Danmark, Estland, Finland, Tyskland, Lettland, Litauen, Polen, Ryssland och Sverige. Läkemedelsavfall från hushåll, sjukhus och sjukvårdsinrättningar, läkemedelsindustrin och veterinärer ingick i utvärderingen.

Andelen av befolkningen som lämnar in oanvända läkemedel till utsedda insamlingsställen varierar mycket mellan länderna runt Östersjön; från cirka 10 % till 70 %. Cirka 16–80 % av befolkningen lägger läkemedelsresterna i hushållsavfallet och 3–30 % spolar ner dem i avloppet. Det vanligaste skälet till hushållens felaktiga hantering av läkemedelsavfall är bristen på information om läkemedlens miljöpåverkan och hur man kan göra sig av med dem på ett miljövänligt sätt. Separata insamlingssystem för oanvända läkemedel finns inte eller är inte organiserat i Ryssland, och i exempelvis Lettland, Litauen och Polen är insamlingen bristfällig. Det finns mer tillgänglig information om insamlingssystem för oanvända humanläkemedel än om läkemedel för djur.

I projektet identifierades totalt 21 goda exempel och rekommendationer på insamling och bortskaffande av oanvända läkemedel och annat läkemedelsavfall samt för att främja en rationell användning av läkemedel i Östersjöregionen. Men implementeringen av dessa exempel nationellt måste noggrant övervägas på grund av skillnaderna i nationell lagstiftning och andra förutsättningar i EU:s Östersjöländer och Ryssland. De framtagna goda exemplen i denna rapport uppfyller behov som lyfts i Europeiska unionens strategi om läkemedel i miljön.

Nyckelord: Goda exempel, oanvända läkemedel, aktiva läkemedelssubstanser (APIs), återlämning/insamling, kassation/bortskaffande, läkemedelsavfall, Östersjöregionen, hushåll, läkemedelsindustrin, sjukhus, sjukvårdsinrättningar, veterinärer

Preface

This report presents the current practices for take-back and disposal of unused human and veterinary medicines and other pharmaceutical waste in Baltic Sea coastal countries, and it proposes good practices for decreasing pharmaceutical emissions from improper disposal of that waste. The practices and their legal background are described country-specifically and then summarized for an overall picture at Baltic Sea level. All the relevant waste-producing activities are included – i.e., those of households, hospitals and other health care institutions, veterinarians and veterinary practices, farms, and the pharmaceutical industry.

This study was part of the CWPharma project funded by the EU's Interreg Baltic Sea Region Programme 2014–2020. In supplemental work, information about national practices was collected with a questionnaire on management of medical waste, in cooperation with HELCOM. The report was prepared by the following project partners: Jukka Mehtonen, Lauri Äystö, Ville Junttila and Noora Perkola from Finnish Environment Institute (SYKE), Terhi Lehtinen from Finnish Medicines Agency (Fimea), Jeppe Bregendahl from Kalundborg Utility, Ülle Leisk and Vallo Kõrgmaa from Estonian Environmental Research Centre (EERC), Pille Aarma from Estonian Waterworks Association (EVEL), Jan Schütz and Michael Stapf from Berlin Centre of Competence for Water (KWB), Anete Kublina and Ieva Karkovska from Latvian Environment Geology and Meteorology Centre (LEGMC), Marlena Szumska, Aleksandra Bogusz and Radosław Kalinowski from the Polish Institute of Environmental Protection – National Research Institute (IOS), and Sara Spjuth, Kristina Nyhlén and Torsten Jakobsson from County Administrative Board of Östergötland (CAB). Outside the project partnership, Sergej Suzdalev from Klaipeda University and Elena Kaskelainen from John Nurminen Foundation had a significant role in writing the country specific chapters on Lithuania and Russia respectively.

In addition, we also received valuable information and feedback on the report and its recommendations from colleagues at the project's Associated Organisation: Eevaleena Häkkinen from the Finnish Ministry of the Environment, Johanna Salimäki and Sanna Siissalo from the Association of Finnish Pharmacies, Evelina Jatko and Karin Ramstedt from CAB, Gunnar Thorsén and Christian Baresel from Swedish Environmnetal Research Institute (IVL), Katariina Parker and Maria Linderoth from the Swedish Environmental Protection Agency, Kia Salin from the Swedish Medical Products Agency, and Bengt Mattson from the Swedish Association of the Pharmaceutical Industry (LIF). Also, other stakeholders and colleagues provided valuable input to the report: Dmitry Frank-Kamenetsky from the HELCOM Secretariat, Johanna Borgendahl, Helena Ramström and Marie-Louise Ovesjö from Stockholm Regional Council, Lisa Stern from the Swedish Pharmacy Association, Venla Johansson from the City of Vantaa, Auli Westerholm from Fortum Waste Solutions Oy, and Päivi Fjäder from the Finnish Environment Institute.

I thank all the writers and contributors. With your efforts and expertise, we now have a valuable report about the good and not-so-good practices that are currently being applied. It is my hope that this report will be used to increase regional collaboration and discussion surrounding this topic and to improve the management of pharmaceutical waste in the region.

Helsinki 7.5.2020

Noora Perkola, CWPharma project Coordinator, Leading Researcher,
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Contents

1 Introduction

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Whilst pharmaceuticals enter the environment throughout the production, consumption and disposal of medicines, incorrect disposal of waste containing pharmaceuticals is considered one of the major pathways (EC 2019). Many publications have identified proper disposal of medicine waste as one of the main ways to decrease the emission of active pharmaceutical ingredients.

1.1 Background

Directive 2004/27/EC, related to medicinal products for human use, contains a mandate for EU member states to implement appropriate collection schemes for unused or expired human-use medicinal products. However, it does not provide any guidelines on practical implementation of these schemes, and several studies have pointed out significant differences among the member states in this regard (e.g., BIO Intelligence Service 2013, HCWH 2013). Some APIs are narcotic or psychotropic in nature and, as such, fall within the scope of international conventions designed to prevent the non-medical use of these substances, such as the United Nations Single Convention on Narcotic Drugs and the UN Convention on Psychotropic Substances (adopted in 1961 and 1971, respectively). These conventions specify requirements for the handling and possession of the relevant substances, often reflected also in national waste legislation or guidelines.

According to a survey in Germany, 51% of the general public there consider private households' improper disposal of medicines down the toilet or sink to cause high or very high pharmaceutical emissions (Götz et al. 2019). Respondents assumed this to be the second most important cause of pharmaceuticals' presence in surface water, with emissions from the pharmaceutical industry presumed the most important. This is in contrast against current expert consensus, according to which the consumption and excretion of medicines is the most significant pathway into the environment (e.g., EC 2019). As for solutions, according to Götz et al. (2019), 61% of the general public reported being interested in information on the correct disposal of medicines, and around 50% of experts from Germany, Hungary, and the UK considered standardised regulations on the disposal of unused pharmaceuticals to be one of the most effective ways to reduce pharmaceutical residues in the environment.

The HELCOM status report on pharmaceuticals in the Baltic Sea region, hereinafter 'the Status Report' (HELCOM & UNESCO 2017), provides region-level information on such matters as the inputs of several individual APIs on the Baltic Sea and their concentrations in freshwater and marine environments. However, the report also highlights several data gaps that need attention. One of these gaps involves lack of information on the handling of pharmaceutical waste in several countries in the Baltic Sea region. Information was reported from Estonia, Finland, Germany, Sweden, and to some extent Russia but not from Denmark, Latvia, Lithuania, and Poland. Furthermore, only Estonia, Finland, and Sweden provided information on the amount of pharmaceutical waste collected and on their procedures for handling pharmaceutical waste. Therefore, it was impossible to evaluate the hazards to the environment arising from disposal of unused medicines, whether human or veterinary. Additionally, the Status Report contains very few data on veterinary pharmaceuticals in general. Therefore, the contribution of veterinary pharmaceuticals to freshwater and marine pollution could not be assessed in the report.

The Status Report states among its conclusions that 'measures to reduce the inputs of pharmaceuticals should address all stages of the product life cycle from manufacturing to consumption to waste management', where these measures may include both technical and policy solutions, alongside educational and awareness-raising initiatives. The Status Report takes a stand also on good practices for take-back and disposal of unused medicines: 'Take-back of unused medicines by pharmacies should be applied or developed in countries where such systems are not yet in place or are inefficient, in order to reduce the disposal of unused medicines via solid waste or sewers.'

The European Commission (EC) published a report on a study related to the preparation of an EC strategic approach to minimise the pollution due to pharmaceuticals (BIO Intelligence Service 2013). The authors concluded that in most EU member states, a large share of the unused human medicinal products is not collected separately, with some Member States not having implemented take-back schemes of any sort. Additionally, the report states that the take-back schemes for unused medicinal products represent the simplest ways to reduce the flows of pharmaceutical residues into the environment.

The issue of implementing take-back schemes for unused medicines was further emphasised in the EC's background document for public consultation on pharmaceuticals in the environment (Lockwood et al. 2017). Implementation of take-back schemes is extremely heterogeneous across the Member States, but the take-back of human medicines can be characterised as better organised than that of veterinary medicines in general.

In March 2019, the European Commission published the European Union Strategic Approach to Pharmaceuticals in the Environment (EC 2019). This strategy document outlines six areas for action to reduce the risks posed by medicines and related products released into the environment. The actions cover all stages in the pharmaceutical life cycle, from design and production to disposal and waste management. For the action area 'Reduce wastage and improve the management of waste', it is stated that 'the Commission will assess the implementation of collection schemes for unused pharmaceuticals and consider how their availability and functioning could be improved, how to increase public awareness of the importance of using them, and how extended producer responsibility could play a role in reducing inappropriate disposal'.

The OECD's policy paper on pharmaceuticals (OECD 2019) recommends to ensure appropriate collection and disposal of pharmaceutical waste.

Additionally, pharmacists are making strong calls for action to reduce the environmental impacts of pharmaceuticals, via such means as improved collection of medicine waste (PGEU 2019). As medicine experts, pharmacists are well positioned to increase public awareness, promote the prudent use and appropriate disposal of pharmaceuticals, and provide advice on the availability of 'greener' pharmaceuticals where such information is available.

Proper collection and disposal of household pharmaceutical waste can contribute to reducing the impact of pharmaceuticals on the environment. Importantly, effective collection schemes would divert unused medicines from mixed-waste streams that are not designed to treat pharmaceutical waste (HCWH 2013). The improvement of take-back schemes for unused medicines may be one of the simplest ways to reduce emissions of medicines in the environment (EEA 2010).

1.2 The scope of the report

This report is aimed at filling the knowledge gaps mentioned above and proposing concrete good practices for take-back and disposal of unused human and veterinary medicines and other waste containing pharmaceutical residues.

The current national practices for take-back and disposal of unused medicines and other pharmaceutical waste in Denmark, Estonia, Finland, Germany, Latvia, Lithuania, Poland, Russia, and Sweden were

evaluated, with pharmaceutical waste from households, hospitals and other health care institutions, pharmaceutical-industry operations, and veterinary use being taken into consideration. Furthermore, Baltic Sea region wide best-practice recommendations for efficient take-back and disposal of unused medicines are offered. The aim in this is to spread good take-back and disposal methods that may already be in place in some Baltic Sea countries to countries where such practices are not yet in place or are inefficient.

The report is targeted specifically at policy-makers (e.g., environment, agriculture, and social and health ministries), national environment and medicines agencies, regional supervisory authorities, municipalities, hospitals, interest groups for practitioners (pharmacists, doctors, and veterinarians), and NGOs.

2 Current national practices for take-back and disposal of unused pharmaceuticals and other pharmaceutical waste

In addition to EU legislation, the collection and handling of pharmaceutical waste is regulated by national legislation in each of the Baltic Sea countries. Therefore, the collection schemes and disposal methods may vary between the countries. Information about the legal basis for pharmaceutical waste management, and methods of collection and disposal of pharmaceutical waste originating from different sources was collected for Denmark, Estonia, Finland, Germany, Latvia, Lithuania, Poland, Russia and Sweden.

2.1 Denmark

Jeppe Bregendahl

Kalundborg Utility

2.1.1 Legal basis

In Denmark, returning unused medicines is addressed by several distinct fields of law and, accordingly, affected by various laws and regulations. Among the government orders regulating pharmaceutical waste are the Executive Waste Order (1759/2018), the Executive Order on the Pharmacy Act (801/2018), and the Executive Order on the Waste Database (1742/2018). For veterinary medicines, there are also the Executive Order on the Veterinary Code (48/2017) and the Executive Order on the Act on Holds of Animals (1/2019).

Unused medicines fall under the category of hazardous waste and the subcategory clinical hazardous waste (per the Executive Waste Order). The requirements pertaining to both collection of such waste types and related instructions are administered by the individual municipality. The municipalities are free to construct their respective systems as they prefer. The nationwide practice is that the pharmacies are responsible for accepting any waste of this nature from within their region (1759/2018).

The Executive Order of the Pharmacy Act (paragraph 11, part 7) states that all pharmacies that hold a national licence to distribute medicines are required to accept any unused medicines for destruction. This requirement covers all unused medicines presented by private persons, practising doctors and veterinarians, and nursing homes and other institutions. Hospitals constitute an exception; they have a separate system by which pharmaceutical waste is collected, handled, and transported. All types of pharmaceutical waste from hospitals are classified as hazardous and treated in a similar way. Pharmacies and hospitals are not required to document the waste received or handled (801/2018).

Waste-treatment plants authorised to treat pharmaceutical waste are required to register the amount handled but not the specific type of waste. This is the only documentation for pharmaceutical waste in Denmark.

2.1.2 Current take-back practices

Private individuals are responsible for the handling of their own medicines, as their private property. They can only be encouraged to dispose of expired or otherwise useless medicines through the

pharmacies. On 1 September 2017, there were 237 pharmacies in Denmark and the same number of collection points for unused medicine (Ministeriet for Sundheg og Forebyggelse 2009).

Pharmaceuticals from doctors´ offices and clinics may be delivered to the pharmacy or be disposed of via containers and other collection points if this option is offered by the municipality.

From the pharmacies, the hazardous waste is collected and transported to the treatment plant by companies certified to do so, as is all waste from containers and collection points.

Hospitals are required to handle their own waste and send it directly to incineration.

Pharmaceutical waste from the industry is sent for immediate destruction, through a separate co-ordinated municipal system. The industry is the largest source of pharmaceutical waste, with waste from this source originating from production errors, discharge of reference material, errors in labelling, expiry of medicines, and products that do not work as intended.

The industry accounted for more than 90% (or 7.7 t) of the pharmaceutical waste handled in 2006, when the latest calculation was done. Hospitals produced 3% (270 t) of the waste, and 4% (300 t) came from pharmacies. How large a fraction of the total amount is disposed of through household waste and toilets is unknown (Ministeriet for Sundheg og Forebyggelse 2009).

Evaluation of the pharmacies' take-back system

The latest evaluation of the pharmacies' take-back system was carried out in 2009. This was a qualitative assessment of the composition of the medicines returned to 10 pharmacies.

Table 1 presents the types of medicines sold and the types of medicines returned to the pharmacies. The study involved a survey of the 10 Danish pharmacies, covering one week. The amounts of the pharmaceuticals were stated in numbers of packages, not by weight (Ministeriet for Sundheg og Forebyggelse 2009).

Table 1. The number of packages of pharmaceuticals sold and the proportion of these returned to the pharmacies (Ministeriet for Sundheg og Forebyggelse 2009).

ATC group		Number of sold packages during the one week survey	Share of returned (%)
A	Alimentary tract and metabolism	276	17
B	Blood and blood forming organs	69	4,1
C	Cardiovascular systems	272	16
D	Dermatologicals	86	5,1
G	Genito-urinary system and sex hormones	31	1,9
H	Systemic hormonal preparations	48	2,9
J	Antiinfectives for systemic use	98	5,9
L	Antineoplastic and immunomodulating agents	9	0,5
M	Musculo-skeletal system	91	5,4
N	Nervous system	402	24
P	Antiparasitic products	18	1,1
R	Respiratory system	175	11
S	Sensory system	96	5,7
V	Sensory organs	2	0,1
Total		**1 673**	**100**

The percentages for the types of medicine waste handed in at each pharmacy are in line with these types' relative sales rates. Most pharmaceuticals handed in were of group N (nervous-system drugs), the category with the highest sales.

Table 2 presents the pharmaceutical items returned to the pharmacies by the cause for return. The data are from the above-mentioned study in 2009 (Ministeriet for Sundheg og Forebyggelse 2009).

Table 2. The number of pharmaceutical items returned to the pharmacies and the reason for return (Ministeriet for Sundheg og Forebyggelse 2009).

Cause	Number of returned packages / pharmaceuticals	Share %	Share without death and unknown %
Death of patient	599	33,5	–
Unknown cause	402	22,5	–
Best before date crossed	285	15,9	40
Treatment ended, with unused medicine left	136	7,6	19,1
Treatment ended, stopped by doctor	127	7,1	17,8
Treatment ended by patient	119	6,6	16,7
Dose dispensing medicine, no cause given	77	4,3	–
Treatment never started	18	1	2,5
Patient was hospitalized	17	0,9	2,4
Leftovers from transition to dose dispensing medicine	4	0,2	0,6
Doubts regarding best before date	3	0,2	0,4
Improper storage	3	0,2	0,4
Total	**1790**	**100**	**100**

The most common reason for handing in unused medicine was the death of its user. The study was carried out from an economic standpoint; therefore, there was no evaluation of the fraction disposed of in an improper fashion. The aim was, rather, to minimise economic losses by reducing the amount of pharmaceutical waste generated.

The study found that the pharmaceuticals handed in correspond to 0.5% of the pharmaceutical items sold over the time covered by the survey (Ministeriet for Sundheg og Forebyggelse 2009).

Veterinary medicines

All veterinary medicines must be distributed by a veterinarian, pharmacy, or other approved institution. The pathway in distribution and take-back for veterinary pharmaceuticals follows that for human medicines, with both passing through certain points – i.e., pharmacies or collection points. As the types of the unused medicines are not identified at the pharmacies or collection points, it is not possible to differentiate the amount of veterinary medicines handed in and delivered for disposal. There have been no Danish studies to quantify this fraction or estimate the amounts of veterinary APIs ending up in the environment through animal-keeping, whether related to pets or husbandry (Miljø- og Fødevareministeriet 2020a, Miljø- og Fødevareministeriet 2020b).

Improvement needs

Currently, the Danish system is well-controlled and trust in the system is good. The institutions, doctors and veterinarians are likely to follow the national and regional guidelines for handing in of pharmaceuticals. The largest proportion of improper disposal of medicines probably arises from private households and individuals, and the cause of such improper disposal can be presumed to be either lack of information or intentional inappropriate discharge.

To improve control of the disposal of human and veterinary medicines, it would be useful to have information on the take-back percentages. The point that is most easily controlled is the central take-in point, the pharmacy. Registration and quantification of the sources would improve the state of knowledge about the source. With regard to hospitals, it would be possible to introduce registration of the medicines disposed of here too. The information and data could serve as a central tool in efforts to improve the system and decrease the quantity of APIs entering the natural environment.

2.1.3 Current disposal practices

Denmark has banned all landfilling, and, therefore, the waste system is built around an incineration-based disposal technique (1759/2018). All pharmaceuticals are incinerated at special, licensed plants at high temperatures, above 1100 °C (Brunn Poulsen et al. 2002). These plants are operated by private companies.

Fortum Waste Solutions A/S is one of the biggest plants in Denmark to handle and dispose of hazardous waste. They report decreasing amounts of pharmaceutical waste treated at their plant over the last four years. The reason cited for this is reduction in the amount of this waste coming in from the industry.

The techniques used for incineration of the pharmaceutical waste are dictated by national legislation. They are required to follow the best available techniques (BAT). It can be assumed that this disposal method functions as well as possible.

2.1.4 Summary

The main findings related to collection, classification, and disposal of unused pharmaceuticals and other waste containing pharmaceutical residues in Denmark are presented in Table 3.

Table 3. Summary of the collection, classification and disposal of unused pharmaceuticals and other waste containing pharmaceutical residues in Denmark.

Origin/type of pharmaceutical waste	Types of pharmaceuticals collected separately	Responsible party for arranging reception	Collection point	Types of pharmaceutical waste classified as hazardous	Legal basis	Method of disposal
Unused human and companion animal medicines from households	All	Municipality	Usually local pharmacy (depends on municipality)	All	1759/2018 § 41 801/2018 § 12	High-temperature incineration (above 1100 °C)
Pharmaceutical industry (unsalable products, API-contaminated wastes, etc.)	All products, waste fractions and ingredients classified as hazardous waste	Industry operator	Organized and payed by the industry operator.	Depends on classification of the waste fraction. Final products and certain ingredients are classified as hazardous.	1759/2018 § 41	High-temperature incineration (above 1100 °C)

Origin/type of pharmaceutical waste	Types of pharmaceuticals collected separately	Responsible party for arranging reception	Collection point	Types of pharmaceutical waste classified as hazardous	Legal basis	Method of disposal
Pharmaceutical waste from hospitals and health care institutions	All	Hospitals, institutions and municipality	Depends on municipality. Usually local pharmacy. Also individual hand in from hospital or health care institution.	All	1759/2018 § 41 801/2018 § 12	High-temperature incineration (above 1100 °C)
Veterinary medicines from veterinarians and veterinary practices	All	Municipality	Usually local pharmacy	All	1759/2018 § 41 1/2019	High-temperature incineration (above 1100 °C)
Veterinary medicines for farmed animals	All	Municipality	Usually local pharmacy	All	1759/2018 § 41 1/2019	High-temperature incineration (above 1100 °C)

The following key points were noted with regard to the Danish take-back system and disposal of unused pharmaceuticals:

Advantages:

+ The pharmacy take-back scheme appears efficient. The network of collection points is extensive and easy for the citizens to use when the pharmacies act as collection points. All the pharmaceuticals are returned to professionals, and there is no chance of vandalism or possibility of pharmaceuticals being retrieved by third parties from the collection point. One need not identify oneself when returning medicines to pharmacies.
+ The waste returned to pharmacies consists of only active pharmaceuticals. The staff at the pharmacy do not need to handle needles or mercury thermometers.
+ The high-temperature treatment appears controlled, efficient, and well-implemented.
+ The return scheme is operated well by the public institutions.

Areas that need improvement:

- The public information and data on the actual returning of unused pharmaceuticals by households are very sparse.
- Lack of public awareness of the take-back scheme might limit its usage and lead to such results as inappropriate disposal via the toilet. Raising public awareness would certainly increase the proportion of pharmaceuticals disposed of correctly.
- Statistics on the returned pharmaceuticals are needed, so that progress and the amounts of pharmaceutical waste can be tracked and analysed

Uncertainties:

- Limited availability of data casts validation of the take-back scheme into doubt. Most of the studies and data available on the subject focus on the economic issues and do not address the environmental aspects. Also, the quantities of publicly available data and information on the high temperature incineration are limited, because it is performed by private companies.

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2.2 Estonia

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2.2.1 Legal basis

The take-back and disposal of unused medicines in Estonia is regulated with two main laws – the Medicinal Products Act and the Waste Act.

The Medicinal Products Act (§35) states that all medicinal products not complying with quality requirements, whose shelf life has expired, the use of which is prohibited in Estonia, or that for other reasons cannot be used for their intended purpose must be withdrawn from the market.

Persons handling pharmaceutical products professionally are required to separate unusable medicinal products from other goods and mark such products accordingly in a clearly understandable manner. Medicinal products withdrawn from the market must be stored under conditions that prevent their marketing or use and must ensure that their storage is safe for humans, animals, and the environment.

Unusable medicinal products that are defined as hazardous waste, in accordance with either Commission Regulation (EU) 1357/2014 (OJ L 365, 19.12.2014, pp. 89–96) or the list established under Subsection 2(5) of the Waste Act, must be collected separately from other waste, in the manner specified for the relevant categories listed, and must be marked in line with the procedure established under Subsection 62(3) of the Waste Act.

Special conditions apply for unusable narcotic drugs and psychotropic substances, which must be stored in conditions appropriate for such substances and destroyed as non-hazardous waste in the presence of a representative of the State Agency of Medicines.

The non-hazardous substances must be separated from other waste, and the destruction procedure must be performed immediately (per the Medical Products Act's §36, paragraphs 3 and 4, packaging used for collecting or transporting cytostatic or cytotoxic medicinal products must be marked with a clearly distinguishable additional warning to this effect).

Unusable medicinal products regarded as hazardous waste must be destroyed by a licensed company. For the purposes of the Waste Act, destruction is disposal or recycling of pharmaceutical waste via a process that eliminates the hazardous properties of the active substances as specified in Commission Regulation (EU) 1357/2014.

The person handling medicinal products to be destroyed as non-hazardous waste must, directly before their destruction, remove the packaging of the medicinal products, render any printed packaging material unreadable, and crush any solid medicine waste. The receiver of medicinal products from the handler must document the delivery information of the products and the identities of the persons involved in delivery and reception of the medicinal products. The deliverer and recipient must verify the transaction by signing the document created. The handler of the medicinal products must document the destruction of these products, including the method of destruction.

2.2.2 Current take-back practices

The first press releases in Estonia about potential environmental problems associated with pharmaceuticals were prepared about 10 years ago. At about the same time, universities started to investigate the occurrence and behavior of pharmaceutical residues in sewage sludge. Hospitals began putting more attention on reducing the environmental impact of health care activities, and municipal waste-collection stations were established, which improved the system for take-back of unused pharmaceuticals (Ruut 2017).

Currently, people may dispose of unused medicines in either of two ways – bringing them to municipal waste-collection stations or to pharmacies. Disposal is free of charge and usually requires no paperwork. While Regulation of the Minister of Social Affairs 2005/25 states that people disposing of unused medicines at a pharmacy must supply their contact information (name and phone number) and that the names and quantities of unused medicines have to be documented against the signature of both parties (with digital signing), this procedure is seldom strictly followed. Also, pharmacies must keep the returned unused medicines separate from other medicines before handing them over to waste-management companies.

