Recommendations for efficient dissemination of environmental information regarding pharmaceuticals

Clear Waters from Pharmaceuticals (CWPharma) Activity 4.2 Report

County Administrative Board in Östergötland in cooperation with Finnish Environmental Institute (SYKE), Finnish Medicines Agency (FIMEA), Kalundborg Utility (Denmark), Estonian Environmental Research Centre (EERC), Estonian Waterworks Association (EVEL), Berlin Centre of Competence for Water (KWB), Latvian Environment, Geology and Meteorology Centre (LEGMC), Institute of Environmental Protection- National Research Institute (IOS, Poland).

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CWPharma

CLEAR WATERS FROM PHARMACEUTICALS

Recommendations for efficient dissemination of environmental information regarding pharmaceuticals

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Förord

Denna rapport är en del av det treåriga projektet Clear Waters from Pharmaceuticals (CWPharma) som finansierades av EU:s Interreg Baltic Sea Region Program. Syftet med projektet var att minska spridningen av läkemedelsrester till Östersjön.

Länsstyrelsen Östergötland deltog i projektet tillsammans med andra myndigheter, forskare och avloppsreningsverk från sju östersjöländer. Projektet delades in i fyra arbetspaket med fokus på att kartlägga (1) utsläpp, miljörisker och konsumtion, (2) avancerad rening av avloppsvatten, (3) uppströmsåtgärder och (4) handlingsplan. I denna rapport presenteras rekommendationer på uppströmsåtgärder som kan vidtas för att öka medvetenheten hos såväl personal inom sjukvården som hos allmänheten kring läkemedels miljöpåverkan.

De totalt åtta rekommendationerna i denna rapport utgår från goda exempel i Sverige och består av åtgärder som kan implementeras i andra Östersjöländer. Rekommendationerna har delats upp i följande fyra fokusområden; *utbildning, databaser och vägledningar, informationsspridning till allmänhet*, och *samarbete mellan intressenter och nyckelaktörer.* Vissa rekommendationer går att genomföra utan stora utmaningar eller ekonomiska insatser medan andra rekommendationer kan kräva exempelvis ekonomiska investeringar eller förändring i lagar och förordningar.

Samarbetet i Sverige är en av de främsta orsakerna till de framsteg som gjorts för läkemedel i miljön. Till exempel är Läkemedelsverkets nystartade ”Kunskapscentrum för läkemedel i miljön” en bra plattform för olika aktörer att diskutera miljöfrågor kopplade till läkemedel. Bland alla de olika aktörer som är med i nätverket finns en känsla av en gemensam miljövision med gemensamma mål. Därmed är en rekommendation att Östersjöländerna undersöker möjligheterna att etablera liknande nationella kunskapscentra inom sina nationella läkemedelsmyndigheter. Även befintliga nätverk kan användas som utgångspunkt för att även involvera andra miljöfrågor relaterade till läkemedel och för att hitta nya samarbetsmöjligheter. Slutligen är samarbete mellan EU-länderna också avgörande för att framgångsrikt genomföra miljöaspekter i läkemedels livscykel.

Tack
Länsstyrelsen Östergötland vill rikta ett stort tack till lead partner Finnish Environment Institute (SYKE) samt övriga projektpartners som alla bidragit aktivt till denna rapport. Vi är även tacksamma för stödet från projektets associerade organisationer och alla som på något sätt bidragit till projektet.

Länsstyrelsen Östergötlands arbete i projektet har, utöver bidrag från EU:s östersjöprogram, även medfinansierats av Havs- och vattenmyndigheten genom anslag 1:11 Åtgärder för en bättre havs- och vattenmiljö.

Abstract

During the last decades, it has become evident that some active pharmaceutical ingredients (API) have harmful environmental impacts on aquatic ecosystems. Therefore, there is a need to decrease the amount of pharmaceutical residues that end up in the environment. Information gaps related to increased awareness of the environmental impacts of pharmaceuticals in the health care sector and the promotion of sustainable consumption of pharmaceuticals have been identified in the Status Report on Pharmaceuticals in the aquatic environment of the Baltic Sea Region (BSR) published by UNESCO and HELCOM in 2017. The aim of the current report is to fill in some of the identified knowledge gaps identified in the HELCOM report, specifically increasing awareness about the environmental impacts of pharmaceuticals. In Sweden, there are good practices for healthcare professionals about how to consider the environmental impacts of medications already at the prescription phase, as well as guidelines for how to make the environmental information available and accessible to healthcare professionals and the public. The Swedish practices are described and evaluated, and the measures that can be implemented in the other BSR countries are formulated as recommendations.

Eight recommendations were formulated through dialogues with stakeholders in Sweden. The recommendations are divided into four main areas i.e. *education, databases and guidelines, dissemination of information to public*, and *collaboration among stakeholders*. Some recommendations might be implemented without any large challenges or financial costs while other recommendations require large changes such as economic investments and changes in legislation.

This report also contains information about existing practices in other countries in the Baltic Sea region (BSR), provided by the project partners in the CWPharma project. The countries in the BSR are currently at different levels when it comes to management of pharmaceuticals and their residues in the environment. Public awareness of the environmental impacts of pharmaceuticals differs, as do the systems for returning leftover medications. Basic education for health care personnel regarding the environmental consequences of different medications and pharmaceutical compounds exists in most of the BSR countries but the scope and content differs.