Information about the nearest waste-collection station or pharmacy that takes back unused medicines can be found easily via Web sites or apps (e.g., https://kuhuviia.ee/). Pharmacies are not obligated to accept other waste – such as food supplements, natural products, or medical devices. The unused medicines should be kept in their original packaging and not removed from it (for example, as separate pills).

Unused pharmaceuticals generated through one's business activities (incl. health and veterinary services) must be transferred to a waste-management company that holds a licence for handling hazardous waste, including pharmaceuticals. As a rule, legal entities such as companies are not allowed to bring their pharmaceutical waste to the waste stations the local municipality has arranged for its residents; rather, these entities must have their own contract with a licensed waste-management company, while municipalities cover only the costs of hazardous-waste management for their residents, not companies. For instance, if a farm is registered as a legal entity, then it must have a contract signed with a waste-management company. Exceptions are made only in cases wherein the contract is with the same waste-management company that manages the local collection station. In this event, the waste-management company must still have an agreement in place with the local municipality for making exceptions.

Only those hospitals that have a waste permit must submit waste reports. These describe the facility's generation of pharmaceutical waste and the waste quantities conveyed to waste management companies. Pharmacies, small hospitals, clinics, dental practices, and other small-scale handlers do not have a reporting obligation, but the quantities of the unused medicines collected in these cases are still reported by the waste-management companies.

A similar system is applied for take-back of veterinary medicines from professional users (e.g., farms and veterinary hospitals). Farms that have an integrated environmental permit report on their use and handling of pharmaceutical waste, but smaller farms (not obliged to hold an environmental permit, because of their size) and veterinary hospitals do not have any obligation of reporting. As in the case of unused human-use medicines, smaller facilities gather their unused veterinary medicines and the information about collection is presented by licensed waste companies.

The reported quantities of unused medicines collected are presented in Figure 1 and Table 4.

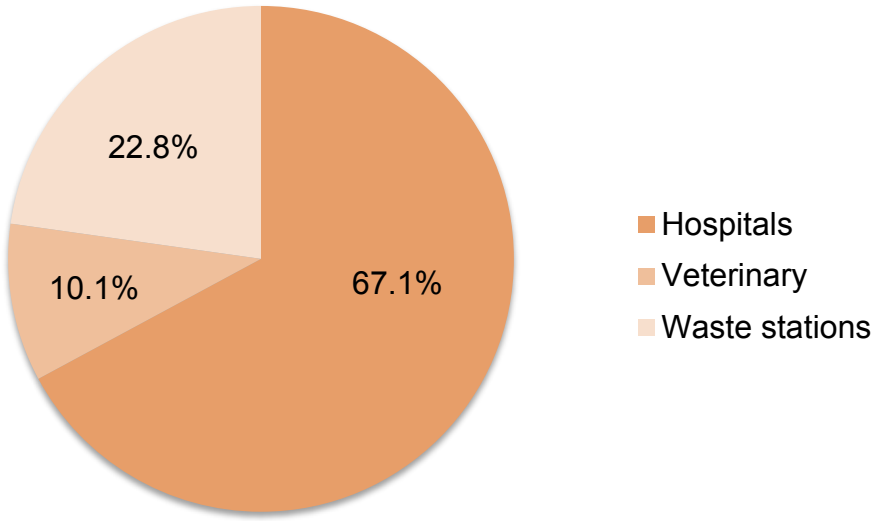

Figure 1. The distribution of the unused medicines collected, by source.

Figure 1 shows that most of the unused medicine is collected from hospitals. All bigger hospitals have in-house quality-management systems that regulate the collection of unused medicines. The veterinary medicines reported upon are only those from professional use, and the figures from waste stations include both human and veterinary medicines used by households.

Table 4: Reported quantities of unused medicines collected in Estonia.

Tons per year	Waste code	2014	2015	2016	2017
Collected from hospitals	18 01	56,1	51,1	118	98,6
Collected veterinary medicines	18 02	11,0	14,5	8,0	8,6
Collected from waste stations	20 01	24,3	20,0	24,1	36,2
Total		**91,4**	**85,6**	**150**	**143**

There are no data about the functionality of the collection system by which unused medicines are collected from the population, and the quantity of unused medicines sent to municipal landfills as regular waste is unclear.

2.2.3 Current disposal practices

Unusable medicinal products deemed to be hazardous waste must be destroyed by an enterprise holding an appropriate licence for handling hazardous waste. In total, there are 76 companies in Estonia that are licensed to handle hazardous waste, including pharmaceuticals, but most of these companies do not handle unused medicines. According to the waste reports received by the Environmental Board, between 2014 and 2017, only 15 companies declared that they transport and/or collect unused medicines. There is one company in Estonia that uses combustion for pharmaceutical residues (waste-handling in line with code R1).

According to the waste reports, the main methods of disposal of unused medicines are R1 (use principally as a fuel or other means of generating energy) and R12 (exchange of waste for submission to any of the operations denoted as R1 to R11). In Estonia, the unused medicines collected are sent to Kunda Cement Plant's incinerator and burned at 1300 °C.

2.2.4 Summary

The main findings on collection, classification, and disposal of unused pharmaceuticals and other waste containing pharmaceutical residues in Estonia are presented in Table 5.

Table 5. Summary of the collection, classification, and disposal of unused pharmaceuticals and other waste containing pharmaceutical residues in Estonia.

Pharmaceutical waste	Types of pharmaceuticals separately collected	Responsible party for arranging reception	Collection point	Types of pharmaceutical waste classified as hazardous	Legal basis	Method of disposal
Unused human and companion animal medicines from households	All pharmaceuticals	Municipality (setting rules)	Local pharmacy Or Municipal waste collection stations	Prescribed pharmaceuticals	Medicinal Products Act, Waste Act, local municipality waste management rules	Incineration at temperature of 1300°C
Pharmaceutical industry (unsalable products, API-contaminated wastes, etc.)	All pharmaceuticals	Industry operator; state rules	Waste management company or municipal waste collection point	Depends on the hazardous properties of the waste	Medicinal Products Act, Waste Act, local municipality waste management rules	Incineration at temperature of 1300°C
Pharmaceutical waste from hospitals and health care institutions	All pharmaceuticals	Hospitals and health care institutions; state rules	Waste management company	Depends on the hazardous properties of the waste	Medicinal Products Act, Waste Act, local municipality waste management rules	Incineration at temperature of 1300°C
Veterinary medicines from veterinarians and veterinary practices	All pharmaceuticals	Veterinarians and veterinary practices State rules	Waste management company	Depends on the hazardous properties of the waste	Medicinal Products Act, Waste Act, local municipality waste management rules	Incineration at temperature of 1300°C
Veterinary medicines for farmed animals	All pharmaceuticals	Farmer; state rules	Waste management company	Depends on the hazardous properties of the waste	Medicinal Products Act, Waste Act, local municipality waste management rules	Incineration at temperature of 1300°C

In conclusion, the following points were identified with regard to the Estonian take-back system and disposal of unused pharmaceuticals.

Advantages:

+ The pharmacy take-back scheme appear efficient, and information on collection points is widely available via Web sites or apps.
+ Pharmacy staff are trained in the take-back system and willing to participate in it.
+ Consumers have an understanding of pharmaceutical residues as hazardous waste.

+ Controlled treatment of pharmaceutical waste is performed via high-temperature (1300 °C) incineration.

Areas that need improvement:

- The pharmaceutical production plants do not have any environmental permits, and their quantities of the waste types in question are unknown (handling is subject to private contracts).
- A more detailed database should be available, to aid in analysing waste-management efficiency.
- There should be more informational materials, for raising of public awareness.

Uncertainties:

- Scarcity of data on veterinary medicines makes analyses difficult.

2.2.5 References

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2.3 Finland

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2.3.1 Legal basis

The collection, transport, and disposal of pharmaceutical waste in Finland are regulated by several legislative acts. Among these are the Waste Act, or WA (646/2011); the Narcotics Act, or NA (373/2008); and the Act on the Medication of Animals, or AMA (387/2014), along with several decrees issued on the basis of these acts. Also, professionals in the pharmaceutical sector are required to comply with regulations issued by the Finnish Medicines Agency (Fimea), some of which also address handling of pharmaceutical waste.

The WA (§6) defines hazardous waste as any waste (whether substance or object) that is flammable, explosive, infectious, or hazardous to health or the environment, or that has some similarly hazardous property. The European Commission's list of waste (2014/955/EU) classifies unused cytostatic and cytotoxic pharmaceuticals as hazardous waste, while other types of pharmaceutical waste are considered non-hazardous. In a national exception, Finland has classified all pharmaceutical waste produced by health care institutions and households as hazardous waste, under Annex 4 to the Waste Decree, WD (179/2012). Pharmaceutical waste produced by the pharmaceutical industry may be classified as either hazardous or non-hazardous, depending on the hazard properties of the waste (concentrations of hazardous substances and other properties).

The operator is obliged to keep a record of the hazardous waste produced (WA, §118). The WA (§28) mandates that, in general, the holder of the waste must arrange its transport and management. In an exception to this rule, the reception and management of hazardous waste produced by households and reasonable amounts of hazardous waste produced by farming and forestry are to be arranged by the local municipality (WA, §32). This is often arranged through a bilateral contract between the municipality and local pharmacies. Thus, pharmacies are not obliged to arrange the reception of unused pharmaceuticals; they do so voluntarily. According to Fimea regulation 2/2016, pharmaceutical waste delivered to pharmacies must be handled and stored separately from the pharmaceuticals for sale there, and there must exist instructions for handling, storage, and release for transport.

The municipal waste management regulated by Section 32 of the WA does not cover pharmaceutical waste streams originating from health care institutions, human or veterinary health care practitioners, or the pharmaceutical industry, as these operators are required to arrange their own waste management, according to Section 28 of the WA. For instance, veterinarians are obliged to ensure that unused pharmaceuticals are disposed of appropriately (AMA, §14) and to keep records of the pharmaceuticals disposed of (AMA, §21). It is the veterinarian's responsibility to deliver expired or otherwise unusable pharmaceuticals for hazardous-waste treatment (under the Ministry of Agriculture and Forestry's decree on the use and transfer of medicines in veterinary medicine, MMMa 17/2014, Annex 1; see also the WA). Veterinarians also must provide customers with sufficient instructions on storage and disposal of pharmaceuticals that are handed over to customers (MMMa 17/2017, Annex 1). The veterinary practitioner/hospital's records on pharmaceutical waste must specify at least the quantities and generation dates for pharmaceutical waste, along with the method of final treatment for the waste (per the Ministry of Agriculture and Forestry's decree on veterinarians' medical records, MMMa 22/2014, §8). The record must be retained for, at minimum, five years, and it must be presented to the competent authorities upon request (MMMa 22/2014, §10).

According to the NA (§26), narcotic substances must be stored in a separate locked compartment, with restricted access. Operators are obliged to deliver all unused narcotics for hazardous-waste treatment (§28).

According to the WA's Section 29, waste may only be handed over to a party that holds the environmental permits or similar authorisation that the Environmental Protection Act (527/2014) mandates for receiving the waste in question. Section 16 of the WA states that hazardous waste must be accompanied by all of the necessary information and must be packaged and marked in a way that allows the waste transport to be tracked all the way from the waste originator (excl. households) to final treatment. Hazardous-waste streams may be diluted or mixed with other waste only if this is necessary for the treatment of that waste and if the operator holds the necessary environmental permits (WA, §17).

2.3.2 Current take-back practices

Human-use medicines

In Finland, all pharmaceutical waste produced by the health care sector and households is classified as hazardous waste. Hazardous waste must be collected as a separate waste fraction. Under the Waste Act, municipalities are responsible for collection, transportation, and disposal of unused medicines from households. It must be guaranteed that the number of collection points for hazardous waste is sufficient and that the collection points are easily reachable and information about collection of hazardous waste is shared frequently and in sufficient extent. In the vast majority of municipalities, pharmacies act as collection points for unused medicines. At the end of 2017, there were 812 pharmacies in Finland. It should be noted that, in practice, all pharmacies in Finland arrange reception of unused pharmaceuticals, despite not having any legal obligation to do this.

Without charging, the pharmacies voluntarily accept all medicines and mercury thermometers returned by customers. In return for acting as collection points, pharmacies may include their own pharmaceutical waste with the material collected, without incurring costs. The municipality provides the pharmacy with transportation containers for the pharmaceutical waste and transports the waste to a hazardous-waste facility for proper disposal/treatment. The municipalities pay for the transport and treatment of the waste, and the costs are eventually covered by waste-disposal fees collected from the waste producers.

It has been estimated that 3–4% of the medicines sold in Finland (by medicine price, not production quantity) goes unused (Association of Finnish Pharmacies 2017). According to a survey conducted by Yliopiston Apteekki in 2006, 64% of customers return unused pharmaceuticals to the pharmacies while 17% dispose of them as mixed household waste and 15% flush them down the drain. About 9% of the survey respondents indicated that they did not dispose of medicines in any way.

In a survey Yliopiston Apteekki carried out in 2009, 9% of Finns admitted to having thrown medicines into mixed waste or flushed them into the sewer system. The reason most commonly given for improper disposal of medical waste was not knowing how to handle it (i.e., not knowing that pharmacies take it back for free). Other reasons mentioned in the survey were indifference, being in a hurry, long distances to collection points, and the medicine consisting of only a small amount or being thought to be harmless.

In a more recent survey, by the Association of Finnish Pharmacies (Kujala ym. 2016, Salimäki & Kujala 2016), the main reasons cited for returning medicines were changes in medication, adverse effects, and the amount used being smaller than that prescribed. Of all the prescription medicines returned, around 50% was returned in the original package, and the amount of returned pharmaceutical waste had an estimated worth of 95–125 million euros annually. In addition, it is estimated on the basis of earlier studies that about 60–80% (65% in 2010; see Association of Finnish Pharmacies 2010) of unused medicines gets returned to pharmacies.

Municipalities are responsible only for management of residential waste and, therefore, not for the waste generated at social- and health service facilities or locations such as veterinary clinics. Under the legislation in force, each operator has to keep a record of the hazardous waste produced. Pharmaceutical waste produced at a health care institution has to be collected and transferred to a hazardous-waste management plant. For hospitals, the collection and transfer for disposal is usually handled through the hospital pharmacy.

Per a Fimea ordinance (6/2012), unused medicines from domiciliary care and from supported and service housing should be disposed of in a co-ordinated manner by transfer to the pharmacies that provide medicines for the facility. However, there have been no surveys on the actual waste-management practices of the health care institutions.

Transportation companies collect unused medicines from pharmacies on an as-needed basis or at fixed intervals. Waste-transport companies do not accept pharmaceutical waste for which collection is not ordered or otherwise subject to contract (Marttila 2018). The transportation company delivers new collection containers to the pharmacies at the time of pick-up.

A study of pharmaceutical waste's collection from households and public health care (Syrjälä 2012) indicated that the pharmaceutical-waste collection system in Finland is of a high standard on international scale. Additionally, the collection network is extensive and the waste is appropriately treated. Nevertheless, problematic issues were noted. Lack of clarity as to liabilities and instructions were sources of dissatisfaction for pharmacies and waste-management companies, with more than half of the pharmacies indicating that sorting of pharmaceutical waste took too much time and nearly 70% experiencing some difficulties with it. The study showed also that many pharmacies do not have appropriate space for storing pharmaceutical waste and that occupational safety hazards are common. One recommendation made in the report is that national instructions on pharmaceutical waste's collection be created. The instructions should specify the liabilities and sorting practices related to the waste's collection. Finally, all relevant actors should be sufficiently informed about these instructions.

Veterinary medicines

Municipalities are responsible for organizing the collection of unused veterinary medicines generated within households and, in reasonable amounts, in agriculture. Both households and farms are instructed to return their unused veterinary medicines to local pharmacies, with the costs of collection and disposal covered by municipalities.

Farmers are obliged to keep records of all medicines given to the animals. The information about the medicines used must be recorded in the health care monitoring system. Veterinary practitioners, in turn, are obliged to keep a record of the medicines they purchase, allocate, dispose of, and give or order to be given to animals. Factories, wholesalers, and pharmacies are obliged to keep records of the thyreostatic, beta-agonist, oestrogenic, and androgenic veterinary medicines produced, sold, distributed, imported, or used. Wholesalers are required to report their sales of antimicrobials to the Finnish Medicines Agency twice a year.

2.3.3 Current disposal practices

According to Fimea-issued administrative regulations (Fimea 2016), pharmacies must dispose of customers' unused medicines as medical waste. A suitable space separate from sale-connected storage must be allocated for storage of medical waste, and a guide on handling of medical waste must be available. Special attention must be paid to preventing the misuse of unused medicines.

All medical waste must be marked as hazardous waste. In hospitals, all medical waste must be returned to the facility's pharmacy, where the packages containing medical waste must be sealed and the contents recorded. Hazardous waste is to be transferred – in accordance with regulations on the transport of hazardous waste – to a hazardous-waste processing plant. In the case of non-household waste, the

holder of the waste is responsible for maintaining the transfer book for transportation of hazardous waste.

Veterinary clinics, health care institutions, etc. are responsible for organising the treatment of hazardous waste in accordance with the applicable waste legislation, at their own expense. These operators are instructed to arrange this treatment with waste-management companies that have a permit to receive the relevant type of hazardous waste. All pharmaceutical waste is to be disposed of at a hazardous-waste incineration plant.

There are no nationally implemented detail-level instructions on how the personnel at, for example, veterinary clinics should dispose of unused medicines. The Finnish Food Authority has instructed veterinarians to dispose of pharmaceutical waste as hazardous waste and stated that it is the operators' responsibility to ascertain the local practices (there may be variations in the practices' specifics).

In Finland, most separately collected pharmaceutical waste is incinerated at Fortum Waste Solutions Oy's hazardous-waste treatment plant. The transport containers, manufactured either from rigid cardboard or from plastics, are incinerated without opening, except in the case of random inspection. According to the environmental permit of the plant (permit YSO/119/2007), the temperature of the incineration process in the reel oven has to be above 1050 °C when the halogen concentration (measured in terms of chlorine) in the feed material is greater than 1% or unknown. At this temperature, the medicines are disposed of irreversibly (they lose their pharmaceutical properties). Additionally, combustion gas is treated via BAT with, for instance, an HCl scrubber and removal of dioxins and mercury via activated carbon. In practice the temperature is 1 100 – 1 300 °C during incineration (Marttila 2018 & Westerholm 2019). To some extent, material in pharmaceutical waste collected separately is exported to Sweden and Germany, where the waste is processed in accordance with national requirements.

2.3.4 Summary

The main findings on collection, classification, and disposal of unused pharmaceuticals and other waste containing pharmaceutical residues in Finland are presented in Table 6.

Table 6. Summary of the collection, classification, and disposal of unused pharmaceuticals and other waste containing pharmaceutical residues in Finland.

Pharmaceutical waste	Types of pharmaceuticals collected separately	Responsible party for arranging reception	Collection point	Types of pharmaceutical waste classified as hazardous	Legal basis	Method of disposal
Unused human and companion animal medicines from households	All pharmaceuticals	Municipality	Usually local pharmacies; seldom municipal waste collection stations (depends on municipality)	All	Waste Act 32 §	Mainly high-temperature incineration (1100-1300°C)
Pharmaceutical industry (unsalable products, API-contaminated wastes, etc.)	All waste classified as hazardous waste	Industry operator	To be organized by the industry operator, sometimes specified in environmental permit	Depends on hazard properties of waste (concentrations vs. concentration limits of hazard classified substances)	Waste Act 28 §	Depends on the classification of the waste, sometimes specified in the environmental permit of the industrial plant

Pharmaceutical waste	Types of pharmaceuticals collected separately	Responsible party for arranging reception	Collection point	Types of pharmaceutical waste classified as hazardous	Legal basis	Method of disposal
Pharmaceutical waste from hospitals and health care institutions	All pharmaceuticals	Hospital or health care institution or municipality	To be organized by the hospital or health care institution / for hospitals usually hospital pharmacy	All	Waste Act 28 §	Mainly high-temperature incineration (1100-1300°C)
Veterinary medicines from veterinarians and veterinary practices	All pharmaceuticals	Veterinarian or veterinary practice	To be organized by the veterinarian or veterinary practice	All	Waste Act 28 §	Mainly high-temperature incineration (1100-1300°C)
Veterinary medicines for farmed animals - reasonable amounts	All pharmaceuticals	Municipality	Usually local pharmacies; seldom municipal waste collection stations (depends on municipality)	All	Waste Act 32 §	Mainly high-temperature incineration (1100-1300°C)
Veterinary medicines for farmed animals - unreasonable amounts	All pharmaceuticals	Farmer	To be organized by the farmer	All	Waste Act 28 §	Mainly high-temperature incineration (1100-1300°C)

The following points were noted with regard to conclusions on the Finnish take-back system and Finland's disposal of unused pharmaceuticals.

Advantages:

+ The country's separate collection based on municipality–pharmacy co-operation appears quite efficient (with 60–80% of pharmaceutical waste being collected properly).
+ There is an extensive network of pharmacies and collection points, making the scheme easy for citizens to use.
+ The system encourages pharmacies' appropriate disposal of unused medicines, in that pharmacies can include their own pharmaceutical waste with the collected waste to be delivered for proper disposal and incur no additional costs for this.
+ Knowledge about the collection system is quite widespread among citizens.
+ There are no direct costs for the household users, and they do not need to identify themselves when returning the medicines to pharmacies.
+ The treatment of pharmaceutical waste via high-temperature (1100–1300 °C) incineration seems efficient.

Areas that need improvement:

- There remains some ignorance and lack of information about proper sorting on citizens' part, so continued education and awareness-raising among citizens are needed.
- Instructions on sorting of waste (iodine-containing waste etc.) are slightly heterogeneous.
- Unclear liabilities and instructions create dissatisfaction among pharmacies and waste management companies. Over half of the pharmacies surveyed indicated that separation of pharmaceutical waste takes too much time, and nearly 70% reported having had some difficulties with it.

- The collection of veterinary medicines is not uniformly arranged at veterinary clinics, and information on specific collection practices is not reaching veterinary clinics' personnel.
- No information is available on the actual amounts of unused pharmaceuticals by mass.

Uncertainties:

- Is high incineration temperature of 1100–1300 °C necessary for the irreversible treatment of pharmaceutical waste, or would a lower temperature, such as the 850 °C used for household waste be suffice?

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2.4 Germany

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2.4.1 Legal basis

General waste

The management of general waste (its collection, transport, and disposal) in Germany is regulated by the Waste Management Act, or Kreislaufwirtschaftgesetz, KrWG (2012). The general principle underpinning the KrWG is promotion of circular economy (§1). This includes avoidance of waste, appropriate waste disposal, recovery, and elimination of waste (§3, Abs. 19–28 ff). The duty to recover and dispose of waste follows the 'polluter pays' principle (per § 7 and §15). This means that the producer and owner of waste must fulfil their obligation of waste's recycling and disposal, in principle. It is possible to authorise third parties such as service providers, associations, or institutions of the self-governance bodies of industry (under § 17 and §22). If producers or owners of waste cannot fulfil their waste-recycling and disposal obligation, they have to hand over the waste to the municipal waste-disposal authorities (per the same sections of law).

The KrWG is supplemented by a series of other regulations, which specify and complement the terms of the KrWG by means of waste-class lists and waste-monitoring provisions, requirements related to waste disposal, operation regulations, product- and production-related regulations, and specifications addressing the treatment of sewage sludge and organic waste.

European regulations such as the European List of Waste (2000/532/EC), or LoW (2000), and Annex III to Directive 2008/98/EC are implemented through the Waste Register Ordinance, or Abfallverzeichnis-Verordnung (AVV 2017).

Since June 2005, a requirement has been in place that municipal waste be treated via a mechanical biological pre-treatment stage or advanced solid-waste incineration, ASWI (at 850–1300 °C). Hazardous classes of waste are to be treated only by means of hazardous-waste incineration, HWI (at 1000–1300 °C).

Pharmaceutical waste from manufacturer facilities is classified as commercial/industrial waste and has to be treated at special plants that ensure safe destruction of hazardous compounds (e.g., high-temperature incineration, physico-chemical treatment, or incineration by a power plant).

Waste from medical and veterinary institutions

Collection, transport, and disposal of waste from medical and veterinary health care institutions are specified by the LAGA guideline document titled 'Richtlinie über die ordnungsgemäße Entsorgung von Abfällen aus Einrichtungen des Gesundheitsdienstes' (LAGA 2015), which is based on the KrWG and the AVV. Following these guidelines is obligatory for the health sector, defined as including human medical facilities, the rescue and ambulance services, veterinary facilities, laboratories, and pharmaceutical distributors.

Hospitals, pharmaceutical manufacturers, and veterinary institutions are obliged to implement a waste management system compliant with national regulations (KrWG 2012, AVV 2017) and also regional specifications of these acts and decrees. The operators themselves are responsible for the separate collection of the various waste fractions. Consumer-use pharmacies, medical practices, and veterinary practices are not obliged to implement a waste-management system, but their hazardous medical waste still must be collected and disposed of separately.

In general, hazardous waste types such as unused cytostatic and cytotoxic pharmaceuticals have to be treated on special incineration sites, whereas non-hazardous classes of waste may be disposed of with municipal waste.

2.4.2 Current take-back practices

Human-use medicines

No unified national take-back system for unused pharmaceuticals exists in Germany, and pharmacies and pharmaceutical manufacturers are not obliged to take back unused pharmaceuticals. Some pharmacies do take back unused pharmaceuticals on a voluntary basis, however, even though they themselves have to pay for the disposal. Pharmacies recommend that their customers dispose of unused pharmaceuticals with municipal waste.

Veterinary medicines

No take-back system exists for unused veterinary pharmaceuticals.

2.4.3 Current disposal practices

Human-use medicines

In the context of the German national research project RiSKWa, recommendations to customers for dealing with unused pharmaceuticals were published on the Internet[1]. The recommendations are specified at local level. Disposal is possible via the following options:

- Inclusion in municipal waste, in locations where municipal waste is incinerated or mechanical biological treatment is available
- Use of a mobile collection vehicle, through which many municipalities offer disposal of chemicals (incl. pharmaceuticals) at local collection points at regular intervals (the waste is transferred from the vehicle for incineration or mechanical biological treatment)
- Recycling centres
- Collection at pharmacies

The disposal mechanisms recommended for each of the eight districts of the federal state of Mecklenburg-Vorpommern (in the Baltic Sea region) are summarised in Table 7.

[1] http://www.arzneimittelentsorgung.de/

Table 7: The options for disposal of unused pharmaceuticals recommended on the RiSKWa project Web site[2] (RiSKWa 2018) for the eight districts of Mecklenburg-Vorpommern, in the Baltic Sea region.

Districts	Municipal waste	Mobile collection vehicle	Recycling centres	Pharmacies
Landkreis Rostock		x	x	x
Ludwigslust-Parchim		x		
Mecklenburgische Seenplatte		x		x
Nordwestmecklenburg	x	x		x
Rostock	x	x	x	x
Schwerin	x			
Vorpommern-Greifswald		x		x
Vorpommern-Rügen		x	x	x

Veterinary medicines

According to the German national drug law, or Arzneimittelgesetz (AMG 2017), and the regulation on animal-husbandry medicinal products and certification (Tierhalter-Arzneimittelanwendungs- und Nachweisverordnung) (THAMNV 2015), farmers and veterinarians are obliged to document all pharmaceuticals purchased, assigned, and given to the animals. Farms must have a waste-management system in place. Hazardous waste must be collected separately and treated by means of hazardous-waste incineration, while non-hazardous pharmaceutical waste may be disposed of via municipal waste or through a contracted service provider. Pet-owners may dispose of their unused pharmaceuticals with municipal waste or use the disposal routes recommended for the relevant district.

Evaluation of behaviour related to disposal of unused human-use medicines

Information about disposal behaviour related to unused human pharmaceuticals in Germany is scarce. In a non-representative study, Zimmer et al. (2000) reported that 71% of respondents return their unused pharmaceuticals to the pharmacy while 22% dispose of them with household waste. No information was provided on the disposal behaviour of the remaining 7% of respondents. A few years later, Goetz and Keil (2007) carried out a representative study that used 2,000 interviews to investigated the extent to which consumers in Germany dispose of their unused pharmaceuticals via the toilet and by other means. The main research question was this: to what degree have respondents ever disposed of liquid pharmaceuticals via the toilet or sink?

The results of the survey are shown in Table 8. About 43% of the respondents stated that they had disposed of liquid pharmaceutics via the toilet or sink, whereas only 16% of them had done the same with solid pharmaceutics (e.g., tablets or pills). One possible explanation for this disposal behaviour might be found in the high level of willingness to recycle among the German population (Götz 2007). Liquid pharmaceuticals are usually sold in plastic tubes or glass bottles, which are often disposed of separately from household waste, in line with Germany's waste-separation system. Hence, consumers might send their liquid pharmaceuticals down the drain and then dispose of the plastic tubes or glass bottles separately via the common recycling path. Disposal of unused pharmaceuticals at pharmacies was an option for about two thirds of the respondents, while disposal along with household waste was

[2] www.riskwa.de

available in recommended form for just under half the respondents (43%). Discarding the items as hazardous or as packaging waste was an option for about 15% and 23%, respectively.

Within the last few years, pharmaceutical residues in wastewater and drinking water, the (inappropriate) disposal of unused pharmaceuticals, and other such topics have been discussed more extensively in the media. Therefore, disposal behavior might have changed in the years since Goetz and Keil's study.

In 2020, a nationwide media campaign whose title translates to 'Do not flush down the toilet!' is being conducted by the Federal Environment Ministry (BMU) in order to inform citizens not to discard unused pharmaceuticals via the toilet or sink. The recommended ways of disposing of unused pharmaceuticals are to deliver them to the pharmacies or mobile collection vehicles and to include them in household waste[3].

In addition, the Interreg project MORPHEUS[4] has increased public awareness of proper disposal of unused medicines in Germany, Lithuania, and Poland.

Table 8: Behaviour identified by Goetz and Keil (2007) with regard to the various pathways for disposal of unused pharmaceuticals (multiple answers were possible).

	Pharmacies [%]	Household Waste [%]	Hazardous Waste [%]	Toilet/Sink (solid) [%]	Toilet/Sink (liquid) [%]	Packaging Waste [%]
Yes	28,9	6,5	1,1	1,0	10,2	2,3
Yes, most	11,0	9,4	1,8	2,1	8,3	3,4
Yes, sometimes	15,0	14,3	4,1	6,8	13,1	8,2
Yes, rare	11,4	13,1	7,7	5,8	11,8	9,0
No	33,7	56,7	85,3	84,3	56,6	77,1

The quantities of unused human and veterinary pharmaceuticals disposed of are recorded only for hazardous pharmaceuticals (codes 18 01 08 and 18 02 07). Figure 2 presents the quantities of this type of waste disposed of in Mecklenburg-Vorpommern (the country's Baltic Sea area).

When the data were gathered, the hazardous pharmaceutical waste from Mecklenburg-Vorpommern was treated at facilities outside the region. Detailed breakdowns of the quantities of unused hazardous medicines disposed of by pharmacies, hospitals, and households are not available (Mecklenburg-Vorpommern 2014).

[3] http://www.bmu.de/richtigentsorgenwirkt\

[4] http://www.morpheus-project.eu/dont-flush/

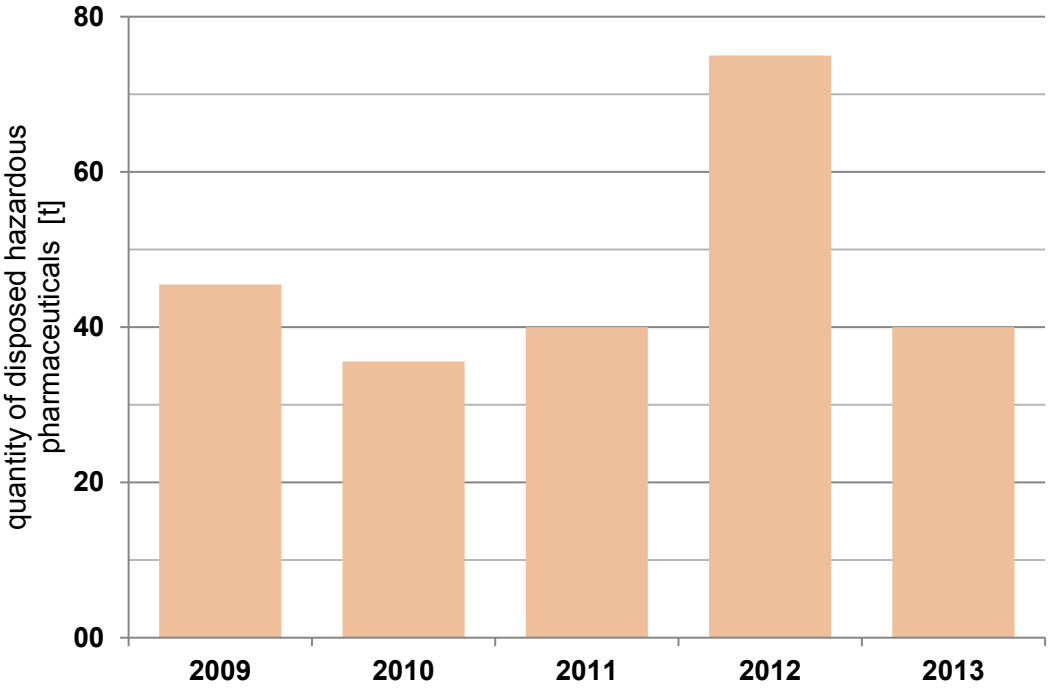

Figure 2. The mass of the hazardous pharmaceuticals disposed of in Mecklenburg-Vorpommern in 2009–2013 (Mecklenburg-Vorpommern 2014).

2.4.4 Summary

The main findings related to the collection, classification, and disposal of unused pharmaceuticals and other waste that contains pharmaceutical residues in Germany are presented in Table 9.

Table 9: Summary of the collection, classification, and disposal of unused pharmaceuticals and other waste containing pharmaceutical residues in Germany.

Pharmaceutical waste	Types of pharmaceuticals collected separately	Responsible party for arranging reception	Collection point	Types of pharmaceutical waste classified as hazardous	Legal basis	Method of disposal
Unused human and companion animal medicines from households	Nothing separately collected	Municipality	Depends on the municipality	Cytostatic and cytotoxic pharmaceuticals	AAV, KrWG	Mechanical biological pre-treatment stage, advanced solid waste incineration (850-1300 °C) or high-temperature incineration (1000-1300°C)
Pharmaceutical industry (unsalable products, API-contaminated wastes, etc.)	All	Service provider, industrial operator	To be organized by the industry operator	All unsalable products, API-contaminated wastes, etc.	LAGA, AAV KrWG, AMG	High-temperature incineration (1000-1300 °C), physico-chemical treatment, or incineration in power plants.
Pharmaceutical waste from hospitals and health care institutions	Cytostatic and cytotoxic pharmaceuticals	Hospital, service provider	To be organized by the hospital or health care institution	Cytostatic and cytotoxic pharmaceuticals	LAGA, AAV KrWG, AMG	Hazardous waste: High-temperature incineration (1000-1300 °C). Non-hazardous waste: Mechanical biological pre-treatment stage or an advanced solid waste incineration (850-1300 °C).
Veterinary medicines from veterinarians and veterinary practices	Cytostatic and cytotoxic pharmaceuticals	Veterinarian or veterinary practice, service provider	To be organized by the veterinarian or veterinary practice	Cytostatic and cytotoxic pharmaceuticals	AAV, KrWG, AMG, THAMNV	See above Pharmaceutical waste from hospitals and health care institutions
Veterinary medicines for farmed animals - reasonable amounts	Cytostatic and cytotoxic pharmaceuticals	Municipality, service provider	Usually local pharmacy (depends on the municipality)	Cytostatic and cytotoxic pharmaceuticals	LAGA, AAV KrWG, AMG, THAMNV	See above Pharmaceutical waste from hospitals and health care institutions
Veterinary medicines for farmed animals - unreasonable amounts	Cytostatic and cytotoxic pharmaceuticals	Farmer, industrial operator	To be organized by the farmer	Cytostatic and cytotoxic pharmaceuticals	LAGA, AAV KrWG, AMG, THAMNV	See above Pharmaceutical waste from hospitals and health care institutions

The following points were noted with regard to Germany's system for take-back and disposal of unused pharmaceuticals, in conclusion.

Advantages:

+ Recommendations for customers on how to dispose of unused pharmaceuticals correctly are available from the Web site http://www.arzneimittelentsorgung.de/.
+ Ever since the KrWG amendment entered force in 2005, municipal waste must be treated by means of a mechanical biological pre-treatment stage or advanced solid-waste incineration (850–1300 °C), whereas hazardous waste-fractions (e.g., cytostatic and cytotoxic pharmaceuticals) always have to be disposed of via hazardous-waste incineration (1100–1300 °C).
+ Waste streams from pharmaceutical production are regarded as commercial/industrial waste, which is, for the most part, classified as hazardous waste. Pharmaceutical waste generated by manufacturers has to be treated at special plants that ensure safe destruction of hazardous compounds (e.g., high-temperature incineration, physico-chemical treatment, or incineration at a power plant).

Areas that need improvement:

- No unified national take-back scheme for unused pharmaceuticals exists (e.g., at the level of pharmacies or recycling boxes at grocery stores).
- Pharmacies are not obliged to take back unused pharmaceuticals. While some of them do so on a voluntary basis, they have to pay for the disposal themselves.
- Consumers' awareness related to proper means of disposing of their unused pharmaceuticals should be increased.

Uncertainties:

- No recent data have been available on German people's disposal behaviour since the study by Goetz and Keil (2007). Since topics such as pharmaceutical residues in wastewater and drinking water but also, more directly, (inappropriate) disposal of unused pharmaceuticals have received more media attention in the last few years, disposal behaviour might have changed.
- No data on the amount of unused pharmaceuticals disposed of, either from human or from veterinary usage, are available for Germany.

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2.5 Latvia

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2.5.1 Legal basis

According to Cabinet Regulation 302, of 19.4.2011, waste that includes cytotoxic and cytostatic pharmaceuticals is classified as hazardous waste. This includes

- cytotoxic and cytostatic pharmaceutical waste originating from human health care activities (class 18 01 08),
- cytotoxic and cytostatic pharmaceutical waste originating from veterinary activities (class 18 02 07), and
- separately collected cytotoxic and cytostatic pharmaceutical waste (class 20 01 31).

Other types of pharmaceutical waste, such as those belonging to waste classes 18 01 09, 18 01 08, 18 02 08, and 18 02 07 (please see Appendix 1 for the waste classes), are not classified as hazardous waste. Chapter 20 of the Cabinet Regulation "Domestic waste (household waste and similar waste from commercial and industrial enterprises and institutions), including separately collected waste types" specifies which types of waste are to be collected separately: cytotoxic and cytostatic pharmaceuticals (class 20 01 31) and other pharmaceutical waste (class 20 01 32).

The Waste Management Law's Section 16 provides that the initial producer or holder of municipal waste shall cover all costs related to the management of that waste, inclusive of municipally produced hazardous waste. Section 8 states that a local government in its administrative territory, in conformity with the binding regulations of the local government regarding management of municipal waste, taking into account the State waste management plan and regional plans, shall organize the management of all municipal waste, including municipally produced hazardous waste.

The actions presented in the State Waste Management Plan for 2013–2020 are related to those types and streams of medical waste regarded as hazardous waste, including medical treatment waste and waste from practising veterinary medicine. Under the plan, medical treatment facilities and veterinary medical practices must provide separate collection, packaging, labelling, and storage of hazardous waste. Medical institutions and veterinary medical practices may themselves stabilise separately collected hazardous waste and prepare it for final treatment. The majority of hazardous waste generated at medical institutions and veterinary medical practices is managed by waste-management companies specialising in the management of hazardous waste. No take-back scheme for pharmaceuticals from residents or animal-owners is specified in the State Waste Management Plan.

A good example of the regulation of waste management at municipal level can be found in the City of Riga's binding regulations of 17.12.2013 on municipal waste management. In Chapter IV ('Obligations of the household waste holder'), point 17 stipulates that it is prohibited to place hazardous waste and infectious waste in waste tanks. The city's binding regulations contain no rules for the take-back of pharmaceutical waste at pharmacies or special collection points, but there are take-back-related requirements published on the Web pages of the Department of Housing and Environment, under Riga City Council jurisdiction. In the section 'Waste management', the online materials state that household pharmaceutical waste should be taken to pharmacies. This rule applies to pharmaceuticals that have expired or are not being used; aerosol packaging; sharp objects such as syringes, needles, and scalpels; and mercury thermometers.

In Latvia, pharmaceutical waste from medical treatment institutions, social-care institutions, and distributors of human medicinal products is classified as hazardous waste, as specified in these regulations:

- Cabinet Regulation 220, of 27.3.2007, prescribes the procedures by which medical treatment institutions and social-care institutions shall acquire, store, and use medicinal products and dangerous psychotropic substances that may be abused and are specified by Register III of narcotic substances, psychotropic substances, and precursors as to be controlled in Latvia. It also sets forth the procedures by which narcotic and psychotropic substances shall be registered and disposed of.
- Cabinet Regulation 416, of 26.6.2007, prescribes the procedures for such operations as the distribution and quality control of medicinal products (except veterinary medicinal products). The collection and disposal of unused medicines must be arranged in accordance with the regulations pertaining to hazardous waste. The same applies to the disposal of medicaments that are not suitable for distribution.
- Cabinet Regulation 353, of 22.5.2012, dictates that low-quality or unsuitable medicines that are not returned to suppliers belong to either hazardous waste or waste handled as hazardous waste. This applies also for waste from cytotoxic and cytostatic medicinal products.

With respect to waste from veterinary medicinal products, there are no specific requirements in place for smallholdings or for owners of companion animals. Their unused veterinary medicines fall under general waste-management legislation. Latvian regulations assign medicine waste from veterinary medical practice institutions the category of hazardous waste and that from 'large productive animal holdings' the category of general waste:

- Cabinet Regulation 768, of 10.9.2013, sets requirements related to the handling of veterinary waste, including unused veterinary medicines. Its point 9.2 states that 'veterinary medical waste is collected and disposed of in accordance with the regulations regarding the management of hazardous waste'.
- Cabinet Regulation 326, of 31.5.2016, sets forth requirements for the distribution and control of veterinary medicinal products in large productive animal holdings. According to this regulation, veterinary medicinal products not issued or not used are to be disposed of in accordance with regulations regarding waste management (per point 19.4).
- Cabinet Regulation 1456, of 15.12.2009, specifies in its Chapter IV ('Procedures for the destruction of narcotic and psychotropic medicines') that the primary packaging of insufficient-quality narcotic medicines and psychotropic medicinal products and of used medicines shall be destroyed or handed over for disposal in accordance with the waste-management legislation.
- Cabinet Regulation 258, of 5.4.2011, states in its Chapter II ('Procedures for the purchase and storage of medicinal products'), under point 10, that the veterinary medical care institution and the practising veterinarian submits non-quality or unused medicinal products and primary packaging for used medicines for disposal in accordance with the requirements of regulations on waste management'

2.5.2 Current take-back practices

Human-use medicines

Some of Latvia's pharmacies accept unused medicine but doing this is not an obligation. Under Latvian legislation, medical treatment institutions and social-care institutions are obliged to deliver unused medicine to an operator holding a permit to manage hazardous waste. Residents are to return unused medicinal products to pharmacies, special disposal sites, or hazardous-waste sorting sites voluntarily. Only some medicine-related waste is considered hazardous waste.

A representative of the Ministry of Environmental Protection and Regional Development of Latvia has explained that the Ministry of Health takes the position that any additional requirements for pharmacies, for example, to ensure the collection and further management of medicinal products not suitable

for use would lead to an increase in prices of medicines. This was cited as the reason for the lack of such mandatory terms in the country's legislation (Bierande 2011).

Veterinary medicines

Under the legislation mentioned in the previous section, large animal holdings are required to deliver their unused medicine to an operator with a permit to manage hazardous waste.

The Food and Veterinary Service of Latvia controls veterinary medical-practice institutions and large productive animal holdings. This body controls the storage of veterinary medicine that is not suitable for use and the primary packaging of used medicine and these materials' delivery to hazardous-waste managers. Such waste is not controlled at the level of individual households (Survey of Food and Veterinary Service of Latvia, 2018).

Take-back practices

Human-use medicines

In all member states of the EU, Latvia being no exception, unused medicines may be delivered to pharmacies or special collection points for hazardous waste. However, the process is not an organized one in Latvia, and not all pharmacies accept them. This is not a duty that pharmacies are required to fulfil – it is a matter of the free will of each pharmacy. The disposal of unused medicine creates additional costs such as those for a contract with a hazardous-waste manager, which entity must be licensed – and this is not an inexpensive service.

Veterinary medicines

Residents can bring unused veterinary medicinal products to the same pharmacies where unused medicinal products intended for human use are returned or to special collection points for hazardous waste. Veterinary medicines should be prepared for hand-over in the same way as unused human-use medicinal products: the outer carton from the package should be removed, and the tablets, bottles, ampoules, gel tubes, etc. must be placed in a plastic bag.

As for veterinary pharmacies and practices, there are no provisions for hand-over of unused medicinal products in place.

Evaluation of the take-back practices

Human-use medicines

Research was conducted in 2012 to assess household medicine waste (Menise 2012). The results of that survey indicate that 62% of respondents had expired, leftover, or otherwise unwanted medicines at home. According to the statistics reported from the survey,

- only 5% of respondents actually bring such medicines to pharmacies;
- 1% of respondents bring such medicine to special hazardous-waste disposal sites;
- most respondents (41%) discard unwanted medicines via household rubbish;
- 12% flush unwanted medicine down the toilet;
- 33% of respondents continue storing medications at home after the expiry date, just in case; and
- 8% do not have pharmaceuticals at home.

Statistics are available from one network of pharmacies that cover the total amount of returned medicines delivered for disposal. The EURO Aptieka pharmacy network (with 40 pharmacies in total) concluded an agreement with special hazardous-waste management company BAO SIA, and the associated data provided on the chain's Web site indicate that, on average, they collect 10 kilograms of

expired medicine per month at each of their pharmacies in Riga and around five litres at each pharmacy in other areas.

In 2014, Latvia's society of pharmacists arranged a campaign with the theme of taking 'invalid' medicines back to pharmacies. The campaign, which was very enthusiastically supported by pharmacies, was designed with the goal of educating people and informing them about how to get rid of unnecessary medicines properly. It was financially supported by the Latvian Environmental Protection Fund. The campaign involved around 600 pharmacies, and it included displaying posters and distributing informative materials and bags for the transfer of unused medicines to pharmacies. In the opinion of the Latvian Environmental Protection Fund, the number of people who are aware of the problem and of the correct way of behaving in response is still small, however. No single project can resolve the situation; long-term education and awareness-raising is needed. The situation requires interest on the part of all key players in the industry and demands sufficient motivation to mitigate the problem.

In 2014, the NGO Health Projects for Latvia carried out a study examining residents' awareness of the possibilities related to disposal of medicinal products and surveying their habits. This study (Prola 2017) found that

- the majority of respondents (62%) discard unwanted medicines with general rubbish,
- only 10% of respondents in Latvia take unnecessary medicines back to pharmacies or discard them in suitable containers,
- 17% of respondents continue to store medicine at home,
- 5% of respondents flush medicine down the toilet,
- 4% of respondents burn medicine, and
- 2% of respondents gave some other response related to their behavior.

The main reason for the low proportion of correctly discarded medicines is a lack of information: 60% of respondents admitted to not being aware of how to get rid of medicines properly. The second major reason is lack of motivation – not thinking about the consequences or believing that their behavior does not harm the environment.

Health Projects for Latvia recommends highlighting information about the negative impact on the environment, getting people motivated not to discard unused medicines as municipal waste, and encouraging them to use medicines rationally and not to buy unnecessary ones.

As part of an analysis-oriented survey (Purmale 2018), an experiment was done on the ways in which invalid medicines are accepted by pharmacies. Twelve pharmacies, in the pharmacy groups Mēness Aptieka, Saules Aptieka, and BENU, were examined. The results indicate that the ways in which medicines are accepted differ even within the same pharmacy network, with pharmacies variously

- leaving the medicine in its blister pack after removing it from the cardboard box;
- leaving the medicine in the blister pack after taking it out of the cardboard box, then putting the blister pack in the plastic bag for collection;
- leaving the medicine in its full package; and
- separating the tablets from the solutions, squeezing doses out of blister packs, and placing the solutions and solids in separate plastic bags.

During this research, Purmale's team asked some residents whether they were aware of the possibility of taking unused medicines back to pharmacies. Three of the four people interviewed indicated that they knew about this possibility, but two of those three did not do so, because it consumes time, energy, and resources or because of living in the countryside where such options are not available. The people who did not bring medicines to pharmacies stated that they get rid of them by discarding or burning.

Purmale (2018) also referred to a statement by the State Environmental Service of Latvia. In this opinion, the agency stated that bringing unused medicines back to pharmacies is sufficient and ensures their further processing. In addition, Purmale presented some fresh statistics for the medicines that have been taken back to pharmacies, comprising

- in total, 100 kg a month for the BENU pharmacies and
- 1,5 kg in the first six months of 2018 (250 kg/month) for the Apotheka pharmacy network.

General information about domestic hazardous waste is provided via the online portal Atkritumi[5]. The requirements addressing how medicines should be delivered to pharmacies are summarised thus:

- Tablets should be taken out of their cardboard packaging, and foil blister packs should all be placed in a single plastic bag.
- Ampoules should be removed from their cardboard packaging.
- Syrups and drops are to be removed from the cardboard packaging.
- Mercury thermometers should be placed in a water-filled glass container that is closed with a metal lid.

In the CWPharma project, LEGMC reviewed the way information is made available online about the possibility of bringing unused medicines back to pharmacies and calculated the proportion of pharmacies where this is possible.

Medical waste is generated at medical treatment institutions, by pharmaceutical producers, and at veterinary institutions, as well as by residents. Medical waste includes expired and unused drugs, spray bottles, sharp tools (syringes, needles, and scalpels), and mercury thermometers. This waste is hazardous on account of its specific biological activity. For instance, unused medical preparations in combination with other waste may cause toxic compounds to develop, and they may be harmful to the environment.

The Atkritumi portal provides information about where in Latvia one can hand over invalid medication and mercury thermometers for further processing (see Figure 3), with information available for the EURO Aptieka and Mana Aptieka networks and on the BAO waste-collection points. When the user clicks on any of the locations marked on the map shown, information is displayed about the relevant company's Web site, its physical address, and what kind of waste can be handed over. For most locations, there is a phone number provided and there are guidelines on how to prepare the medicines for hand-over.

Figure 3. The portal's presentation of hazardous-waste disposal points (marked in red) and waste-sorting locations (marked in blue) in Latvia. Map data ©2020 Google.

[5] https://www.atkritumi.lv/lv/karte/sadzive-radusies-medicinas-atkritumi/

There are four waste-sorting locations in Latvia, all of which are in the Riga region. These are in Riga, Olaine, Rumbula, and Kekava parish (Figure 3). Residents can hand over invalid medicines at any of these sorting facilities.

There are five networks of large pharmacy companies in Latvia and a few smaller pharmacies. There are 350 pharmacies of different owners (independent pharmacies). The total number of pharmacies in Latvia in 2010 was 945, but the figure had fallen to 899 at the beginning of 2017. It should be noted that there are still regions of Latvia without any pharmacies.

In 2010, 60% of the country's pharmacies were independent and the other 40% belonged to a company network. The figures were reversed by 2017: 60% of pharmacies were part of networks while 40% remained independent (Spakovska 2017).

The information available on the Internet indicates that Latvia has 334 pharmacies where people may hand over invalid medicines. These medicines may be turned in to a pharmacist or discarded in special containers at the pharmacies.

Medicines become invalid for many reasons. They expire; there is no longer an obvious use for them; the name of the product is not readable or the packaging is damaged; the products were improperly stored; or the look, smell, or taste of the medicine has changed.

Availability of information via pharmacy Web sites:

- The EURO Aptieka Web site suggests handing over invalid medicines to the chain's pharmacies and gives information on how the medicines should be prepared for hand-over. There is no information on which pharmacy residents can visit to hand in the invalid medicines.
- On the Web site for a. Apotheka, users can easily find information indicating which pharmacies they can visit to turn in their invalid medicines.
- On the BENU Aptieka company Web site, one can readily find information about the pharmacies where invalid medicines can be handed over.
- For Mēness Aptieka, the Web site lets the user easily find information about which pharmacies permit hand-over of invalid medicines.
- For Aptieku Alianse, the company Web site presents easily findable information about the pharmacies at which invalid medicines can be handed over.

No information on where to hand over invalid medicines could be found on the company Web sites of the Saules Aptieka, Latvijas Aptieka, or Mana Aptieka pharmacies.

For each network, Table 10 presents the total number of pharmacies in Latvia and the number of pharmacies where invalid medicines can be handed over.

Table 10: A summary of Latvia's pharmacies and the related disposal opportunities.

Pharmacy network	Number of pharmacies in Latvia	Number of pharmacies where invalid medicines can be handed over
a. Apotheka	114	114
BENU aptieka	74	67
EURO aptieka	50	50
Mēness aptieka	221	71
Latvijas aptieka	66	66
Mana aptieka	95	33
Aptieku alianse	42	31
Saules aptieka	3	1

The Web site of waste-management company Lautus states that they co-operate with the a. Apotheka and BENU pharmacy companies in the management of invalid medicines.

Several interest groups and actors in the management of unused medicines and other medical waste have offered opinions on the matter. The Pharmaceutical Advisory Board of Latvia maintains that financing for the management of medical waste should come not from the pharmacies but from sources such as other parties involved, such as municipalities, the state, the pharmaceutical industry, and pharmaceutical wholesalers. The board concluded that the contribution from pharmacies should be non-financial (Pharmaceutical Advisory Board meeting of 23.3.2016). The opinion of the Latvian Pharmaceutical Wholesalers´ Association is that the collection of invalid medicines could be optimised via their transfer to pharmaceutical wholesalers and onward to a waste-management company (Pharmaceutical Advisory Board meeting of 23.3.2016).

The opinion of the Ministry of Environmental Protection and Regional Development of Latvia, meanwhile, is that Latvian legislation is developed in accordance with EU legislation, under which medicines are not primarily classified as hazardous waste. The ministry stresses that medicines should be prescribed and used rationally, for avoidance of households' accumulation of invalid medicines. Under Latvia's waste-management laws, the municipalities are responsible for organising the collection of municipal waste in their territory. The fee for managing certain categories of waste could be included in the service's total cost to municipalities and cover the expenses incurred by pharmacies, which could then conclude contracts with waste managers. The cost should include both waste collection and processing. In contrast, increasing natural-resources tax is not a good solution, according to the ministry, because it would increase medicine prices. In the Ministry of Health's opinion, it is necessary to draw a distinction between household waste and other medical waste – e.g., waste from the pharmaceutical industry, hospitals, and other health care institutions (Pharmaceutical Advisory Board meeting of 23.3.2016).

Veterinary medicines

There is no information available on the quantities of invalid veterinary medicines handed in at pharmacies or taken to waste-sorting facilities. In Latvia, there is no requirement to specify what kinds of medicines one is returning to a pharmacy or taking to a waste-sorting location.

2.5.3 Current disposal practices

Companies specializing in the management of hazardous waste are responsible for disposal of unused medicines after the waste-producing operators have transferred the waste to them. Hazardous-waste management companies must have a permit for polluting activity of this type (Law on Pollution; Cabinet Regulation 1082, of 30.11.2010).

Medicines are burned in high-temperature hazardous-waste incinerators so that pollution of the environment (including water) is avoided. Hazardous waste produced in Latvia is incinerated in Estonia (Gulbinska et al. 2017).

There are two main companies that manage medical waste in Latvia. They are described below.

BAO covers the full spectrum of medical-waste management services in Latvia, and it owns the hazardous waste storage site in Gardene. According to its permit for category-A polluting activity, the company imports, recycles, and passes on both cytotoxic and cytostatic human and veterinary unused medicines and other types of unused human and veterinary medicines (waste classes 18 01 08, 18 01 09, 18 02 07, 18 02 08, and 20 01 32; see Appendix 1). They are passed on and transported in suitable containers. According to statistical report "3-Waste", BAO transfers non-cytotoxic and non-cytostatic human medical waste (class 18 01 09) to Tartu, Estonia, conveying it to the company Epler & Lorenz. According to the Epler & Lorenz Web site, the company incinerates pharmaceutical waste in a process that is strictly controlled, to reduce harmful emissions.

Lautus is a limited-liability company that manages various types of medical waste, including invalid medication. The company provides collection and short-term storage for all types of pharmaceutical and medicine waste (waste classes 18 01 08, 18 01 09, 18 02 07, 18 02 08, 20 01 31, and 20 01 32; see Appendix 1). Unsorted medical waste collected from medical institutions is sterilized, after which recyclable waste – plastic, glass, and metal – is manually separated. Cytotoxic and cytostatic drugs are not subject to sterilization. Separately collected non-cytotoxic and non-cytostatic pharmaceuticals (waste class 20 01 32) are cracked at a Vecoplan plant and transported to the Getliņi landfill. The terms of the company's permit include a requirement from the State Environmental Service to manage medication after the storage or cracking process in accordance with the Basel Convention methodological guidelines for the environmentally safe management of biomedical and health care waste. The activities of Lautus are considered to be an interim recovery operation, which must in all cases be followed by an appropriate final operation such as incineration per the methodological guidelines.

In the course of the CWPharma project, LEGMC reviewed how much waste of classes directly related to medicines (18 01 08, 18 01 09, 18 02 07, 18 02 08, 20 01 31, and 20 01 32) is created, collected, imported, exported, disposed of, and recycled by means of '3-Atkritumi' statistical reports. The results are presented in Figure 4. There are no summary statistics for other medicinal waste under code 18 – such as used syringes and nappies – in connection with which API pollution is commonplace. Statistics for cytotoxic and cytostatic pharmaceuticals for human use (class 18 01 08) are available only from 2016 (1 kg collected) and 2017 (3 kg collected). Statistics for other types of medicines for human use (class 18 01 09), in contrast, can be found for a span of several years for the waste created, collected, exported, disposed of, and recycled. On average, the amount of non-cytotoxic and non-cytostatic human medicaments medicines from human health care institutions in 2011–2017 came to

- 5.8 t of waste generated,
- 54 t of waste collected,
- 0.6 t of waste exported,
- 47 t of waste disposed of, and
- 23 t of waste pre-treated for recycling and recovery.

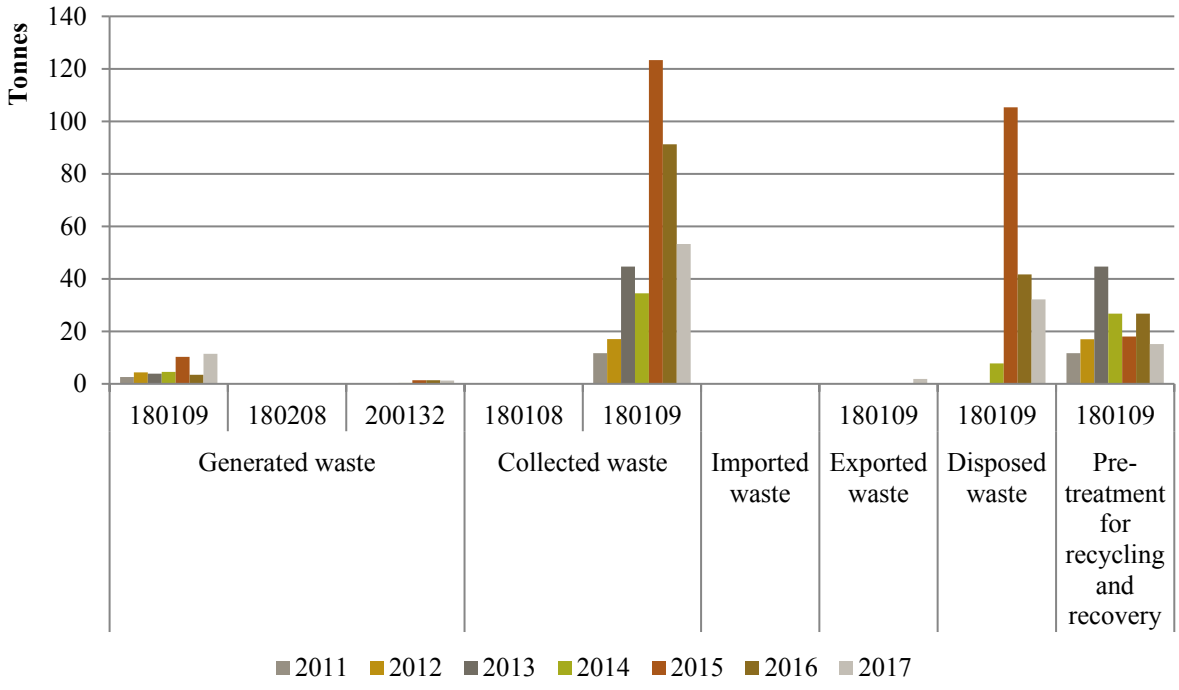

Figure 4. Waste in medicine-related classes that was created, collected, imported, exported, disposed of, and recycled in 2011–2017.

The exported waste was incinerated in Estonia (4% of the waste of class 18 01 09 collected in Latvia, per data for 2017). All other waste of class 18 01 09 collected is delivered to municipal landfills after shredding. Waste of class 18 01 06 (filter residues) also contains APIs; in 2017, the amount of this waste collected was 26.3 t, of which exported waste (sent for incineration) accounted for 7.1 t.

Statistics for waste in class 18 01 09 (non-cytotoxic and non-cytostatic human medicines) are reported from human health care institutions, pharmaceutical and chemical companies, prisons, and nursing homes.

Appendix 2 provides more information on the medicine-waste study carried out by LEGMC within the framework of the CWPharma project.

2.5.4 Summary

The main findings related to collection, classification, and disposal of unused pharmaceuticals and other waste containing pharmaceutical residues in Latvia are presented in Table 11.

Table 11: Summary of the collection, classification, and disposal of unused pharmaceuticals and other waste containing pharmaceutical residues in Latvia.

Pharmaceutical waste	Types of pharmaceuticals collected separately	Responsible party for arranging reception	Collection point	Types of pharmaceutical waste classified as hazardous	Legal basis	Method of disposal
Unused human and companion animal medicines from households	All pharmaceuticals	Municipality / state for hazardous types of waste	Usually local pharmacy or waste sorting area	Cytotoxic and cytostatic medication	Waste management law, section 16, p.2, section 8, p.1	Incineration at 850 °C or waste disposal at municipal landfill after shredding – for taken-back medicines
Pharmaceutical industry (unsalable products, API-contaminated wastes, etc.)	All pharmaceuticals	Industry operator	To be organized by the industry operator	Cytotoxic and cytostatic medication; API pollution is common also for waste class of residues of filter, that is hazardous waste	Cabinet Regulation of 26.06.2007. Nr. 416, p. 144	Incineration at 850 °C (waste of class 180106) / waste disposal at municipal landfill after shredding (waste of class 180109)
Pharmaceutical waste from hospitals and health care institutions	All pharmaceuticals	Hospital or institution	To be organized by the hospital or health care institution	Cytotoxic and cytostatic medication	Cabinet Regulation of 22.05.2012. Nr. 353, p. 3 Waste management law, section 17	Waste disposal at municipal landfill after sterilization, shredding
Veterinary medicines from veterinarians and veterinary practices	All pharmaceuticals	Veterinarian or veterinary practice	To be organized by the veterinarian or veterinary practice	Cytotoxic and cytostatic medication	Cabinet Regulation of 10.09.2016 Nr. 768, p. 9.2.	Waste disposal at municipal landfill after sterilization, shredding

Pharmaceutical waste	Types of pharmaceuticals collected separately	Responsible party for arranging reception	Collection point	Types of pharmaceutical waste classified as hazardous	Legal basis	Method of disposal
Veterinary medicines for livestock - reasonable amounts	All pharmaceuticals	Farmer	To be organized by the farmer	Cytotoxic and cytostatic medication	Cabinet Regulation of 31.05.2016. Nr. 326, p. 19.4	Waste disposal at municipal landfill after sterilization, shredding
Veterinary medicines for livestock - unreasonable amounts	All pharmaceuticals	Municipality / state for hazardous types of waste	Usually local pharmacy or waste sorting area	Cytotoxic and cytostatic medication	Waste management law, section 16, p.2, section 8, p.1	Incineration at 850 °C or waste disposal at municipal landfill after shredding – for taken-back medicines

In conclusion, the following points were noted with regard to the take-back system and the disposal of unused pharmaceuticals in Latvia.

Advantages:

+ Pharmacies are quite active in ensuring take-back of invalid medicines (67% of pharmacies ensure it), although they have no obligation to do so.
+ Waste from medical treatment institutions (waste in all '18' classes) is delivered to hazardous-waste collection points. After sterilisation and shredding, the materials are unable to spread infections and are safe with regard to uncontrolled consumption by humans, birds, or other animals.

Areas that need improvement:

- Residents' level of information is low with regard to the possibility of bringing unused medicines back to pharmacies (10% of residents availed themselves of this opportunity in 2014).
- A large proportion of invalid medicines from pharmaceutical wholesalers and manufacturing companies is delivered to landfills for municipal waste after shredding at hazardous-waste collection points, thanks to clear labelling – it is unambiguous that the material is not to be classified as hazardous waste. Roughly 96% of waste from class 18 01 09 was delivered to landfills for municipal waste in 2017 after shredding.
- Improvements are needed in gathering of waste statistics, to reveal the amount of waste that residents return to pharmacies. Waste managers should label medicine waste from pharmacies with code 20 01 32 (not 18 01 09 as before). Corresponding improvements are needed for veterinary waste of class 18 02 08.

Uncertainties:

• It is impossible to obtain information about waste or medicines from veterinary pharmacies and veterinary-medicine institutions, and same is true for farmers.

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2.6 Lithuania

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2.6.1 Legal basis

According to the Lithuanian Law on Pharmacy (No. X-709, of 22 June 2006), pharmaceutical waste is defined as medicinal products that are subject to disposal and chemical materials either used in implementation of trials for medicinal products or that are defective / past their expiry date and were acquired for the purpose of conducting such trials.

The same law specifies that 'pharmaceutical waste shall be collected from the residents and pharmaceutical waste holders, managed and paid for according to the procedure established by the Government. The management of pharmaceutical waste collected from the residents shall be paid for from the State budget'.

Requirements for the management of veterinary medical waste (approved by an order of the director of the State Food and Veterinary Service) establishes procedures for sorting, packaging, labelling, initial processing, temporary storage, and accounting for veterinary medical waste in Lithuania.

In Lithuania, medical waste must be collected as a separate category of waste and treated in accordance with waste-management regulations.

2.6.2 Current take-back practices

All pharmacies are obligated to accept unused and expired medicines and pass them to a waste management organization established by the government. Specialist organizations carry out the transport and disposal of pharmaceuticals, which is financed by the local government (CCB 2017).

The hazardous-waste managers (enterprises holding a license to collect and dispose of hazardous waste, including unused medicines) are entities selected by the Lithuanian Ministry of Health in accordance with established public-procurement procedures.

Pharmacies must document the medicines collected not later than the next working day after their collection. The following information is registered in the journal: the date, the type of waste received, the code (per the Waste Management Regulations and European Waste Codes (EWC) classification), and the weight (CCB 2017).

The government is responsible for the financing of the system, but, because the roles of the various institutions remain unclear, the pharmacies are currently paying the costs for disposing of the unused medicines collected. Therefore, pharmacies do not actively distribute information on their obligation to receive unused medicines. In interviews conducted in 2013, more than 60% of the subjects stated that they did not remember having received information about the correct ways of disposing of pharmaceuticals. (HCWH 2013)

According to an interview-based study (HCWH 2013) carried out in 2013, 54% of participants were aware of the possibility of returning unused and expired medicines to pharmacies or hazardous-waste collection sites. Only 10–13% of subjects indicated that they did return unused medicines to these collection points, while 50–64% discarded medicines by throwing them in the rubbish bin (HCWH 2013). In 2007, 73% of survey respondents reported not knowing that pharmacies would take back medicines and 50–80% stated that they indeed throw unused medicines away with standard rubbish (Kusturica et al. 2016).

The quantities of unused medicines collected by the hazardous-waste management authorities are officially reported annually by the Lithuanian Environmental Protection Department (see Table 12).

There are no official statistical data on the amount of unused medicines flushed into the sewers and/or discarded with municipal waste.

Table 12: Amounts of unused medicines (in tons) collected by the hazardous-waste management operators in Lithuania.

Waste name (code)	Year	Collected and generated	Exported	Incineration (R1)	Incineration (D10)	D8, D9, D14, R12
Chemicals consisting of or containing hazardous substances (18 01 06) *	2014	29			29	2,9
	2015	34		13	26	0,4
	2016	60			62	1,6
	2017	35			43	2,0
Chemicals other than those mentioned in 18 01 06 (18 01 07)	2014	0,44				
	2015	0,70		0,096	0,28	
	2016	0,64			0,77	0,14
	2017	1,4			1,9	
Cytotoxic and cytostatic medicines (18 01 08) *	2014	7,0			6,8	
	2015	22		0,29	23	
	2016	4,9			5,5	
	2017	2,1			1,9	
Medicines other than those mentioned in 18 01 08 (18 01 09)	2014	230	91			140
	2015	170	57	100		
	2016	120	58	22	45	
	2017	140	45	70	90	1,8
Chemicals consisting of or containing hazardous substances (18 02 05) *	2014	4,8			0,78	
	2015	3,4			2,1	
	2016	1,7			3,6	
	2017	2,1			2,3	0,076
Chemicals other than those mentioned in 18 02 05 (18 02 06)	2014	0,001				
	2015					0,001
	2016					
	2017				0,003	

* Classified as hazardous waste.
R1=Use principally as fuel or other means to generate energy (not considered recovery to a final product).
R12=Exchange of wastes pending any of the operations numbered R1 to R12 (excluding temporary storage, pending collection, on the site where it is produced).
D8=Biological treatment resulting in final compounds or mixtures which are discarded by any of the operations numbered D1-12
D9=Physico-chemical treatment resulting in final compounds or mixtures which are discarded by any of the operations numbered D1-12 such as evaporation, drying, calcination
D10=Incineration on land.
D14=Repackaging prior to submission to any of the operations numbered D1 to D12.

2.6.3 Current disposal practices

By law, medicinal products to be disposed of by the general public are to be treated in accordance with the requirements pertaining to hazardous-waste management and must be handed over to the waste managers (currently UAB „AV investicija“) selected by the Ministry of Health. These waste managers have the right to handle hazardous waste in the manner prescribed by the Lithuanian Law on Waste Management and other acts of law.

‘Inactivated’ hazardous medical and pharmaceutical waste is material that has been rendered non hazardous. This makes it suitable for storage (repository time is up to a year) and ready for landfilling, incineration, or recycling (CCB 2017).

The medical waste collected is incinerated. Reports state that 31 t of medical waste was collected in 2009, but there is no clear information on whether this figure refers only to household medical waste or covers other categories of medical waste too (HCWH 2013, CCB 2017).

2.6.4 Summary

The main findings pertaining to collection, classification, and disposal of unused pharmaceuticals and other waste containing pharmaceutical residues in Lithuania are presented in Table 13.

Table 13: Summary of the collection, classification, and disposal of unused pharmaceuticals in Lithuania.

Pharmaceutical waste	Types of pharmaceuticals collected separately	Responsible party for arranging reception	Collection point	Pharmaceutical wastes classified as hazardous	Legal basis	Method of disposal
Unused human and companion animal pharmaceuticals from households	No information	Unclear; government responsible for financing but in practice pharmacies pay the costs	Local pharmacies	Not known	–	Incineration (temperature not known)

The following points were noted as conclusions related to the Lithuanian system for the take-back and disposal of unused pharmaceuticals.

Advantages:

+ The situation related to collection of obsolete pharmaceutical products is improving, and the amount of pharmaceutical waste collected by pharmacies is increasing (CCB 2017).

Areas that need improvement:

- The roles of the various actors and the financing for collection and disposal of unused medicines should be clarified.
- People are bringing other kinds of waste to pharmacies also – such as outdated food additives (CCB 2017).
- The incineration temperature employed for unused human-use and companion animal pharmaceuticals is not known.

2.6.5 References

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HCWH 2013. Unused pharmaceuticals – Where do they end up? A snapshot of European collection schemes. https://noharm-europe.org/documents/unused-pharmaceuticals-where-do-they-end-snapshot-european-collection-schemes [Visited 9.7.2020.]

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Republic of Lithuania. Law on Pharmacy 22 June 2006 No X-709 Vilnius.

2.7 Poland

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2.7.1 Legal basis

The main law regulating waste management in Poland is the Waste Act, or WA (Dz. U. 2013, poz. 21). This act specifies the management principles (recovery, means of preventing emergence, recycling, treatment, disposal, storage, and transport) for various types of waste, including medical and veterinary waste. In addition, the act specifies the competencies and responsibilities of individual territorial authorities with regard to waste management and monitoring. Medical waste and veterinary waste, for the purposes of the WA, is waste arising in connection with the examination and treatment of people and animals or in the provision of medical and veterinary services, along with that generated in connection with scientific research, including medical trials and experiments using animals.

The European Commission's list of waste categories (2014/955/EU) classifies unused cytostatic and cytotoxic pharmaceuticals as hazardous waste and declares other types of pharmaceutical waste non hazardous. This is the classification system in use in Poland.

The WA imposes an obligation to supervise and dispose of medical waste, including pharmaceuticals, at the level of Polish territorial units.

Current collection practices

Waste must be collected by distinct waste type in the place where it is produced. Collecting medical and veterinary waste beyond the location of its production is forbidden (WA, Art. 23, item 2). The marshal of the voivodeship, by way of a decision, may authorise the collection of this waste for safety reasons or to ensure continuity of waste collection. In the case of providing medical services on request, the producer of such waste is obliged to deliver it immediately to rooms adapted for this purpose and meeting the requirements for the storage of such waste (WA, Art. 23, items 8 and 9). The economic operator producing the waste is required to obtain the appropriate permits for that waste's generation (per the WA's articles 18–22) and must submit reports on the waste amounts to the National Waste Base (BDO). At present, the BDO database is in the implementation stage. The access to this public database has been possible since January 2020 via the Ministry of the Environment Web site, http://www.bdo.mos.gov.pl.

Responsibility for waste generated

Each operator is obliged to manage its own waste. In the case of waste generated at organisational facilities, such as a hospital, clinic, or pharmacy, the producer of the waste is responsible for its disposal, while the municipalities are responsible for seeing to the management of pharmaceutical waste from households (Dz. U. 1996, No. 132, poz. 622 and amendments: Dz. U. 2012, poz. 391 and 951 and Dz. U. 2013, poz. 21 and 228). In practice, this has been implemented via municipal agreements with pharmacies or pharmacy-operated points for the selective collection and treatment of pharmaceuticals. Once the material has been disposed of at a hazardous-waste incineration plant, the producer of medical and veterinary waste is relieved of the responsibility for the waste generated. The transfer of responsibility for waste management to the next waste holder is documented via the document confirming neutralisation (DPU) (WA, Art. 27, items 5 and 6 and Dz. U. 2014, poz. 107). The DPU document is issued at the request of the waste producer (WA, Art. 95, item 4).

The office monitoring compliance with the Waste Act is the Inspection of Environmental Protection (IEP) entity, in accordance with the act of law on inspection of environmental protection (Dz. U. 2018, poz. 1471 and 1479). Also, any irregularities related to waste management may be reported to the IEP

by other control units, such as Veterinary Inspection, Pharmaceutical Inspection, and Sanitary and Epidemiological Inspection.

Several regulations have been issued in conjunction with the WA, which address various details of the issues of classification and handling of waste. These are the most important:

- The regulation of the Minister of Environment pertaining to the waste catalogue (see Appendix 1) (Dz. U. 2014, poz. 1923). Under the WA, every operator handling hazardous waste is obliged to keep up-to-date records of its quantities and types in accordance with the categories presented in the ordinance.
- The regulation issued by the Minister of Health (Dz. U. 2016, poz. 1819) on requirements and disposal methods to be applied for medical and veterinary waste, which specifies the following: permissible means of disposal (see Table 14, based on Annex 1 to said regulation), conditions for carrying out the D10 incineration process (see Annex 2 to the regulation) and D9 process (per Annex 3), the method and scope for monitoring of disposal processes, and the methods and frequency for testing of waste generated as a result of these processes. The pharmaceutical waste in Poland is combusted in hazardous-waste incinerators.
- The regulation from the Minister of Health on dealing with medical waste (Dz. U. 2010, No. 139, poz. 940). This applies to medical waste with several codes (§1.1) and lays down detailed rules for the collection of medical waste, its temporary storage before its subjection to a disposal process, and the relevant transport conditions.
- The regulation issued by the Minister of Health (Dz. U. 2015, poz. 1116) on medical and veterinary waste that may be subject to recovery (e.g., surgical instruments, bedding, chemical reagents, and waste containing dental amalgams if these do not contain infectious material). In contrast, drugs are not consisdered recoverable in Poland.

Table 14: Permissible methods of disposing of medical waste and veterinary waste that do not have infectious properties in Poland (Dz. U. 2016, poz. 1819).

Waste code	Medical and veterinary waste	Disposal method
18 01 08	Cytotoxic and cytostatic drugs	Thermal transformation on land (D10)
18 01 09	Medicines other than those mentioned in 18 01 08	
18 02 07	Cytotoxic and cytostatic drugs	
18 02 08	Medicines other than those mentioned in 18 02 07	

Medical and veterinary cytotoxic and cytostatic drugs are classified in Poland as hazardous waste and other medicines as non-hazardous waste (according to waste catalogue), but additionally in Appendix 4 of WA, there is a list of ingredients that may cause waste a hazardous waste. The list includes pharmaceuticals and other compounds used in medicine and veterinary medicine. Therefore, the interpretation of the regulations is unclear, and it should be assumed that all pharmaceuticals in waste are hazardous waste.

Another important legal mechanism regulating issues related to pharmaceuticals in Poland is the Pharmaceutical Act, or PA (Dz. U. 2001, No. 126, poz. 1381; Dz. U. 2017, poz. 2211; Dz. U. 2018, poz. 650, 697, 1039, 1375, 1515, 1544, 1629, 1637, and 1669).

These are the most important issues regulated by the PA with regard to pharmaceutical waste:

- The rules and procedures for admitting medicinal products to trading – addressing their quality, effectiveness, safety of use, manufacturing, and marketing conditions. The regulation also includes requirements for specifying the particulars of the environmental hazards posed by a particular medicine, in the marketing-authorisation dossier.

- The tasks of Pharmaceutical Inspection and Veterinary Inspection and the competencies of the offices in question: supervision of production processes, trade, marketing, and return of medicinal products (per articles 67.1 and 122).
- The obligation to keep records of the medicinal products sold and maintain an inventory of medicines given to animals, required under the PA and specified in combination with the act on animal health care and fighting contagious diseases among animals (Dz. U. 2004, No. 69, poz. 625). This makes it possible to determine the size of the market for veterinary medicines and, potentially, the amount of waste generated.

In addition to the PA, several other legal instruments specify details of the rules for trading in pharmaceuticals:

- The regulation of the Minister of Health about basic conditions for running a pharmacy (Dz. U. 2002, No. 187, poz. 1564 and 1565). This imposes, among other obligations for the pharmacy, a requirement to keep detailed records of expired and damaged medicines submitted for disposal, as well as documentation on medicinal products for which a decision on suspension of sale or withdrawal from the market has been issued.
- The act of law for countering drug addiction, or DA (Dz. U. 2005, No. 179, poz. 1485), and the regulation of the Minister of Health (Dz. U. 2012, poz. 236) that regulates the obligation to notify Pharmaceutical Inspection about the expiry of narcotic and psychoactive substances, the rules and methods for the appropriate protection of these against unwanted use until the time of destruction, and formal requirements to be followed during the destruction procedure.

2.7.2 Current take-back practices

Poland has one of Europe's highest consumption of medicines, especially ones available without a prescription. In autumn 2009, nearly 71% of the population used pharmaceuticals, and the value of the country's pharmaceutical market reached PLN 38.5 billion (about 9 billion euros) in 2017, according to QuintilesIMS analysts.

According to the data provided by the Rynek Aptek Web site[6], in the April of 2020 there were:

- 12 424 generally accessible pharmacies,
- 1 210 pharmacy points,
- 1 278 hospital and other pharmacies – e.g., company and government pharmacies, and
- 307 pharmacies without permission.

The high consumption of medicines in Poland creates the risk of producing large amounts of pharmaceutical waste. For 2011–2013, the Council of the Supreme Audit Office (NIK) has reported the numbers of medical-waste producers shown in Figure 5 and the amounts of medical waste generated that are presented in Figure 6 (NIK 2014).

[6] http://www.rynekaptek.pl/,

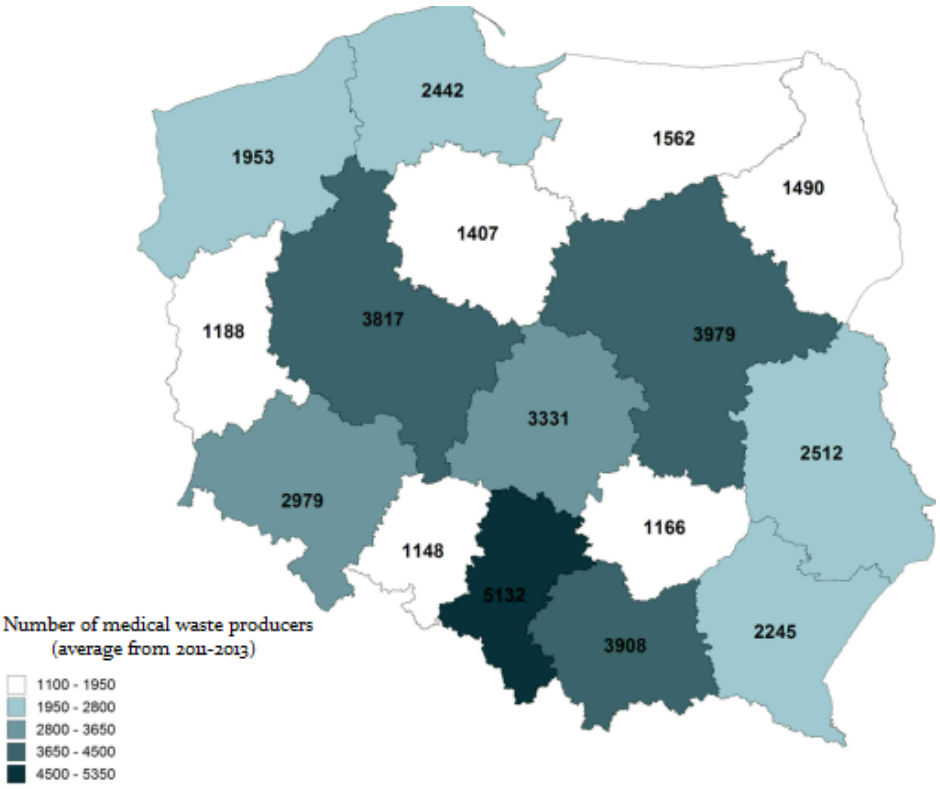

Figure 5. The number of medicine-waste producers (hospitals, other health care institutions, pharmaceutical plants, etc.) in the individual voivodeships in 2011–2013 (NIK 2014).

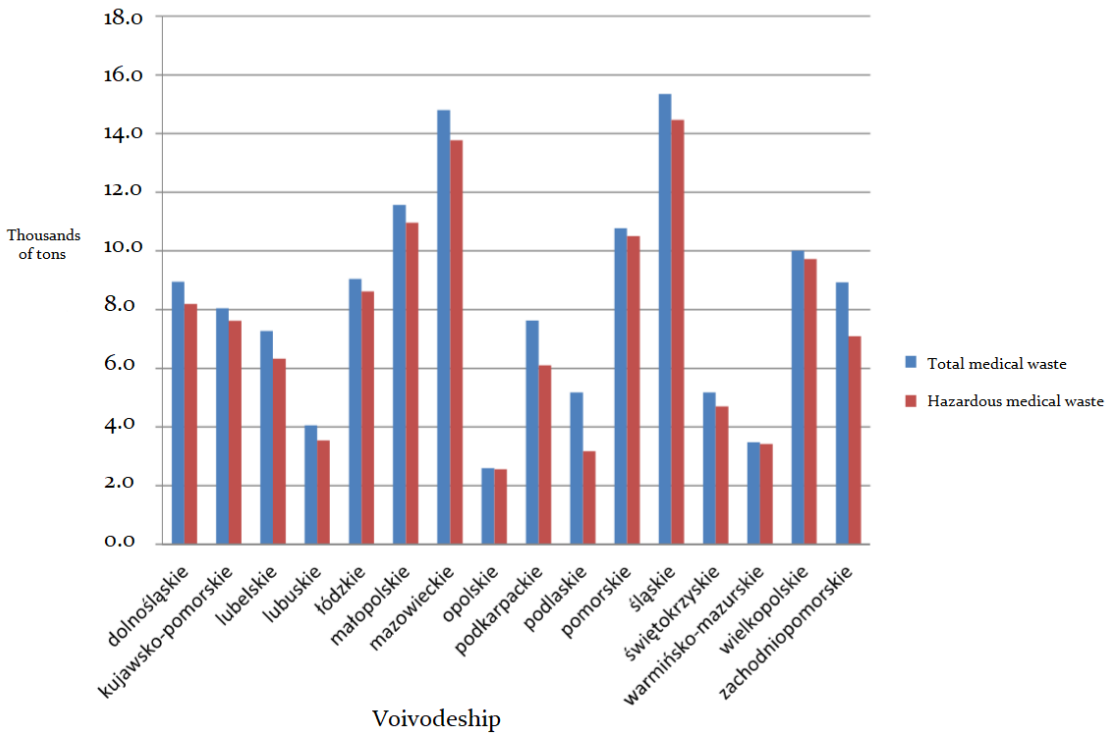

Figure 6. The amount of medical waste produced in the individual voivodeships in 2011–2013 and the share of hazardous waste in it (NIK 2014).

Operator responsibility for take-back of unused medicines

According to the WA, the operator responsible for collecting and handling expired pharmaceutical and veterinary waste is the producer of waste. Health care facilities (i.e., hospitals and clinics), pharmacies and medical academies are obliged to collect all their medical waste (incl. pharmaceuticals) in an appropriate manner, as set out by regulations, and then transfer it to the appropriate disposal operators. The proof of transferring the waste (and, thereby, of responsibility for the waste) to the next operator – the recycling company – is the DPU document.

Expired pharmaceuticals from households should be collected in accordance with their type and deposited in marked locations – e.g., at pharmacies, health care facilities, municipal offices, or waste-collection points. The authority responsible for the reception of expired medicines from households is the municipality. In practice, this is implemented through mutual agreements between municipalities and pharmacies.

Actual take-back practices of unused medicines; how it is organized

Unused medicine may be delivered to pharmacies or to special points for hazardous-waste collection. However, the process is not organised, and not all pharmacies participate in this programme. Most often, it is implemented on the basis of a bilateral agreement with the municipal office. All pharmacies are obligated to keep records of all waste sent for disposal via high-temperature incineration.

Unused veterinary medicinal products from households may be handed over to pharmacies where unused human-use medicinal products are taken back or at special points for hazardous-waste collection. Animal breeders who use veterinary pharmaceuticals in Poland have an obligation to retain records of these and to document their consumption and disposal.

The report released by the Council of the Supreme Audit Office (NIK 2014) on the treatment of medical waste in Poland revealed several irregularities in many national medical centres' compliance with the WA regarding the controls related to the provision of health services and conducting medical research and experiments. The audit covered such aspects as:

- organization of the medical waste's management,
- activities related to the disposal of medical waste and the associated recording and reporting,
- proceedings related to the conclusion of contracts with entities collecting waste, and
- organization of sanitation supervision activities connected with the handling of medical waste.

The assessment of these was negative, on account of the scale of the irregularities found. The following shortcomings were identified:

- Information on the disposal of hazardous waste and on its management in a manner other than that required by law is lacking – there are deficiencies in the relevant disposal documentation.
- Reliability is lacking with regard to reporting on the quantity and nature of the waste generated, a situation often stemming from errors in the records and in classification of waste (incorrectly assigned waste codes) but one that has also been created deliberately for economic reasons.
- There is failure to comply with the proximity principle referred to in the WA, which has often resulted in transfer of infectious or dangerous waste over long distances. This is a result of favouring the economic criterion in selection of the contractor for the waste disposal service.
- At 83% of the facilities inspected, the waste was segregated, stored, and transported incorrectly (NIK 2014).

Evaluation of the take-back practices of unused medicines

All medications in Poland should be utilised in thermal transformation employing the D10 method, but, as research by Staniszewska et al. (2015) has shown (Figure 7), the way pharmaceutical waste is dealt with in practice deviates significantly from that mandated by the WA. According to their questionnaire based survey, which involved two groups of respondents – patients with chronic illnesses, who are

permanently on medication (the 'Ch' group), and patients taking drugs occasionally (the 'O' group) – the most common way of dealing with expired medications was to discard them with ordinary rubbish (about 60%) or flush them down the toilet (24–33%), which attests to low public awareness. Discarding them in marked containers, at a pharmacy, accounted for under 10% of the responses. The main sources of knowledge about expired-medication collection programmes were (from the most to the least often cited) the radio, posters/leaflets, family/friends, television, the Internet, the press, and pharmacies.

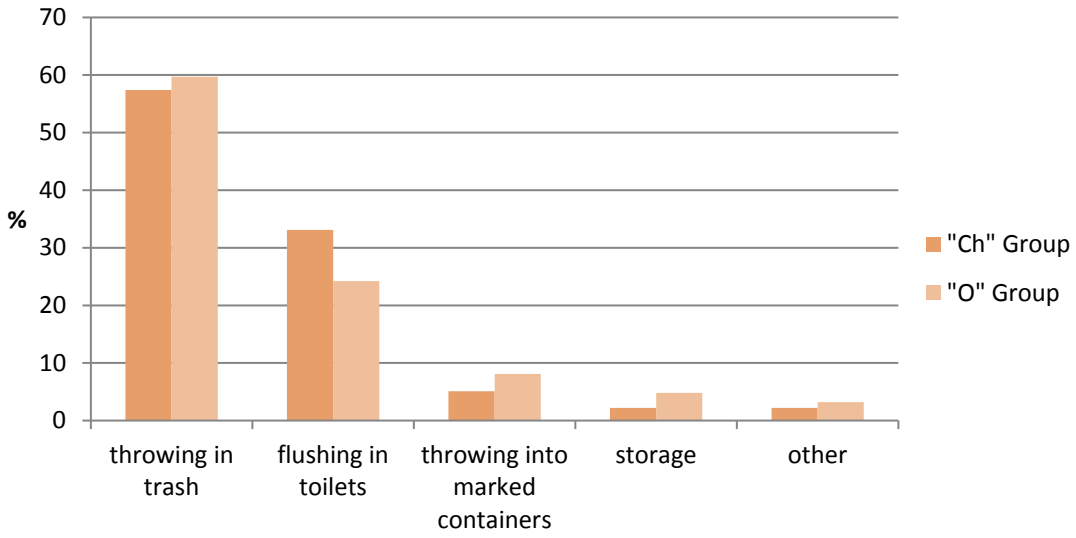

Figure 7. The most common ways of dealing with expired medications among respondents (n=198), where 'Ch' refers to patients with chronic illnesses, who are on medication permanently, and 'O' denotes patients who use drugs only occasionally (Staniszewska et al. 2015).

2.7.3 Current disposal practices

Operator responsibility for disposal of unused medicines

In Poland, the operators responsible for disposal of unused medicines are the companies that utilise the waste. They pick up the selectively collected waste from medical/veterinary centres and pharmacies. The transfer of waste to utilisation must be reported upon (by 15 March each year) to the Marshal's Office of the relevant voivodeship. Utilisation is confirmed by the DPU document.

An operator performing recovery, disposal, collection, and transport of waste is obligated to hold the following permits for carrying out the business in question (per the WA's articles 232 and 233 and Section 4 of the Environmental Protection Law (Dz. U. 2001, No. 62, poz. 627):

- An integrated permit
- Permission to operate in the field of collection or transport of waste
- Permission to collect and process waste
- Permission for the transport of hazardous and non-hazardous waste
- Registration in the register of the Chief Inspectorate of Environmental Protection (CIEP)

Actual disposal practices of unused medicines

After medicines are delivered to hazardous-waste management companies, they are subjected to high temperature hazardous-waste incineration (using the D10 method: thermal transformation at a temperature of 1100 °C) for purposes of avoiding pollution of the environment (water etc.). In Poland, the pharmaceutical waste collected may be incinerated at a hazardous- or municipal-waste incineration plant.

In 2014, there were 45 active medical-waste incineration plants (NIK 2014) and seven municipal-waste incineration plants in Poland. The former plants are found mainly at hospitals and handle the disposal of infectious waste and other types of waste generated at medical facilities.

Evaluation of the disposal practices of unused medicines

On behalf of the NIK, Inspection for Environmental Protection carried out inspections of 29 of the 45 entities operating thermal waste-treatment installations in 2014. These uncovered significant irregularities connected with more than 62% of the entities audited. The deficiencies identified are related to either not performing legally required measurements of pollutant emission levels or performing them at times other than those dictated by administrative decisions, untimely transfer of waste data to supervision authorities, irregularities in storage and records, and lack of appropriate authorisation of various types.

From the information presented above, it can be concluded that the management of medical pharmaceutical waste in Poland is duly regulated by law but also that various types of information and training actions are required for compliance with the law in this regard.

2.7.4 Summary

The main findings on collection, classification, and disposal of unused pharmaceuticals and other waste containing pharmaceutical residues in Poland are presented in Table 15.

Table 15: Summary of the collection, classification, and disposal of unused pharmaceuticals and other waste containing pharmaceutical residues in Poland.

Pharmaceutical waste	Types of pharmaceuticals collected separately	Responsible party for arranging reception	Collection point	Types of pharmaceutical waste classified as hazardous	Legal basis	Method of disposal
Unused human pharmaceuticals from households	All pharmaceuticals	Municipality	Usually local pharmacy (depends on municipality) or other collection points	Cytotoxic and cytostatic drugs waste // All pharmaceuticals (appendix 4 of WA) *	WA, Act about maintaining cleanliness and order in communes,	High temperature incineration (1100°C)
Unused companion animal pharmaceuticals from households	No information	Veterinarian or veterinary practice Municipality	Veterinarian or veterinary practice Usually local pharmacy (depends on municipality)	Cytotoxic and cytostatic drugs // All pharmaceuticals *	WA, art 23.	High temperature incineration (1100°C)
Pharmaceutical industry (unsalable products, API-contaminated wastes, etc.)	All pharmaceuticals, active substances, semi-finished products and API-contaminated wastes	Industry operator	To be organized by the industry operator, sometimes specified in the environmental permit of the industrial plant	All pharmaceuticals	WA, and Environmental Protection Law	Pre-treatment of wastes High temperature incineration (1100°C)

Pharmaceutical waste	Types of pharmaceuticals collected separately	Responsible party for arranging reception	Collection point	Types of pharmaceutical waste classified as hazardous	Legal basis	Method of disposal
Pharmaceutical waste from hospitals and health care institutions	All pharmaceuticals	Hospital or health care institution–	To be organized by the hospital or health care institution	All pharmaceuticals	WA, art 23	High temperature incineration (1100°C)
Veterinary medicines from veterinarians and veterinary practices	All pharmaceuticals	Veterinarian or veterinary practice	To be organized by the veterinarian or veterinary practice	All pharmaceuticals	WA, art 23	High temperature incineration (1100°C)
Veterinary medicines for farmed animals	No information	Veterinarian or veterinary practice Municipality	Veterinarian or veterinary practice Usually local pharmacy (depends on municipality)	Cytotoxic and cytostatic drugs // All pharmaceuticals *	WA, art 23	High temperature incineration (1100°C)

* problems with interpretation of national legislation

In conclusion, the following points were noted with regard to Poland's take-back system and disposal of unused pharmaceuticals.

Advantages:

+ The pharmacy take-back scheme appears to be efficient, and third parties cannot retrieve pharmaceuticals from the collection point.
+ The legal system's specification of the method of dealing with pharmaceutical waste is adequate – pharmaceutical waste must be directed to a suitable disposal process (recovery of such waste is not permitted).
+ The system is easy for citizens to use – they are not required to identify the waste categories involved.
+ There is an extensive network of pharmacies and collection points.
+ There are no direct costs to the consumer.
+ The treatment of pharmaceutical waste via high-temperature (1100 °C) incineration seems efficient.

Areas that need improvement:

- Interpretations of the regulations remain unclear.
- Low public awareness of the take-back scheme could result in inappropriate disposal.
- Public awareness would certainly increase the proportion of pharmaceuticals disposed of correctly – citizens' ignorance and lack of information on proper sorting point to a need for continued education and awareness-raising.
- The law does not specify any technical requirements related to pharmaceutical waste's treatment.

Uncertainties:

- Scarce data available call the take-back scheme's validation into question. Most of the study reports and data published on the subject focus on an economic perspective and do not take the environmental side of matters into consideration.
- There is a paucity of public data/information on the amounts of discarded pharmaceuticals that are disposed of at high temperatures. Only general data on the amount of medical waste utilised are available.

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Dz.U. 2012 poz. 236. Rozporządzenie Ministra Zdrowia z dnia 27.02.2012 w sprawie szczegółowych warunków I trybu postępowania ze środkami odurzającymi, substancjami psychotropowymi I prekursorami kategorii 1, ich mieszaninami oraz produktami leczniczymi, sepsutymi, sfałszowanymi lub którym upłynął termin wazności, zawierającymi w swoim składzie środki odurzające, substancje psychotropowe lub precursory kategorii 1 - Regulation of the Minister of Health of 27.02.2012 regarding specific conditions and procedures for dealing with narcotic drugs, psychotropic substances and category 1 precursors, their mixtures and medicinal products that have been spoiled, falsified or have expired, containing narcotic drugs, psychotropic substances and group 1 precursors. http://prawo.sejm.gov.pl/isap.nsf/download.xsp/WDU20120000236/O/D20120236.pdf [Visited 9.7.2020]

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2.8 Russia

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2.8.1 Legal basis

Russian legislation does not regulate collection and disposal of household pharmaceuticals. Neither does it require pharmacies to collect unused medicines from the public (CCB 2017).

Article 59 of the Law on Medicinal Product Circulation sets out general procedural requirements and grounds for medicinal products' destruction. According to that law, substandard and counterfeit medicinal products shall be withdrawn from circulation and destroyed. Another law prescribes the procedure for the disposal of controlled drugs and precursors.

Federal Law 61-FZ on Circulation of Medicinal Products, dated 12.4.2010

In 2019, this law was amended, with the amendments taking effect on 1 March 2020. The law includes the following specifications, among others, regarding the medicinal products:

- Substandard and counterfeit medicinal products shall be withdrawn from circulation and destroyed in accordance with the procedure established by the Government of the Russian Federation.
- Counterfeit medicinal products shall be withdrawn from circulation and destroyed in accordance with a court decision.
- The owner of counterfeit, substandard, or falsified medicinal products shall provide reimbursement for the destruction costs.
- The owner of relevant medicinal products must submit a certificate of destruction or a duly certified copy thereof to the authorised federal executive authority.
- The authorised federal executive authority making a decision to destroy medicinal products shall be responsible for supervising their destruction.
- Medicinal products shall be destroyed by duly licensed operators at specially equipped sites, at landfills, or on specially equipped premises, in compliance with the environmental requirements specified by Russian laws and regulations.
- Narcotic, psychotropic, and radiopharmaceutical drugs shall be destroyed in accordance with Russian laws and regulations.

Ordinance 382 of the Ministry of Health of the Russian Federation on Guidelines on the Procedure of Medicinal Product Destruction, dated 15.12.2002

This ordinance's terms specific to medicinal products' destruction dictate the following:

- Liquid medicinal products shall be destroyed by dilution with water at a 1:100 ratio, with the solution to be flushed into the industrial sewer system.
- Solid water-soluble drugs shall be destroyed by crushing into a powder, after which dilution with water is to be performed (1:100) and the solution flushed into the industrial sewer system.
- Solid water-insoluble and soft medicinal products (ointments etc.) shall be destroyed by incineration.
- Narcotic drugs and psychotropic substances shall be destroyed in accordance with Russian laws and regulations.
- Flammable drugs, explosive drugs, and pharmaceutical raw materials with a high radionuclide content shall be destroyed under special conditions by means of a special technique available to disposal operators, in accordance with their licence.

When medicinal products are destroyed, a certificate of destruction is prepared and signed by the persons participating in the procedure. Pharmaceutical-industry entities shall be responsible for medicinal products' destruction in accordance with Russian laws and regulations.

2.8.2 Current take-back practices

Russia has no official centralised system to collect expired pharmaceuticals and medical waste (packages, syringes, IV lines, etc.) from the public without charge. Pharmacies do not make collection points for unused pharmaceuticals available to the public, and neither they nor other health care institutions (hospitals and clinics) accept any pharmaceutical waste from households (Malina 2018).

Russia does not have any coherent system for handling of unused pharmaceuticals from households. Therefore, these medicines end up at landfills or in municipal sewer systems (HELCOM & UNESCO 2017). Nevertheless, about four tonnes of pharmaceutical waste are collected every year in Russia. This collection is arranged via mobile collection points and recycling centres (CCB 2017).

However, Russian legislation does specify procedures for handling and disposal of medical waste from health care institutions and pharmacies (CCB 2017).

According to various sources, up to 1,000,000 tonnes of medical waste is generated in Russia annually.

A survey (Trofimova & Getman 2013) conducted in the country's large cities indicated that

- 80% of expired pharmaceuticals is disposed of in household waste or taken to landfills and
- 15% is flushed into the sewer system.

Roughly 50% of respondents were aware that such disposal methods can harm the environment and indicated that they were ready to support the initiative to collect expired and unwanted pharmaceuticals in special containers installed at pharmacies for their safe disposal.

Currently, while some operators in Russia are licensed to provide commercial services for pharmaceutical waste's transportation and disposal, no government support is available for such companies, regrettably. These operators accept expired pharmaceuticals for a fee from both health care institutions and the public. The price per kilogram of pharmaceuticals is, on average, between 150 and 250 Russian rubles (about 2–3 euros). Such operators have a special licence for performing the activities in question, and they carry out pharmaceutical-waste collection, transportation, and disposal at landfills. However, there are very few such operators in Russia at present.

The Russian Ministry of Health has been receiving requests for establishment of special collection points where the public can return expired pharmaceuticals. A decision has not been made yet. There are hopes that the Pharma-2030 Strategy is going to address the issue of pharmaceutical-waste collection and disposal and that Russia will implement a system for collecting household pharmaceutical waste with segregation by hazard class.

2.8.3 Current disposal practices

According to the guidelines issued by the then Ministry of Health and Social Development in 2010, the following methods may be used: incineration, discharge into industrial sewers, and landfilling at designated sites. However, environmentalists argue that none of these methods is environmentally safe. According to Russian environmentalists, the most efficient pharmaceutical-waste disposal method is a thermal technique with multi-stage flue-gas cleaning. Such incineration and dumping of medical waste at designated sites have been identified as the most preferable destruction method for medicines in Russia (CCB 2017).

Disposal of pharmaceuticals by health care institutions (hospitals, health care centres and pharmacies)

According to Regulation SanPiN 2.1.7.2790-10, titled 'Sanitary and Epidemiological Requirements for Medical Waste Disposal', expired pharmaceuticals and waste from laboratories, pharmacies , and the pharmaceutical industry are categorised as Class G toxic substances and subject to destruction accordingly.

The following destruction methods shall be applied:

- Thermal (incineration)
- Chemical (use of alkalis or acids)
- Thermochemical (crushing, heating, and immobilisation)

Specialist licensed operators transport waste from medical or pharmaceutical institutions to designated immobilisation and disposal sites, in special vehicles. Large health care institutions have their own equipment (microwave treatment units) for medical waste's immobilisation and disposal. Thus, pharmacies, hospitals, and (other) large health care institutions take care of the disposal of the pharmaceutical waste they produce.

2.8.4 Summary

The main findings related to the collection, classification, and disposal of unused pharmaceuticals and other waste containing pharmaceutical residues in Russia are presented in Table 16.

Table 16: Summary of the collection, classification, and disposal of unused pharmaceuticals and other waste containing pharmaceutical residues in Russia.

Pharmaceutical waste	Types of pharmaceuticals collected separately	Responsible party for arranging reception	Collection point	Types of pharmaceutical waste classified as hazardous	Legal basis	Method of disposal
Unused human and companion animal pharmaceuticals from households	None; legislation does not cover unused pharmaceuticals of households	No responsible party	Not exist; small proportion of pharmaceutical waste collected via mobile collecting points and recycling centres	Not known	No legal basis	Landfilling
Pharmaceutical industry (unsalable products, API-contaminated wastes, etc.)	Not known	Not known	Not known	Not known	Ordinance 382 15.12.2002	Incineration, discharge into industrial sewers and landfilling at designated sites
Pharmaceutical waste from hospitals, health care institutions and pharmacies	Not known	Not known	Not known	Not known	SanPiN 2.1.7.2790-10	Incineration, chemical and thermochemical destruction

In conclusion, the following issues related to Russia's take-back and disposal system for unused pharmaceuticals were noted as representing improvement needs:

- Community outreach campaigns would be beneficial for raising public awareness of the environmental impacts created by unused medicines' inappropriate disposal and of the importance of their proper collection and disposal. For unused and expired pharmaceuticals, targeted information and awareness-raising activities are needed, making use of the information resources of health care institutions and pharmacies.
- Establishment of a collection-point network for unused medicines in Russia should be promoted, and the public should be encouraged to take medicines to such points rather than dispose of them with household rubbish.

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2.9 Sweden

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2.9.1 Legal basis

Waste-handling for pharmaceuticals in Sweden is regulated primarily by three pieces of legislation: the Environmental Code (SFS 1998:808), the Waste Ordinance (SFS 2011:927), and the ordinance on producer responsibility for pharmaceuticals (SFS 2009:1031). The overall legal basis for handling of waste, of any type, is found in the Environmental Code and the Waste Ordinance. The Environmental Code provides the overall legal basis for all environmental legislation in Sweden and, together with various ordinances, sets forth the provisions related to emission to the air, water, and soil. That code and its provisions promote sustainable development and apply to all activities that could cause negative impacts on human health or the environment. It addresses, for instance, management of land and water, nature conservation, protection of flora and fauna, environmentally hazardous activities, water-related operations, genetic engineering, chemical products, and waste management. The Environmental Code sets out the framework for implementing environmental protection, while the Waste Ordinance contains details on handling of waste. In addition, there are several ordinances on special waste types, including one on producer responsibility for pharmaceuticals.

According to the Waste Ordinance, cytotoxic and cytostatic pharmaceuticals are classified as hazardous waste and, in consequence, must not be mixed or diluted with other waste, substances, or material, not even other forms of hazardous waste. Transportation of hazardous waste requires a permit under the Waste Ordinance, and this permit must be renewed every five years.

Take-back of household pharmaceuticals

The ordinance on producer responsibility for pharmaceuticals describes provisions for the take-back of leftover household pharmaceuticals. This ordinance states that any retailer of pharmaceuticals (these are mainly pharmacies) is obliged to take back leftover household pharmaceuticals without financial compensation and, further, should inform the public about how and why they should hand in their pharmaceuticals at pharmacies. However, the ordinance on producer responsibility for pharmaceuticals states that the pharmacies are only obliged to take back pharmaceuticals in proportion to the amount of pharmaceuticals that they sell (Sveriges Apoteksförening 2019). For other retailers (such as food stores or petrol stations) selling non-prescription pharmaceuticals over the counter, the party responsible for take-back of pharmaceuticals is the pharmacy that distributed those pharmaceuticals to the retailer (Swedish Medical Products Agency 2012).

Cytostatic and cytotoxic pharmaceuticals are classified as hazardous waste and should be handled as such in accordance with the Waste Ordinance. According to the ordinance on producer responsibility for pharmaceuticals, the collection of hazardous waste falls outside the retailer's responsibilities. Consequently, any leftover cytostatic and cytotoxic pharmaceuticals should not be collected by the pharmacies, per that ordinance and the Waste Ordinance. Instead, the municipalities are responsible for collection, transport, and destruction of any hazardous waste from households. However, cytostatic and cytotoxic pharmaceuticals are handled mainly by hospitals, other health care providers, and veterinaries, so only a very small amount of household pharmaceuticals is classified as hazardous waste.

Veterinary pharmaceuticals (apart from cytostatic and cytotoxic ones) used by households are also covered by the ordinance on producer responsibility for pharmaceuticals. They should be returned to pharmacies for collection, as long as they are not classified as hazardous waste.

The Swedish municipalities have a responsibility to take adequate care of any leftover household pharmaceuticals that are not handed in at pharmacies (Swedish Environmental Protection Agency 2009).

2.9.2 Current take-back practices

Sweden has a long tradition (established in 1971) of returning unused pharmaceuticals to pharmacies; this was introduced by the Swedish monopoly pharmacy chain for security reasons. Sweden's ordinance on producer responsibility for pharmaceuticals has been in effect since 2009, including provisions for the take-back of leftover household pharmaceuticals, and other legislation addresses producers' responsibility and the management of hazardous waste.

The managers of hospitals, health care entities, and veterinary clinics are obliged to collect unused pharmaceuticals and other medical products and make sure they are conveyed to an approved waste-handling system and destroyed by incineration. The most commonplace solution is to have agreements in place with companies approved for incineration of pharmaceutical waste.

All pharmaceutical waste must be separated from other waste, and the pharmaceuticals classified as hazardous waste should be handled separately from other pharmaceuticals. The hospitals and human-health care and veterinary clinics have a responsibility for the traceability of hazardous waste until its destruction by an approved company.

Take-back from households and pharmacies

The take-back collection system consists of a chain of responsibilities that starts with the producers. The ordinance on producer responsibility for pharmaceuticals requires producers to ensure that their pharmaceutical waste from fabrication activities is transported and disposed of in compliance with the law. When the pharmacies have received the pharmaceuticals, they are required to ensure the availability of free take-back collection systems for pharmaceutical waste from households.

The households are, for their part, responsible for sorting their leftover pharmaceuticals and returning them to the pharmacies. The same is true of veterinary pharmaceuticals.

Take-back at region level from hospitals and veterinary clinics

Pharmaceutical waste from hospitals or veterinary practices is not covered by the ordinance on producer responsibility for pharmaceuticals. These parties are responsible for their own appropriate waste-handling activities, under the Environmental Code.

Sweden is divided into 21 regions, politically controlled organisations responsible for leading the work toward sustainable development on regional level, with the mission being primarily to manage public hospitals and health care. Region-level health care is composed of primary care, local health care, and specialist care, which together result in many prescriptions of pharmaceuticals. Hence the regions have a significant responsibility to reduce the impact that pharmaceuticals may entail for the environment (MistraPharma 2011).

Most hospitals and health care centres have their own environmental stations for source-separated waste. The majority of the sorted waste, such as outdated and leftover pharmaceuticals, is sent directly for incineration, per agreements with waste contractors. Some regions send their outdated or leftover pharmaceuticals to pharmacies, which, in turn, send them to special incinerators (Johansson 2019). For those pharmaceuticals classified as hazardous, such as cytostatic and cytotoxic pharmaceuticals, the hospitals and centres must have agreements with transport and handling facilities licensed to destroy pharmaceutical waste (Johansson 2018, Region Östergötland 2019, Region Stockholm 2019).

In Sweden there are also advanced home care (ASIH) or specialized, hospital connected home care (LAH or SAH) that offers an alternative for patients of all ages with multiple diagnoses or serious chronic diseases (Region Stockholm 2020 & Nationella rådet för Pallativ vård 2014). Thus, health care

for severely ill patients is increasingly provided in the home, so pharmaceutical waste from this kind of treatment represents an important issue. The routines for advanced treatment in the home may differ slightly between regions, but in most cases the patients themselves are responsible for seeing that the unused portions of the drugs prescribed are returned to pharmacies. As for pharmaceuticals that the care personnel bring for the home treatment of patients, it is the responsibility of those personnel to return the waste to the hospitals and discard it in accordance with current practices applied in the health care sector (Jatko & Ramstedt 2019).

Information about take-back systems and environmental factors

In 2012, a national campaign was conducted primarily under the auspices of the Swedish Medical Products Agency, together with all pharmacy chains and a trade association, the Swedish Association of the Pharmaceutical Industry (LIF). The focus of the campaign was on raising environmental awareness and on spreading the information that leftover pharmaceuticals, wherever they were bought, should be handed in at pharmacies for disposal (Swedish Medical Products Agency 2012). Since then, the pharmacies themselves have been working for the dissemination of information on the environmental impacts of pharmaceuticals and on how households can reduce these impacts. For example, all pharmacies present information about take-back of unused pharmaceuticals on the Web, although the extent of this varies. The individual chains also work separately, with their own campaigns, to increase the take-back of unused drugs, while also taking part in efforts co-ordinated by the Swedish Pharmacy Association.

In 2014, one of the chains conducted an online interview-based survey of members of the Swedish public, examining habits in handling of unused pharmaceuticals. Only 60% of the participants reported returning their leftover drugs to the pharmacies; on the basis of this result, the pharmacy company initiated concerted efforts to improve the take-back of leftover pharmaceuticals (Burlin Hellman 2014).

In 2017, one of the pharmacy chains introduced the ‘big collection day’ for unused pharmaceuticals in order to raise awareness among the Swedish public. The campaign continued for four weeks, offering customers double the usual amount of bonus points as an ‘environmental bonus’ for handing in unused pharmaceuticals. During the campaign, the number of customers handing in unused pharmaceuticals tripled, and that year saw the collection systems of the country’s various pharmacies receive, in total, 1,200 t (i.e., 1,200,000 kg) of material. The big collection day was repeated in 2018, with twice as many customers as in 2017 handing in pharmaceuticals (Sveriges Apoteksförening 2018, Frisk 2018).

Almost all of the pharmacy chains offer their members bonus credits for handing in unused pharmaceuticals. This has proved to be an effective incentive for citizens’ return of their leftover pharmaceuticals. Also, it benefits the pharmacies when customers visit the location and might buy some products while there (Bergeå 2018).

Evaluation of the take-back practices

Jointly with the largest pharmacy entity in Sweden, LIF conducted surveys aimed at assessing the public awareness related to handling of leftover prescription and/or non-prescription pharmaceuticals in Sweden. These were performed in the years 2001, 2004, 2007, 2011, and 2012. The results (Table 17) show that the larger-scale campaign in 2012 might have had a positive effect with regard to people handing in their pharmaceutical waste at pharmacies, and they also show that ongoing campaigns are necessary for long-term awareness.

Table 17: The Swedish public's awareness about the handling of pharmaceutical waste (per Persson et al. 2009, Swedish Medical Products Agency 2012).

Year	Aware that pharmaceutical waste should be handed in to pharmacies (% of respondents)	Handed in pharmaceutical waste to pharmacies (% of respondents)
2001	86	no data
2004	85	67
2007	85	73
2011	84	69
2012	82	75

The Swedish Medical Products Agency has estimated that 1,500 t of pharmaceuticals will get destroyed or otherwise disposed of in Sweden every year. The bulk of this material is taken care of appropriately, but approximately 250 t gets flushed down drains or discarded with household waste (see Table 18). The latter accounted for about 5% of all prescription pharmaceuticals sold in 2011, with an estimated value of 1,500 million Swedish crowns, equivalent to circa 140 million euros (UNESCO & HELCOM 2017).

Table 18: Amounts of pharmaceutical waste collected in Sweden in 2011 (UNESCO & HELCOM 2017).

Pharmaceuticals estimated to be involved in take-back schemes	1 500 tons
Returned to pharmacies	800 tons
Ending up in the mixed waste from households	250 tons
From public municipalities recycling centres	10 tons
Discarded by internal operations of the pharmacies	50 tons
Discarded by the internal operations of the wholesale's traders	250 ton
Discarded in hospital health care	100 tons

In 2003, a study was performed among Swedish pharmacy customers for investigating the factors in their disposal of unused pharmaceuticals (Ekedahl 2006). The four most commonly cited reasons for pharmaceuticals going unused were that they had passed their expiry date (22% of the respondents), that the patient was deceased (19%), that the pharmaceuticals were not needed anymore on account of an improvement in the user's health (18%), and that the pharmaceutical therapy employed had changed (23%).

Since 2011, there has been neither any calculation of the quantities of pharmaceutical waste collected nor any statistical information from the Medical Products Agency. Since 2017, the Swedish Pharmacy Association has reported the amounts of pharmaceuticals returned to pharmacies. They felt a need to collect this kind of information for purposes of forming an overview of the management of pharmaceuticals. Hence, they have compiled materials on the pharmaceutical industry as a whole. In their last business report, they showed that the total amount of pharmaceuticals collected by the pharmacies in 2018 came to 1,400 t (Sveriges Apoteksförening 2019).

2.9.3 Current disposal practices

In Sweden, pharmaceutical waste is currently collected by pharmacies, by municipalities' collection systems (at recycling centres), and via other health care or hospital management. The hospitals and health care units have well-established routines for handling pharmaceutical waste. For example, some regions have central guidelines regarding disposal of pharmaceuticals, and their health care centres have their own routines and instructions in place that address local circumstances. The pharmacies and regions, then, have agreements with facilities in Sweden that are licensed to destroy pharmaceutical waste (UNESCO & HELCOM 2017).

When pharmaceuticals are returned to pharmacies, they should be placed in transparent plastic bags (to ensure easy identification of the contents) provided by the pharmacies. The pharmaceutical waste is then placed in sealed boxes and transported to the authorised waste destruction facilities. After this, the pharmaceuticals are subjected to controlled burning at 850–1100 °C, and the gas produced is cleaned before release (per the ordinance on incineration of waste, SFS 2013:253). Through this process, complete destruction of the pharmaceutical waste is achieved (Swedish Medical Products Agency 2012, Persson et al. 2009). The same procedures are applied for veterinary pharmaceuticals from households and (in cases of reasonable amounts) from farmers and veterinary clinics.

All farmers and all other traders are obliged to report to the municipality if their activities give rise to hazardous waste. When the veterinary pharmaceuticals used for farmed animals extend to 'unreasonable' amounts, primary responsibility to ensure that the pharmaceutical waste is treated in accordance with the law lies with the farmer/trader. In these cases, the farmers often have an agreement in place with facilities licensed to destroy pharmaceutical waste.

Evaluation of the disposal practices

The practices for disposal of unused pharmaceuticals function well in Sweden. Awareness of the system for disposal of pharmaceutical products is high among citizens (with regard to returning unused pharmaceuticals to pharmacies and not discarding them as household rubbish or via the drain). The system itself is structured with several actors involved, having their own distinct areas of responsibility, which can present both an advantage and a challenge. One benefit for the actors responsible for waste management is that they can divide up the tasks, but pharmaceutical waste can still be found in the hazardous-waste area at recycling centres (mainly because of misunderstanding of the take-back system) rather than returned to pharmacies as it should be.

While the Swedish system for disposal of unused pharmaceuticals can offer good examples for other countries, there are areas that need improvement. The proportion of pharmaceuticals that goes to waste can still be decreased, by such means as developing solid routines related to orders and prescriptions (MistraPharma 2011).

2.9.4 Summary

The main findings pertaining to collection, classification, and disposal of unused pharmaceuticals and other waste containing pharmaceutical residues in Sweden are presented in Table 19.

Table 19: Summary of the collection, classification, and disposal of unused pharmaceuticals and other waste containing pharmaceutical residues in Sweden.

Pharmaceutical waste	Types of pharmaceuticals collected separately	Responsible party for arranging reception	Collection point	Types of pharmaceutical waste classified as hazardous	Legal basis	Method of disposal
Unused human and companion animal pharmaceuticals from households	All Pharmaceuticals	Pharmacies, Municipalities	Pharmacies	Cytostatic and cytotoxic pharmaceuticals	SFS 2009:1031, SFS 2011:927	Incineration for collected waste 800-1000°C For hazardous waste may other methods be use, such as wet chemical treatment, biological treatment or disposal
Pharmaceutical industry (unsalable products, API-contaminated wastes, etc.)	All products, waste fractions and ingredients classified as hazardous waste and pharmaceuticals	Pharmaceutical industry	Agreements with facilities licensed to destroy hazardous waste	Depending on the classification of waste fraction	SFS 2011:927, Environmental Code 1998:808	See above
Pharmaceutical waste from hospitals and health care institutions	All Pharmaceuticals	Hospital, health care institutions management	Routines and agreements with pharmacies and facilities licensed to destroy hazardous waste	Cytostatic and cytotoxic pharmaceuticals	SFS 2011:927, Environmental Code 1998:808	See above
Veterinary pharmaceuticals from veterinarians and veterinary practices	All Pharmaceuticals	Veterinarian, veterinary practices	Pharmacies,for hazardous waste the farmer has agreements with pharmacies and facilities licensed to destroy hazardous waste	Cytostatic and cytotoxic pharmaceuticals	SFS 2011:927, Environmental Code 1998:808	See above
Veterinary pharmaceuticals for livestock animals - reasonable amounts	All Pharmaceuticals	Farmers	Pharmacies, for hazardous waste the farmer has agreements with pharmacies and facilities licensed to destroy hazardous waste	Cytostatic and cytotoxic pharmaceuticals	SFS 2011:927, SJVFS 2019:32, Environmental Code 1998:808	See above
Veterinary pharmaceuticals for livestock animals - unreasonable amounts	All Pharmaceuticals	Farmers	For hazardous waste the farmers must have an agreement with transport and facilities licensed to destroy medical waste	Cytostatic and cytotoxic pharmaceuticals	SFS 2011:927, SJVFS 2019:32, Environmental Code 1998:808	See above

In conclusion, the following aspects of Sweden's take-back system and the disposal of unused pharmaceuticals in Sweden were identified as noteworthy.

Advantages:

+ The pharmacy take-back scheme appears to be efficient. There is clear legislation that articulates the division of responsibility for take-back of unused pharmaceuticals.
+ Public awareness of take-back management for unused pharmaceuticals is relatively high, at about 80%.
+ There are no direct costs to the consumer for returning leftover pharmaceuticals. In fact, customers often get rewarded via bonus systems at the pharmacies, which create an incentive for citizens to return these pharmaceuticals.
+ Swedish pharmacies see environmental profiling as a competitive advantage, which may act in favour of the take-back system's further development and aid in the environmental aspects of pharmaceutical management.

Areas that need improvement:

- More information needs to be distributed to the public about handling of unused pharmaceuticals, along with pharmaceutical management overall. Sweden has a well-functioning take-back scheme, but the amounts of unused pharmaceuticals and their mishandling should still be decreased. For example, consumers often keep additional amounts of pharmaceuticals at home 'for safety's sake', and this necessitates changes in behaviour.
- The pharmacies' costs for handling returned household pharmaceuticals are presumed to be covered by trade margins set by the Dental and Pharmaceutical Benefits Agency (TLV) in Sweden. This margin, consisting of a fixed amount and a percentage surcharge based on the purchase price, is meant to cover the costs of dispensing prescriptions, providing related counselling to the customer, and handling generic exchange of medicines. If other factors are added in, however, such as keeping pharmaceuticals in stock and the labour involved in take-back of leftover pharmaceuticals, the pharmacies are underfunded. Either the trade margins have to rise or some changes to regulations must be made, to prevent pharmacies from finding it difficult to maintain their current level of service in the long run (Sveriges Apoteksförening 2019).

Uncertainties:

• According to the HELCOM report from 2018, 70% of Sweden's unused pharmaceuticals are collected. This is a healthy figure, but uncertainties remain with regard to what this 70% really represents: the mass of the actual pharmaceuticals or mostly their packages. We need more up-to-date information also.
• There is some uncertainty related to proposing more 'starter' packages. On one hand, there are advantages to smaller packages for medicines, which enable easier adjustment of the prescription after the necessary dosage has been ascertained. On the other hand, these packages are more expensive and often are not stocked by pharmacies.

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3 Findings on national practices for take-back and disposal of unused pharmaceuticals and other pharmaceutical waste

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In general, the information basis of this study is scarcer for Lithuania and Russia than for Denmark, Estonia, Finland, Germany, Latvia, Poland and Sweden. This should be kept in mind when considering the results brought up in chapter 3. Statistics about pharmaceutical waste do not allow for comprehensive comparison between masses produced by households, industrial activities and other sources for the whole Baltic Sea Region.

3.1 Classification of pharmaceutical waste

In general, the Baltic Sea region displays great variation with regard to which types of pharmaceutical waste are classified as hazardous waste (see Table 20). In Denmark and Finland, all unused household pharmaceuticals, those meant for humans and those intended for companion animals alike, are considered to be hazardous waste. In Germany, Latvia, Poland, and Sweden, only unused cytostatic and cytotoxic pharmaceuticals are regarded as hazardous waste in line with the European Commission's list of waste categories (2014/955/EU). In Estonia, only unused prescribed pharmaceuticals are deemed hazardous waste. The Lithuanian and Russian situation related to this issue is unknown.

In general, the classification of the waste produced by the pharmaceutical industry in the Baltic Sea region depends on the hazardous properties of the waste fraction.

The classification varies also in the cases of hospitals and residential institutions, veterinarians, and farms. In Denmark and Finland, all unused pharmaceuticals from these sectors are classified as hazardous waste; in Estonia, their classification depends on the hazardous properties of the waste; and in Germany, Poland, and Sweden, cytostatic and cytotoxic pharmaceuticals are classified as hazardous. In Latvia, all pharmaceutical waste from hospitals, residential institutions, veterinarians, and veterinary practices is classified as hazardous, but in cases of farms this is true for only that waste generated in the process of animals' birth; the diagnosis, treatment, or prevention of illness in animals; and experiments involving animals. The classification schemes employed in Lithuania and Russia are unknown.

Table 20: Summary information on which kinds of unused human-use and veterinary pharmaceuticals and other waste containing pharmaceutical residues are classified as hazardous waste in the countries studied.

Country	Households - humans	Households - companion animals	Industry	Hospitals and healthcare institutions	Veterinarians & veterinary practices	Farms (livestock)
Denmark	All	All	Depending on classification of the waste fraction. Final product and certain ingredients are classified as hazardous	All	All	All
Estonia	Prescribed pharmaceuticals are considered as hazardous waste	Prescribed pharmaceuticals are considered as hazardous waste	Depends on hazardous properties of the waste	Depends on hazardous properties of the waste	Depends on hazardous properties of the waste	Depends on hazardous properties of the waste
Finland	All	All	Depends on hazardous properties of the waste	All	All	All
Germany	Cytostatic and cytotoxic pharmaceuticals	Cytostatic and cytotoxic pharmaceuticals	All unsalable products, API-contaminated wastes, etc., depends on hazardous properties of the waste	Cytostatic and cytotoxic pharmaceuticals	Cytostatic and cytotoxic pharmaceuticals	Cytostatic and cytotoxic pharmaceuticals
Latvia	Cytostatic and cytotoxic pharmaceuticals	Waste, that occurs in the process of animal birth, diagnosing, treating or preventing animal illness as well as experiments using animals	Cytostatic and cytotoxic pharmaceuticals	All	All	Waste, that occurs in the process of animal birth, diagnosing, treating or preventing animal illness as well as experiments using animals
Lithuania	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown
Poland	Cytostatic & cytotoxic pharmaceuticals// All pharmaceuticals*	Cytostatic & cytotoxic pharmaceuticals// All pharmaceuticals*	All unsalable products, API-contaminated wastes, etc., depends on hazardous properties of the waste	All	All	Cytostatic & cytotoxic pharmaceuticals / All Pharmaceuticals
Russia	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown
Sweden	Cytostatic and cytotoxic pharmaceuticals	Cytostatic and cytotoxic pharmaceuticals	Depending on the classification of waste fraction	Cytostatic and cytotoxic pharmaceuticals	Cytostatic and cytotoxic pharmaceuticals	Cytostatic and cytotoxic pharmaceuticals

* Problems with interpretation of the national legislation.

3.2 Take-back and collection of unused pharmaceuticals and other waste containing pharmaceutical residues

First, it is important to note that the statistics about pharmaceutical waste are often based on EU waste codes, which do not provide detailed information about the composition of the waste. However, other remarks and conclusions can be made based on available information.

3.2.1 Households

Unused human pharmaceuticals

In general, the proportion of surveyed citizens who return the unused pharmaceuticals to the designated collection points varies greatly between the Baltic Sea countries; from about 10% to 70% (no information from Denmark, Estonia and Germany). Respectively, about 16–80% disposed them of as mixed household waste and 3–30% flushed them down the drain (Table 21). Thus, the situation in the Baltic Sea region is similar to that in EU in general, because in the majority of EU member states, a big share of unused medicines (50–90%) are not collected or returned to pharmacies or other appropriate take-back sites (BIO Intelligence Service 2013). It should be noted that uncertainties remain concerning what the figures presented in Table 21 really represent. The figures pertaining to such activities as returning the unused pharmaceuticals indicate the share of people, not the share of the weight of the actual medicines or number of medicine packages. Nevertheless, the figures probably indicate roughly well the differences between BSR countries although they do not include actual amounts of returned unused pharmaceuticals.

Table 21. Citizens ways to get rid of unused pharmaceuticals in the BSR.

Country / year of interviews or year when study was published	Share of the surveyed people that returned unused pharmaceuticals to pharmacies and hazardous waste collection points	Share of the surveyed people that flushed unused pharmaceuticals to sewer	Share of the surveyed people that disposed unused pharmaceuticals to mixed household waste
Finland / studies made 2009–2010	65% (60–80%)	3%	16%
Latvia / studies made in 2012 & 2014	6–10%	5–12%	41–62%
Lithuania / study made in 2013	10–13%	no info	50–64%
Poland / 2015 (study published)	5-8%	24–33%	57–60%
Sweden / studies made in 2011 & 2012	69–75%	≈ 17%	
Russia / 2013 (study published)	no info	15%	80%

The main findings on national take-back schemes of unused human pharmaceuticals from households are as follows (Table 22):

- The responsible party for arranging reception of unused pharmaceuticals from households is usually the municipality, as it is in Denmark, Estonia, Finland, Germany, Latvia, Poland and Sweden. In Sweden also pharmacies are responsible for arranging the reception. In Lithuania the responsible party is unclear. In Russia there is no legislation and thus no responsible party for arranging the reception.
- Russian legislation does not regulate collection of unused pharmaceuticals from households.
- In general, the pharmacies are the collection points in the Baltic Sea region, except in Germany and Russia:
  - in Germany, Latvia and Poland only some pharmacies receive unused human pharmaceuticals.
- It varies a lot what kind of unused household pharmaceuticals are separately collected in the Baltic Sea countries:
  - all unused pharmaceuticals separately collected in Denmark, Estonia, Finland, Latvia, Poland and Sweden,
  - no separate collection for unused pharmaceuticals in Germany and Russia.
    - In Germany, where mixed household waste is often incinerated, people are instructed to dispose unused pharmaceuticals with mixed household waste. However, in case household waste is not incinerated, disposal of pharmaceuticals at mobile collection vehicles or recycling centres is recommended.
- Pharmacy-based take-back system is well established, extensive and functions quite well. There is clear legislation which states the division of responsibility for take-back of unused drugs in Denmark, Estonia, Finland and Sweden.
- In some countries (Germany, Latvia, Poland) some pharmacies accept unused medicines on voluntary basis, but that is not their obligation and the collection system is not properly organized. Partly due to these reasons, the citizens of these countries return their unused medicines relatively rarely to pharmacies but dispose them of into toilet or sink or to mixed household waste.
- The most common reason for improper disposal of medicines from households appears to be the lack of information on how to get rid of them in an environmentally sound manner. Other reasons are indifference, hurry, long distances to collection points and that the amount of the medicine was small or that it was thought to be harmless (e.g., Denmark, Finland, and Latvia).
- The returning of unused pharmaceuticals is commonly free of charge for cítizens (e.g., Estonia, Finland, and Sweden). In Sweden pharmacy customers get sometimes rewarded with bonus-

systems at the pharmacies. This creates an incentive for the citizens to return their unused medicines.

- Pharmacy-based take-back systems that were assessed to be efficient, have several common positive features:
  - an extensive pharmacy (i.e., collection-point) network
  - absence of direct costs for the citizens
  - status as a well-known collection system among citizens
  - encouragement of also the pharmacies to dispose of unused medicines properly, because pharmacies can for free include their own pharmaceutical waste among the collected waste to be delivered to proper disposal.
- The Swedish pharmacies see environmental profiling as a competitive advantage, which benefits the development of more efficient take-back system.

Table 22. The national practices on take-back of unused human and companion animal pharmaceuticals from households.

Country	Types of pharmaceuticals collected separately	Responsible party for arranging reception	Collection point
Denmark – human and companion animal	All pharmaceuticals	Municipality	Usually local pharmacies (depends on municipality)
Estonia – human and companion animal	All pharmaceuticals	Municipality	Local pharmacies and municipal waste collection stations
Finland – human and companion animal	All pharmaceuticals	Municipality	Usually local pharmacies; seldom municipal waste collection stations (depends on municipality)
Germany – human and companion animal	Nothing	Municipality	Depends on municipality
Latvia – human and companion animal	All pharmaceuticals	Municipality /state for hazardous waste	Usually local pharmacies and waste sorting areas
Lithuania – human and companion animal	No information	Unclear	Pharmacies
Poland – human	All pharmaceuticals	Municipality	Usually local pharmacies or other collection points (depends on municipality)
Poland – companion animal	Lack of information	Veterinarian or veterinary practice / municipality	Veterinarian or veterinary practice. Usually local pharmacy (depends on municipality).
Russia – human and companion animal	None	No responsible party	Not exist
Sweden – human and companion animal	All pharmaceuticals	Pharmacies / municipalities	Pharmacies

Unused companion animal pharmaceuticals

The main findings on national take-back practices on unused companion animal pharmaceuticals from households are:

- Municipalities are the responsible party for arranging the reception of unused medicines in Denmark, Estonia, Finland, Germany, Latvia, Poland and Sweden.
  - In Poland also veterinarians are responsible for arranging the reception.
  - In Latvia state is responsible for hazardous waste.
  - In Sweden also pharmacies are responsible for arranging the reception.
- Pharmacies act as main collection points in Denmark, Estonia, Finland, Latvia, Poland and Sweden.
  - In Poland also veterinarians or veterinary practices act as collection points.
  - In Germany, Latvia and Poland only some pharmacies receive unused companion animal pharmaceuticals.
  - In Lithuania pharmacies are obligated to receive unused medicines from households and this presumably concerns companion animal medicines, but the pharmacies do not inform citizens about this.
- Russian legislation does not regulate collection of companion animal pharmaceuticals from households.
- There is no information about quantity or quality of unused companion animal medicine.

Identified areas for improvement

Areas of improvement concerning take-back of unused household pharmaceuticals are as follows:

- Raising public awareness on proper disposal of unused household pharmaceuticals is important and would increase the fraction of unused medicines correctly returned (e.g., Denmark, Estonia, Finland, Germany, Latvia, and Sweden).
- Scarce data makes the validation of the take-back scheme questionable. Most of the studies focus on economic aspects and do not consider the environmental aspects. More research-based information regarding the take-back fractions and actual amounts of unused pharmaceuticals is needed in order to follow and improve the efficiency of take-back scheme of human medicines (e.g., Denmark, Estonia, Finland, Germany, Latvia, and Sweden).
- In some countries the interpretations of the regulations are unclear (Poland) and there are serious deficiencies in legislation (Lithuania and Russia).
- Unclear liabilities and instructions cause dissatisfaction to pharmacies and waste management companies (e.g., Finland).
- The project has raised the question of the difference between hazardous-waste management and the management of unused pharmaceuticals. The take-back systems in different countries could benefit from the development of recycling centres so that all household waste can be collected in the same place. It might decrease the mishandling of unused pharmaceuticals and be an incentive for people to leave their pharmaceutical waste to proper management.

3.2.2 Pharmaceutical industry

The main findings on national management practices on pharmaceutical industry waste containing pharmaceutical residues are as follows (Table 23):

- In each of the countries, industrial operators are responsible for arranging the treatment of the pharmaceutical waste produced in their activities.

- In each country, the separate collection of pharmaceutical waste produced by industry is either organised through collaboration with waste-management companies or otherwise arranged by the industry operator.
- Pharmaceutical industry is the largest source of pharmaceutical waste at least in Denmark. This waste originates for instance from errors in production and labelling, and expiry of medicines. However, statistics about pharmaceutical waste do not currently allow for comprehensive comparison between masses produced by households, industrial activities and other sources for the whole Baltic Sea Region. Industry might produce more waste in areas, where there are more industrial activities. The highest number of pharmaceutical industry sites within the Baltic Sea catchment area is located in Poland, Denmark and Sweden (Leisk et al. 2020, Wallberg et al. 2014).
- There is no information from Lithuania and Russia.

Table 23. The national practices on take-back of unused pharmaceuticals from pharmaceutical industry.

Country	Types of waste containing pharmaceutical residues collected separately	Responsible party for arranging reception	Collection point
Denmark	All products, waste fractions and ingredients classified as hazardous waste and pharmaceuticals	Industry operator	Organized and paid by the individual industry operator
Estonia	No information	Industry operator	Licensed waste management company or municipal waste collection point, if a special agreement
Finland	All waste classified as hazardous waste	Industry operator	Organized by the industry operator
Germany	All	Service provider, Industry operator	Organized by the industry operator
Latvia	All	Industry operator, State for hazardous types of waste	Organized by the industry operator (delivered to hazardous waste manager with appropriate environmental permits)
Lithuania	No information	No information	No information
Poland	All products, waste fractions and ingredients classified as hazardous waste and pharmaceuticals	Industry operator	Organized by the industry operator
Russia	No information	No information	No information
Sweden	All products, waste fractions and ingredients which are classified as hazardous waste and pharmaceuticals	Industry operator	Pharmaceutical industry routines through agreements with facilities licensed to destroy hazardous waste

3.2.3 Hospitals and health care institutions

The main findings on national take-back practices on unused pharmaceuticals from hospitals and other health care institutions are as follows (Table 24):

- In Estonia, Denmark, Finland, Germany, Latvia, Poland and Sweden hospitals arrange the handling of pharmaceutical waste by themselves. In Estonia pharmaceutical waste generated as the result of other health services must be transferred to a licensed waste management company.
- In Poland and Sweden also other health care institutions than hospitals are obligated to collect their pharmaceutical waste and transfer them to the appropriate disposal operators.
- In Denmark practising doctors, nursing homes and health care institutions other than hospitals can return unused medicines also to pharmacies. In Finland the unused medicines from domiciliary care or from supported and service housing are usually disposed in a coordinated manner via pharmacies.
- Although practice in which hospitals arrange the handling of pharmaceutical waste by themselves appears to be simple and efficient, there is hardly any actual surveys done about how well this practise is accomplished.
- In Poland, it has been recognized that practices in health care institutions are not always compliant with national waste legislation.
- In Lithuania and Russia the situation is unknown.

Table 24. The national practices on take-back schemes of unused pharmaceuticals in hospitals and health care institutions.

Country	Types of pharmaceuticals collected separately	Responsible party for arranging reception	Collection point
Denmark	All pharmaceuticals	Hospitals or health care institutions / municipality	Individual hand in by hospitals, or municipally organized hand in, usually pharmacy.
Estonia	All pharmaceuticals	Hospitals or health care institutions	Licensed waste management company
Finland	All pharmaceuticals	Hospitals or health care institutions / municipality	Organized by the hospital or health care institution / for hospitals usually hospital pharmacies
Germany	All pharmaceuticals	Hospitals or health care institutions	Organized by the hospital or health care institution
Latvia	All pharmaceuticals	Hospitals or health care institutions	Organized by the hospital or health care institution
Lithuania	No information	No information	No information
Poland	All pharmaceuticals	Hospitals or health care institutions	Organized by the hospital or health care institution
Russia	No information	No information	No information
Sweden	All pharmaceuticals	Hospitals or health care institutions	Hospital and health care institutions routines and agreements with pharmacies and facilities licensed to destroy hazardous waste

3.2.4 Veterinarians and veterinary practices

The main findings on national take-back practices on unused veterinary pharmaceuticals from veterinary practices are as follows (Table 25):

- In Estonia, Finland, Germany, Latvia, Poland and Sweden veterinaries are responsible for arranging the collection of their own unused medicines.
- Usually, there are no specific collection points, but veterinarians and veterinary practices make their own arrangements.
    - In Denmark and Sweden: can also return to pharmacies.
- In Lithuania and Russia the situation is unknown.

Table 25. The national practices on take-back of unused pharmaceuticals from veterinarians and veterinary practices.

Country	Types of pharmaceuticals collected separately	Responsible party for arranging reception	Collection point
Denmark	All pharmaceuticals	Municipality	Usually local pharmacy
Estonia	All pharmaceuticals	Veterinarians or veterinary practices	Licensed waste management company
Finland	All pharmaceuticals	Veterinarians or veterinary practices	Organized by the veterinarian or veterinary practice
Germany	Cytotoxic and cytostatic pharmaceuticals	Veterinarian or veterinary practice or municipality	Organized by the veterinarian or veterinary practice
Latvia	All pharmaceuticals	Veterinarians or veterinary practices	Organized by the veterinarian or veterinary practice
Lithuania	No information	No information	No information
Poland	All pharmaceuticals	Veterinarians or veterinary practices	Organized by the veterinarian or veterinary practice
Russia	No information	No information	No information
Sweden	All pharmaceuticals	Veterinarians or veterinary practices	Pharmacies

3.2.5 Veterinary pharmaceuticals used for livestock in farms

The main findings on national take-back practices on unused veterinary pharmaceuticals used for livestock are as follows (Table 26):

- There is variation in the responsible party for arranging the collection and it can be the farmer, municipality or veterinarian.
- The collection point can also be:
  - a pharmacy in Denmark, Finland (small amounts), Germany (small amounts), Poland and Sweden (non-hazardous only)
  - a veterinarian in Poland
- a farmer is obligated to arrange the collection in Estonia (if the farm is a legal entity), Finland (large amounts), Germany (large amounts), Latvia (big farms) and Sweden (hazardous waste)
- In Lithuania and Russia the situation is unknown.

In general, in several Baltic Sea countries unused veterinary pharmaceuticals used for livestock in farms is collected together with other types of veterinary waste by veterinarians or returned to local collection points (e.g. pharmacies) by farmers or managed via contracted waste operators organized by farmers or they are directly disposed of in the municipal waste stream.

Table 26. The national practices on take-back of unused veterinary pharmaceuticals in farms.

Country	Types of pharmaceuticals collected separately	Responsible party for arranging reception	Collection point
Denmark	All pharmaceuticals	Municipality	Usually local pharmacy
Estonia	All pharmaceuticals	Farmer (if legal entity)	Licensed waste management company
Finland	All pharmaceuticals	Municipality	Usually local pharmacy* (depends on municipality)
Germany	Cytotoxic and cytostatic pharmaceuticals	Farmer / Service provider / Municipality	Usually local pharmacy*
Latvia	All pharmaceuticals	Farmer; Municipality / State for hazardous waste	Pharmacies or waste sorting areas/ farmers of large productive animal sheds must have an agreement with managers of hazardous waste
Lithuania	No information	No information	No information
Poland	Lack of information	Veterinarian or veterinary practice / municipality	Veterinarian or veterinary practice. Usually local pharmacy (depends on municipality)
Russia	No information	No information	No information
Sweden	All pharmaceuticals	Farmer	Pharmacies / for hazardous waste farmers must have an agreement with transport and facilities licensed to destroy medical waste

* Farmer is obligated to arrange the delivery to proper treatment in case of unreasonable amount of unused veterinary pharmaceuticals.

3.3 Disposal of unused medicines and other waste containing pharmaceutical residues

3.3.1 Households

The findings on national disposal practices on unused pharmaceuticals from households are as follows (see Table 27 in the 3.3.6.):

- The main disposal method for the sorted unused human and companion animal medicines in the Baltic Sea region is incineration (Denmark, Estonia, Finland, Germany, Latvia, Poland, Sweden).
- High temperature incineration (> 1100 °C) appears to be a controlled and efficient treatment method at least in Estonia (1300 °C), Finland (1100-1300 °C), Poland (1100 °C) and Denmark (>1100 °C). The incineration temperature is in Latvia 850 °C, in Germany 850–1300 °C and in Sweden 850–1100 °C.
- In Russia the unused household medicines are not collected separately and the main disposal method is landfilling at designated sites
- Uncertainties related to disposal of unused human pharmaceuticals from households are:
  - Few public data and information on the high temperature incineration operated by companies (e.g. Denmark).
  - Is it possible that lower than 1100–1300 °C incineration temperature would be enough for irreversible treatment of pharmaceutical wastes.

3.3.2 Pharmaceutical industry

The findings on national disposal practices of waste from pharmaceutical industry are as follows (see Table 27 in the 3.3.6.):

- The main method of disposal for hazardous wastes produced in manufacturing activities is incineration (temperatures varying from 800 to 1300 °C).
  - Other treatment methods: wet chemical treatment and biological treatment.
  - In Russia waste is treated with incineration, discharge into industrial sewers and landfilling at designated sites.
- At least in Latvia, pharmaceutical wastes originating from wholesaler and production activities may eventually be disposed of in a municipal landfill.
- No information available from Lithuania.

3.3.3 Hospitals and health care institutions

The findings on national disposal practices of waste containing pharmaceutical residues from hospitals and health care institutions are as follows (see Table 27 in the 3.3.6.):

- The main disposal method of pharmaceutical waste from hospitals and health care institutions is incineration with temperatures varying from 800 to 1300 °C (Denmark, Estonia, Finland, Poland, Sweden).
- In Germany advanced solid waste incineration (850–1300 °C) or high temperature incineration (1000–1300 °C) are used.
- In Latvia the method is disposal at hazardous waste landfill or recycling in a bioreactor.
- In Russia waste is treated with incineration and with chemical and thermochemical destruction method.
- In Lithuania the situation is unknown.

3.3.4 Veterinarians and veterinary practices

The findings on national disposal practices of unused veterinary pharmaceuticals from veterinarians and veterinary practices are as follows (see Table 27 in the 3.3.6.):

- Incineration with temperatures varying from 850 to 1300 °C is the general method of disposal of veterinary medicine waste (Denmark, Estonia, Finland, Germany, Poland, Sweden).
- Mechanical and biological treatment of veterinary medicine waste is also used in Estonia, Germany and Sweden and landfilling in Estonia.
- In Latvia the veterinary medicine waste is disposed at hazardous waste landfill or recycled in a bioreactor.
- In Lithuania and Russia the situation of this specific sector is unknown.

3.3.5 Veterinary pharmaceuticals used for livestock in farms

The findings on national disposal practices of unused veterinary pharmaceuticals used for livestock in farms are as follows (see Table 27 in the chapter 3.3.6.):

- The incineration with temperatures varying from 850 to 1300 °C is the general method of disposal. Mechanical and biological treatment is also used in Sweden, Estonia and Germany and landfilling in Estonia.
- In Lithuania and Russia the situation of this specific sector is unknown.

3.3.6 Summary of the disposal of unused medicines

Summary of the information presented in chapters 3.3.1–3.3.5 are presented in the Table 27.

Table 27. Summary of the disposal of unused medicines and other waste containing pharmaceutical residues in the Baltic Sea region.

Country	Households (human & companion animal)	Pharmaceutical industry	Hospitals and health care institutions	Veterinarians and veterinary practices	Farms
Denmark	High temperature incineration for collected waste (1100 °C)				
Finland	High temperature incineration for collected waste (1100–1300 °C)				
Sweden	Incineration for collected waste 800–1000 °C. For hazardous waste may other methods be used, such as wet chemical treatment, biological treatment or disposal				
Lithuania	Incineration		Unknown		
Russia	Landfilling	Incineration, discharge into industrial sewers and landfilling	Incineration, chemical and thermochemical destruction	Unknown	
Estonia	Hazardous waste (prescribed pharmaceuticals): high temperature incineration (1300 °C). Non-hazardous waste: incineration or biological and mechanical treatment or landfilling	Hazardous waste: high temperature incineration (1300 °C). Non-hazardous waste: incineration or biological and mechanical treatment or landfilling			
Germany	Mechanical biological pre-treatment stage, advanced solid waste incineration (850–1300 °C) or high temperature incineration (1000–1300 °C)	High temperature incineration (1000–1300 °C), physico-chemical treatment, or incineration in power plants	Hazardous waste: high temperature incineration (1000–1300 °C). Non-hazardous waste: mechanical biological pre-treatment stage or an advanced solid waste incineration (850–1300 °C)		
Latvia	Incineration at 850 °C or waste disposal at landfills for collected waste. Waste disposal at landfills for unsorted waste.	Incineration at 850 °C or waste disposal (depending on waste class – hazardous waste is incinerated)	Waste disposal at municipal landfill after sterilization, shredding		
Poland	High temperature incineration (1100 °C)	High temperature incineration (1100 °C)	High temperature incineration (1100 °C)		

4 Good practices and recommendations for take-back and disposal of unused pharmaceuticals and other waste containing pharmaceutical residues

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At the EU level, the Strategic Approach to Pharmaceuticals in the Environment emphasizes e.g. sharing good practices, cooperating at international level, and improving understanding of the risks. It has identified action areas throughout the life cycle of pharmaceuticals, with a strong emphasis on source-directed and use-oriented approaches, as opposed to end-of-pipe treatment options.

OECD Policy paper on pharmaceuticals (OECD 2019) states that “a focus on preventive options early in the pharmaceutical life cycle, may deliver the most long-term, cost-effective and large-scale benefits”.

4.1 Preventive recommendations

4.1.1 The rational use of pharmaceuticals

The rational use of human and veterinary pharmaceuticals reduces the amount of pharmaceutical waste produced and is referred in European Commission strategy paper (EC 2019) as one of six areas for action to reduce the risk posed by medicines released into the environment. The mis- and over-use of antibiotics is an important factor contributing to antimicrobial resistance (AMR) which is a global health crisis with enormous negative health, food security and economic consequences. Up to 50% of the antibiotics prescribed for human use are considered unnecessary; the share is even greater in the agriculture and aquaculture sectors where in some countries antibiotics are administered as a growth promoter and as a substitute for good hygiene. Over-prescription, self-medication (over-the-counter pharmaceuticals) and misdiagnosis of symptoms increase the amount of medicines administered and improperly disposed of but also increase the levels in the environment. The use of advanced diagnostics is very important in order to avoid unnecessary prescriptions (OECD 2019).

About 3–4% of the sold medicines (as price of medicines, not as amount) in Finland are left unused (Association of Finnish Pharmacies 2017) and the same figure for Sweden is estimated to be 5% (BIO Intelligence Service 2013, CCB 2017). European Federation of Pharmaceutical Industries and

Associations (EFPIA) has estimated that the unused human medicines represent 3-8% of the sold amount in Europe (BIO Intelligence Service 2013). In some EU countries 5-50% of purchased medicines end up unused or outdated because of treatment interruptions, mostly due to intolerance to the initial medicine and voluntary discontinuation (BIO Intelligence Service 2013). In the USA, about one-third of the prescription items annually become waste (OECD 2019).

Thus, ***unnecessary and duplicated use of medications should be reduced (Recommendation 1).*** Patients getting new prescriptions could initially be given a small package of the medication, as this would minimize the amount of pharmaceutical waste if it becomes necessary to switch this medicine for another (Nystén et al. 2019). Thus, in order to reduce the amount of pharmaceutical waste the human, companion animal and other veterinary medicines should only be prescribed and used when needed and based on the diagnosis. This is specifically important for antibiotics due to increasing problem related to AMR.

Widening and making the requirement for a compulsory prescription stricter in the human and companion animal medicines is an effective way to control the use of environmentally risky medicines and may decrease the amount of pharmaceutical waste produced (Lockwood et al. 2017). This could be effective especially concerning highly problematic or environmentally risky pharmaceuticals. The share of non-prescription medicines, especially analgesics, is steadily increasing in the total consumption of medicinal products in Germany and has already reached an order of magnitude similar to that of prescription medicines (Ahting et al. 2018). Information about environmental effects of pharmaceutical emissions should be included into the studies of medical doctors already as incorporated in pharmacy studies at least in Finland (Sivén et al. 2020). Information campaigns should be carried out also to practicing medical doctors in order to ensure that similar information is available for all doctors regardless of the career stage.

Instructions on the safe usage of medical products, could be given by pharmacy staff or veterinarians when they hand out the pharmaceuticals to the customers (Recommendation 2). As medicine experts, pharmacists are well placed to increase public awareness, promote the prudent use and correct disposal of pharmaceuticals (PGEU 2019). These instructions could concern for example picking up the faeces of companion animals if medicated with cytostatic.

4.1.2 The unification of take-back and disposal requirements or the harmonization of hazardous waste classification

There are national differences on which pharmaceutical wastes are classified as hazardous, resulting in differences in the collection and treatment of these wastes. To unify their treatment, either the take-back and disposal requirements need to be unified and separated from the waste classification, or the classification criteria need to be harmonized regionally or at the EU-level. To unify the take-back and disposal of wastes contaminated with pharmaceutical residues, it is recommended that ***these kinds of wastes should be collected separately and disposed of appropriately, irrespective of the classification of wastes (Recommendation 3).***

This issue is connected to promotion of e.g. Recommendation 6 (human medicines), Recommendation 7 and 8 (companion animal medicines) and Recommendation 19 (industry)

4.2 Households

This chapter deals with both human medicines and companion animal medicines. In general, the range of APIs available for human medication is much broader than the range of APIs used for veterinary purposes. Antibiotics account for a large part of the veterinary market. In general, at EU level only 1-2% of the veterinary antibiotics sold are for companion animal only, as the large majority is for farming animals (93%), About 5 to 7% of veterinary antibiotics can be used for either companion or farming

animals. Nevertheless, a growing segment of the veterinary products market is the companion animals – in contrast with farming animals (BIO Intelligence Service 2013).

4.2.1 Human medicines

Scarce data makes the validation of the national take-back schemes in the Baltic Sea region questionable. More research-based information regarding the take-back fractions and actual quantities of sold and unused pharmaceuticals are needed in order to follow and improve the efficiency of take-back of human pharmaceuticals.

Thus, it is recommended that the studies about the fate of unused household medicines in all Baltic Sea countries should be regularly (e.g. every 3 years) made in order to follow up the situation (Recommendation 4).

- The studies should cover not only the share of people that return the unused pharmaceuticals properly to the collection point but also e.g. the share of the weight of the pharmaceuticals.
- The studies should be linked to the information campaigns on proper handling of unused medicines (see also Recommendation 5).

One of the reasons mentioned for incorrect disposal of unused medicines, e.g. in Finland and Latvia, is that citizens misleadingly believe that the unused pharmaceuticals and pharmaceutical waste is harmless or that pharmaceuticals are removed from waste waters in municipal WWTPs. Therefore, it is recommended ***to increase the awareness of citizens concerning pharmaceuticals in the environment (Recommendation 5)*** with the following ways:

- Information campaigns will be arranged on proper handling of unused human and companion animal medicines stressing the harmful environmental impacts of incorrectly disposed unused medicines targeted to citizens. Campaigns should consider also environmentally safe use of veterinary medicines.
- Information campaigns could be promoted by different actors such as authorities like national ministries of social and health affairs and environment, medical or environmental agencies and pharmacies or their interest groups. However, it is advantageous if several actors would make a joint campaign.
- The pharmacies should actively give sorting instructions for customers e.g. when selling medicines. As medicine experts, pharmacists are well placed and motivated to increase public awareness, promote the prudent use and correct disposal of unused pharmaceuticals.

This action, i.e. increase public awareness on proper handling of unused medicines, has been stated in European Commission strategy paper (EC 2019) as one way to reduce the risk posed by medicines released into the environment. OECD's Policy paper on pharmaceuticals (OECD 2019) recommends e.g. to "Educate and engage with health professionals, veterinarians, consumers and farmers to raise awareness about inappropriate disposal of unused medications". Education about the proper disposal is a relatively low cost and effective reduction measure (Ahting et al. 2018).

For the citizen the easiest and the most recommended way is to return both prescribed and over-the-counter pharmaceuticals (i.e. all unused household medicines) independent of its waste classification to permissible collection point (Recommendation 6).

- Sufficiently high density of permissible collection points as well as their location near citizens is important.
- Information about collection points and sorting instructions should be concise and understandable but also easily accessible for citizens.
- Permissible collection points could be pharmacies or hazardous waste collection sites.
- Costs should be divided to several actors in order to avoid "overload" one actor such as pharmacy.

- Citizens should be able to return unused pharmaceuticals to dedicated permissible collection points free of charge. The costs for separate collection and treatment of these waste fractions should not have to be covered (via separate price tag) by pharmacies.
    - As an incentive, pharmacies should be allowed to put their own pharmaceutical waste without charge into the waste transported to disposal.
    - Municipalities should partly cover the costs e.g. by arranging the delivery of unused medicines from pharmacies to disposal site.

Extra incentives for returning unused pharmaceuticals to pharmacies should be looked into. For example, by giving extra bonus points to customers returning unused pharmaceuticals like has been done via campaigns in Sweden.

4.2.2 Companion animal medicines

Customers should be able to return all unused companion animal medicines, irrespective of their waste classification, to same collection point (e.g. to pharmacies), where the collection of human medicines takes place (Recommendation 7). This possibility should be advertised to citizens in order to avoid confusion.

Customers should be given the option of returning all unused veterinary pharmaceuticals, irrespective of their waste classification, to veterinary clinics, if this is in line with national legislation (Recommendation 8). Costs could be covered in same country-specific way that is already done in cases of pharmacies. This means that the costs for separate collection and treatment of these waste fractions should not have to be covered with separate price tag by veterinary practices. As an incentive, veterinary practices should be allowed to put their own pharmaceutical waste without charge into the waste transported to disposal.

As in the case of unused human medicines, customers should be provided with information about the proper handling of unused companion animal medicines (Recommendation 9). It is recommended that companion animal medicines are included to information campaigns mentioned in Recommendation 5.

All Baltic Sea region countries lack information about the amounts and quality of unused companion animal medicines. Statistics about returned unused companion animal medicines should be produced for the sake of achieving a better view (Recommendation 10). But before this, it is recommended that the consumption information of companion animal medicines should be collected from each country.

4.3 Hospitals and health care institutions

Efficient practice is that hospitals collect their own pharmaceutical waste and send it directly to waste treatment facilities as it is now taking place (Recommendation 11).

Other health care institutions, such as facilities providing service housings, retirement homes, private clinics or other operators providing domiciliary care, should have centralized collection scheme for the pharmaceutical wastes (Recommendation 12). This collection scheme should cover the pharmaceuticals administered to patients in the activities within the facility, but also the unused pharmaceuticals from the personal medications of individual patients. This would ensure, that also people with possible disabilities would have an easily accessible collection point for all of their unused pharmaceuticals.

4.4 Farms

It is stated in the regulation (EU) 2019/2016 that *"antimicrobial medicinal products shall not be applied routinely nor used to compensate for poor hygiene, inadequate animal husbandry or lack of care or to compensate for poor farm management" and "antimicrobial medicinal products shall not be used in animals for the purpose of promoting growth nor to increase yield*". In EU's Strategic Approach to Pharmaceuticals in the Environment (COM/2019/128 final) is presented the Commission's intention to promote prudent use of pharmaceuticals.

The implementation of take-back systems in EU member states is very heterogeneous: the take-back is better organised for human medicines than for veterinary medicines in several EU member states. Veterinary medicine waste is collected together with other types of veterinary waste by veterinarians or directly disposed of in the municipal waste stream (Lockwood et al. 2017). These collection methods and the returning to local collection points (e.g. pharmacies) by farmers or managed via contracted waste operators organized by farmers were found to be current practices in several Baltic Sea countries. But in general information on the take-back schemes for unused human medicines is more readily available than the information concerning veterinary medicines in the Baltic Sea region.

When the veterinarian is making check-up visits to the farm, the farmer should have the option of returning unused veterinary medicines to the veterinarian, who should have a possibility to charge the collection costs. (Recommendation 13).

If the amount of accumulating unused medicines is unreasonable, farmers should be responsible for organizing the delivery of medicines to appropriate treatment in the same way as pharmacies and hospitals do. Reasonable amounts of unused medicines should be allowed to be returned to the same collection points same way as the unused household medicines. However, "reasonable" and "unreasonable" amounts should be defined more specifically (Recommendation 14).

Information campaigns targeted on farmers could improve the knowledge about how unused medicines should be handled appropriately (Recommendation 15). National ministries for the environment and agriculture should promote and offer financial support for the information campaigns.

4.5 Veterinarians and veterinary practices

Efficient practice is that veterinarian and veterinary practices collect the pharmaceutical waste produced by their own activities or returned to them by farmers or households and send it directly to waste treatment facilities as it is now taking place at least in some BS countries (Recommendation 16).

Information about proper disposal and handling of unused medicines and potential harmful environmental effects of pharmaceutical emissions should be included into the education of veterinarians (Recommendation 17).

The information campaigns (incl. guidelines/good practices) should be also carried to veterinarians and other medical staff of veterinary practices in order to ensure that similar information is available for already practicing veterinarians (Recommendation 18).

These information campaigns should be promoted by different actors such as national ministries for agriculture and environment, medical or environmental agencies or agricultural interest groups.

4.6 Pharmaceutical industry

Currently the treatment of industrial wastes contaminated with pharmaceutical residues depends on its waste classification. At the moment, industrial pharmaceutical wastes classified as hazardous are to be collected separately and to be disposed of properly in each of the countries.

However, there are national differences on the application of waste classification criteria. Additionally, the waste directive (2008/98/EC) allows national deviations from the classification to a certain extent. Currently the pharmaceutical wastes produced by industry are not categorically classified as hazardous in any Baltic Sea country but are only classified as such based on the properties of the waste. According to 2008/98/EC, waste is to be classified as hazardous if it has one or more properties listed in Annex III of 2008/98/EC. However, some countries also classify e.g. final products (DK) or unusable products (DE) generated by pharmaceutical industry as hazardous waste, while some others may classify industrial wastes as hazardous based on their cytotoxic or cytostatic properties (LV & PL).

Therefore, it is recommended either that the disposal requirements are unified and separated from the waste classification, or that the classification of pharmaceutical waste is unified regionally or at the EU-level. Harmonizing and clarifying waste classification in the BSR, or at the EU-level, would help to unify the properties that make pharmaceutical waste fraction hazardous.

To unify the disposal of industrial wastes contaminated with pharmaceutical residues in the Baltic Sea region, it is recommended that this kind of wastes should be collected separately and disposed of appropriately, irrespective of its waste classification (Recommendation 19). However, to prevent unnecessary climate impacts and waste of resources, wastes contaminated exclusively with vitamins, electrolytes, amino acids, peptides, proteins, carbohydrates and lipids should not be considered to require intensive treatment (e.g. high temperature incineration) or separate collection, unless there is reason to expect them to cause environmental risk. This applies also to vaccines and herbal medicinal products.

4.7 Disposal

High temperature incineration (at around 1 100–1 300 °C) is recommended treatment method for unused medicines and other pharmaceutical waste, unless a lower temperature is proven to irreversibly transform the active ingredients into non-hazardous substances (Recommendation 20).

All operators managing the disposal of wastes containing pharmaceutical residues must have the appropriate environmental permits required by national legislation (Recommendation 21).

These recommendations apply also to wastes generated in industrial activities with exceptions indicated in Recommendation 19.

4.8 Summary

The proportion of surveyed citizens who return unused pharmaceuticals via designated collection points varies greatly amongst Baltic Sea countries, from about 10% to 70%, with 16–80% disposing of them of as mixed household waste and 3–30% flushing them down the drain. Nevertheless, this kind of information is not available from Denmark, Estonia and Germany. The most commonly cited reason for improper disposal of medicines on households' part is lack of information about their environmental impacts and how to get rid of them in an environmentally sound manner.

Separate collection of unused household pharmaceuticals does not exist in Russia, and the collection mechanism functions poorly in Latvia, Lithuania and Poland. In Germany, where mixed household waste is often incinerated, people are instructed to dispose unused pharmaceuticals with mixed household waste. However, in case household waste is not incinerated, disposal of pharmaceuticals at mobile collection vehicles or recycling centres is recommended in Germany. Pharmacy-based take-back system seem to be well established, extensive and functions quite well. There is clear legislation which states the division of responsibility for take-back of unused pharmaceuticals in Denmark, Estonia, Finland and Sweden.

The take-back for human medicines is usually better organised than for veterinary medicines. Statistics about pharmaceutical waste do not currently allow for comprehensive comparison between masses produced by households, industrial activities and other sources for the whole Baltic Sea Region. Pharmaceutical industry may produce more waste in areas, where there are more industrial activities such as in Poland, Denmark and Sweden.

Information on the take-back schemes for unused human medicines is more readily available than is corresponding information on veterinary medicines. The information basis of this study is scarcer for Lithuania and Russia than for Denmark, Estonia, Finland, Germany, Latvia, Poland and Sweden.

We identified 21 good practices and recommendations for take-back and disposal of unused pharmaceuticals and other pharmaceutical waste and for promoting the rational use of pharmaceuticals in the Baltic Sea region (Table 28).

One of the main recommendations is that citizens should be able to take all unused medicines – both prescribed and over-the counter – to designated collection point such as the site where it has been bought (e.g. pharmacy) or hazardous waste collection site (Recommendation 6). This way, the unused medicines can be properly disposed of. This practice is simple to remember and also easy enough for the citizens. The same practice should also count for the medicines of companion animals.

For pharmaceutical waste generated in hospitals the most efficient practice is that for hospitals to collect their own waste and send it directly to the waste treatment facilities (Recommendation 11). This is also the current practice in the Baltic Sea Region. Other health care institutions, such as private clinics, retirement homes, and facilities providing service housings or domiciliary care, should have centralized collection schemes for their pharmaceutical wastes (Recommendation 12).

In the Baltic Sea region, veterinary medicinal waste is currently mainly either collected together with other types of veterinary waste by veterinarians or returned to local collection points (e.g. pharmacies) by farmers or managed via contracted waste operators organized by farmers or they are directly disposed of in mixed household waste. It is recommended that when a veterinarian makes check-up visits to farm, the farmer should have the option of returning unused veterinary medicines to the veterinarian, who should be able to charge collection and waste management costs (Recommendation 13). Additionally, if the amount of accumulating unused medicines is unreasonable, farmers should be responsible for organizing the delivery of medicines to appropriate treatment in the same way as pharmacies and hospitals do. Reasonable amounts of unused medicines should be allowed to be returned to the same collection points same way as the unused household medicines. However, “reasonable” and “unreasonable” amounts should be defined more specifically (Recommendation 14).

To unify the disposal of industrial wastes contaminated with pharmaceutical residues in the Baltic Sea region, it is recommended that this kind of wastes should be collected separately and disposed of appropriately, irrespective of its waste classification (Recommendation 19).

Targeted information campaigns on the environmental effects of pharmaceutical emissions and how unused medicines should be handled appropriately are recommended for citizens, medical doctors and students, veterinarians and veterinary students and farmers (Recommendation 1, 5, 15, 17, 18). These professionals play a key role in helping implement several practices suggested by the CWPharma project.

In general, high temperature incineration at around 1 100–1 300 °C is recommended treatment method for unused medicines and other pharmaceutical waste unless a lower temperature is proven to irreversibly transform the active ingredients into non-hazardous substances (Recommendation 20).

Nevertheless, implementing recommendations at national level requires particular consideration due to differences in national legislations and other characteristics in EU Baltic Sea countries and Russia.

The good practices identified in this report answer the call for an EU strategic approach for an efficient risk reduction strategy that combines policy options at various stages of the pharmaceutical life cycle. These measures can be divided in the following way (e.g. OECD 2019):

- Source-directed measures: for example, to expand world-widely the regulatory framework for good manufacturing practice (GMP) of pharmaceuticals to include mandatory environmental criteria.
- Use-orientated measures: for example, to reduce self-prescription of pharmaceuticals with high environmental risk.
- End-of-pipe measures: for example, to upgrade wastewater treatment.

Table 28. The good practices and recommendations for take-back and disposal of unused pharmaceuticals and other pharmaceutical waste and to promote the rational use of pharmaceuticals in the Baltic Sea region. See more detailed information in chapters 4.1–4.7.

Preventive
Recommendation 1 (p. 91): Unnecessary and duplicated use of medications should be reduced. • The human, companion animal and other veterinary medicines should only be prescribed and used when needed and based on the diagnostic. This is specifically important for antibiotics due to increasing AMR problem. • Widening and making the requirement for a compulsory prescription stricter in the human and companion animal medicines is an effective way to control the use of environmentally risky medicines and may decrease the amount of pharmaceutical waste produced. • Information about environmental effects of pharmaceutical emissions should be included into the studies of medical doctors. Information campaigns should be carried also to practicing medical doctors to ensure that similar information is available regardless of the career stage.
Recommendation 2 (p. 91): Instructions on the safe usage of medical products, should be given by pharmacy staff or veterinarians when handed out the pharmaceuticals to the customers.
Recommendation 3 (p. 91): To unify the take-back and disposal of wastes contaminated with pharmaceutical residues, it is recommended that these kinds of wastes should be collected separately and disposed of appropriately, irrespective of the classification of wastes.
Households
Recommendation 4 (p. 92): The studies about the fate of unused household medicines in all Baltic Sea countries should be regularly (e.g. every 3 years) made in order to follow up the situation.
Recommendation 5 (p. 92): Increase the awareness of citizens concerning pharmaceuticals in the environment. • Information campaigns on proper handling of unused medicines stressing the harmful environmental impacts of incorrectly disposed unused human and companion animal medicines targeted to citizens will be arranged. • Pharmacies should actively give sorting instructions for customers e.g. when selling medicines.
Recommendation 6 (p. 92): Citizens should be able to return all unused medicines to dedicated, easily accessible collection points. • Sufficiently high density of collection points as well as their location near citizens should be ensured. • Information about collection points and sorting instructions should be concise and understandable but also easily accessible for citizens. • Permissible collection points could be pharmacies or hazardous waste collection sites. • Citizens should be able to return unused pharmaceuticals to collection points free of charge.
Recommendation 7 (p. 93): The customers should be able to return all unused companion animal medicines, irrespective of their waste classification, to same collection point (e.g. to pharmacies), where the collection of human medicines takes place.
Recommendation 8 (p. 93): The customers should be given the option of returning all unused veterinary pharmaceuticals, irrespective of their waste classification, for free to veterinary clinics.
Recommendation 9 (p. 93): The customers should be provided with information about the proper handling of unused companion animal medicines (see Rec 5).

Recommendation 10 (p. 93): Statistics about returned unused companion animal medicines should be produced for the sake of achieving better view (see Rec 4).
Hospitals and health care institutions
Recommendation 11 (p. 93): Hospitals should collect their own pharmaceutical waste and send it directly to waste treatment facilities.
Recommendation 12 (p. 93): Other health care institutions, such as facilities providing service housings, retirement homes, assisted-living facilities, private clinics or other operators providing domiciliary care should have centralized collection scheme for the pharmaceutical wastes. It covers all personal medications of patients.
Veterinarians and farms
Recommendation 13 (p. 94): When the veterinarian is making check-up visits to the farm, the farmer should have the option of returning unused veterinary medicines to the veterinarian, who should have a possibility to charge the collection costs.
Recommendation 14 (p. 94): If the amount of accumulating unused medicines is unreasonable, farmers should be responsible for organizing the delivery of medicines to appropriate treatment in the same way as pharmacies and hospitals do. Reasonable amounts of unused medicines should be allowed to be returned to the same collection points same way as the unused household medicines. Terms “reasonable” and “unreasonable” amounts should be defined more specific.
Recommendation 15 (p. 94): Information campaigns targeted on farmers should be implemented to improve the knowledge about how unused medicines should be handled appropriately.
Recommendation 16 (p. 94): Veterinarian and veterinary practices should collect the pharmaceutical waste produced by their own activities or returned to them by farmers or households and send it directly to waste treatment facilities.
Recommendation 17 (p. 94): Information about proper disposal and handling of unused medicines and environmental effects of pharmaceutical emissions should be included into the studies of veterinarians.
Recommendation 18 (p. 94): Information campaigns (incl. guidelines/good practices) should be also carried to veterinarians and other medical staff of veterinary practices in order to ensure that similar information is available for already practicing veterinarians.
Industry
Recommendation 19 (p. 95): To unify the disposal of industrial wastes contaminated with pharmaceutical residues in the Baltic Sea region, it is recommended that this kind of wastes should be collected separately and disposed of appropriately, irrespective of its waste classification. • Wastes contaminated exclusively with vitamins, electrolytes, amino acids, peptides, proteins, carbohydrates and lipids should not be considered to require intensive treatment (e.g. high temperature incineration) or separate collection, unless there is reason to expect them to cause environmental risk. This applies also to vaccines and herbal medicinal products.
Disposal
Recommendation 20 (p. 95): High temperature incineration (at around 1 100–1 300°C) is recommended treatment method for unused medicines and other pharmaceutical waste, unless a lower temperature is proven to irreversibly transform the active ingredients into non-hazardous substances.
Recommendation 21 (p. 95): All operators managing the disposal of wastes containing pharmaceutical residues must have the appropriate environmental permits required by national legislation.

Glossary

Companion animals	Animals that are kept as pets rather than for work or food
Health care institutions	Defined as public or private institutions that provide people with health care services – hospitals, clinics, retirement homes, assisted-living facilities, dentists, etc.
Livestock	Domestic animals raised in agriculture or aquaculture
Pharmaceutical waste	Covers unused pharmaceuticals from households, health care operators/providers, and farms, also encompassing waste material contaminated with pharmaceutical residues, originating from industrial activities
Waste codes	Based on the European List of Waste (2000/532/EC, 2008/98/EC) and are explained in Appendix 1.

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Appendices

Appendix 1. Waste codes.

Waste code	
18 01	Wastes from diagnosis, treatment and medical prophylaxis
18 01 08	Cytotoxic and cytostatic drugs
18 01 09	Medicines other than those mentioned in 18 01 08
18 02	Wastes from diagnosis, treatment and veterinary prophylaxis
18 02 07	Cytotoxic and cytostatic drugs
18 02 08	Medicines other than those mentioned in 18 02 07
20 01	Municipal waste segregated and collected selectively
20 01 31	Cytotoxic and cytostatic drugs
20 01 32	Medicines other than those mentioned in 20 01 31

Appendix 2. Latvian study on medicine waste within CWPharma project made by LEGMC

There is no statistical information about medicaments of class 20 01 31 (cytotoxic and cytostatic medicines) nor for medicines of class 20 01 32 (other medicines than class 20 01 31). The statistical information of statistical report "3-Waste" regarding medical waste in Latvia is not sufficient to assess the functionality of disposal practices of unused medicines, especially for municipal waste.

There is information about the amount of hazardous and municipal waste sent from and received in Latvia in Waste shipment accounting system (WSAS).

Amounts of transported medicine waste 2012–2017 are summarized in Figure 8.

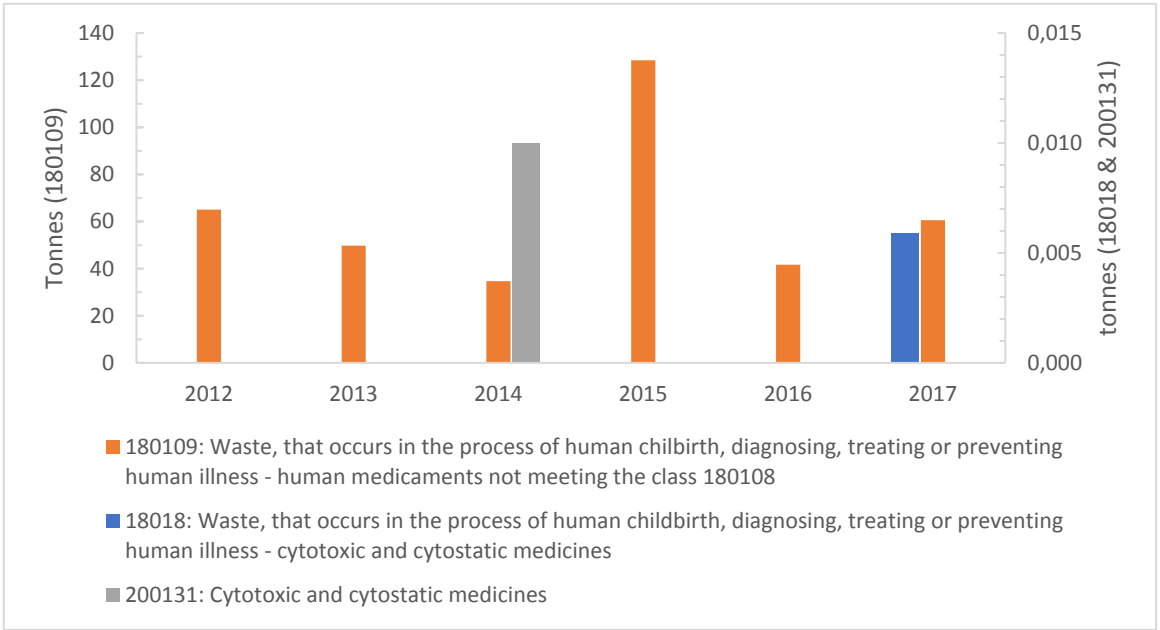

Figure 8. Transported amount of medicine waste in years 2012–2017 (data from Waste shipment accounting system, WSAS).

There is information of waste classes 18 01 08 (only for 2017), 18 01 09, 20 01 31 (only for 2014; WSAS). Waste of category 18 01 08 are sent to BAO Olaine Hazardous Waste Processing Complex for storage. Waste of category 200131 were sent to Corvus Company for storage. Waste of categories 18 01 09:

- from pharmacies are sent to Lautus for recycling or BAO for storage;
- from hospitals are sent to BAO for waste disposal or recycling, or to "Lautus" for recycling;
- from "Grindeks", Olainfarm to BAO for waste disposal;
- from veterinary pharmacies or wholesalers or consultants – to Lautus for recycling.

The waste delivered to Lautus" are disinfected and shredded and further delivered to the Getliņi bioreactor.

Good practices for take-back and disposal of unused pharmaceuticals in the Baltic Sea region – Clear Waters from Pharmaceuticals (CWPharma) Activity 4.1 Report

Finnish Environment Institute

ISBN 978-952-11-5201-6 (PDF)
ISBN 978-952-11-5200-9 (pub.)
ISSN 1796-1726 (online)
ISSN 1796-1718 (print)