One recommendation in the report is that environmental impacts of APIs should be compiled in a national, or ideally an EU level, database. As a first step, the Baltic Sea countries could investigate the possibility to establish national interfaces to the Swedish databases “Pharmaceutical and environment” (Janusinfo) or FASS. Although the data in “Pharmaceutical and environment” and FASS are not complete, they are existing platforms which provide valuable information and gather criteria important for classification. In Sweden, there are several channels for the dissemination of information about the environmental consequences of pharmaceuticals with the aim to raise public awareness regarding this subject. Examples of actions to be considered by other countries are information campaigns driven by pharmacies for returning unused and left over medications (Germany and Finland have similar campaigns), and distribution of leaflets with information about the environmental impacts of pharmaceuticals, which have proven to be efficient in raising awareness among pharmacists, doctors and the public.

The collaboration of different stakeholders is one of the foremost reasons for the progress that has been made regarding pharmaceuticals in the environment in Sweden. The Swedish Medical Production Agency has set up a Knowledge Centre for Pharmaceuticals in the Environment, providing a platform for different actors to discuss environmental issues connected to pharmaceuticals. Among these actors there is a sense of a shared environmental vision with common goals. Hence, one recommendation for the BSR countries is to investigate the possibilities of establishing similar national knowledge centers within medicine agencies, or to use existing networks as a starting point to also involve other environmental issues related to pharmaceuticals and to find new collaboration possibilities. Finally, collaboration between the EU countries is crucial to successfully implement environmental aspects in the lifecycle of the pharmaceuticals.

Keywords: good practices, active pharmaceutical ingredients (APIs), dissemination of information, awareness among pharmacists, doctors and the public, education, databases, collaboration, recommendations, Baltic Sea region, pharmaceutical industry, hospitals, health care institutions

Content

1. Introduction

During the last decades, it has become evident that some active pharmaceutical ingredients (API) have environmental impacts which burden Baltic Sea ecosystems (UNESCO & HELCOM, 2017). This report was prepared in the group of activity (GoA) 4.2 of the CWPharma project (2017–2020), funded by EU's Interreg Baltic Sea Region Programme. The objective of GoA 4.2 was to raise awareness about the environmental impacts of pharmaceuticals and APIs in the health care sector and to promote sustainable consumption of pharmaceuticals. In Sweden, there are good practices for health care professionals about how to consider the environmental impacts already at the prescription phase, and about how to make environmental information available to healthcare professionals and the public. The aim of GoA 4.2 was to describe the practices in Sweden and the possibility to spread them to other Baltic Sea region (BSR) countries. Collaboration between the EU countries is crucial to successfully implement environmental aspects in the lifecycle of pharmaceuticals: from production to prescription, consumption and waste management.

One of the objectives in this report was to meet the information gaps identified by the HELCOM Status Report on Pharmaceuticals in the aquatic environment of the BSR (UNESCO & HELCOM, 2017). These gaps are related to raising awareness about the environmental impacts of pharmaceuticals in the health care sector and the promotion of sustainable consumption of pharmaceuticals. Furthermore, this report is in line with the objectives of the newly published European Union Strategic Approach to Pharmaceuticals in the Environment (COM, 2019). The shared objective of the EU strategy and this report is to identify the knowledge gaps and present possible solutions to fill them in.

In this report, the good practices and experiences on dissemination of environmental information on pharmaceuticals in Sweden are evaluated, and gaps related to the utilization of information are identified. Finally, recommendations are presented as guidance for efficient dissemination of environmental information regarding pharmaceuticals in the BSR.

2. The Swedish National Strategy regarding environmental information

2.1 National Pharmaceutical Strategy

The Swedish National Pharmaceutical strategy 2011–2018 was developed by the Swedish government and the Swedish Association of Local Authorities and Regions (SALAR) in collaboration with several actors in the pharmaceutical field. SALAR is an employers' organization that represents and advocates for local governments in Sweden. All Swedish municipalities and regions are members of SALAR. The Swedish National Pharmaceutical Strategy states they work towards the vision "Rational Use of Medicines to the Benefit of Patient and Society". The vision includes both effective and safe use of pharmaceuticals but also environmentally sustainable use of pharmaceuticals. The environmental aspects of the strategy focus on improving the risk assessment of pharmaceuticals. In 2018, the activities related to the National Pharmaceutical strategy focused on the negative environmental impacts during the production of pharmaceuticals as well as risk assessments of pharmaceuticals (Government Offices of Sweden, 2017).

In order to increase knowledge of the environmental impacts of pharmaceuticals, several activities have been initiated within the framework of the National Pharmaceutical Strategy. For example, the Swedish Environmental Institute (IVL) completed a project (during 2017– 2018) where they developed further a previous environmental assessment model with a focus on the entire lifecycle of the pharmaceutical product (Pålsson et, al. 2019).

The Swedish Medical Agency (MPA) has the governmental mission to coordinate and follow up the activities performed within the framework of the National Pharmaceutical Strategy, and to communicate the results to professionals, the general public and others concerned within the pharmaceutical field (Läkemedelsverket, 2019).

3. Practices in Sweden regarding pharmaceuticals in the environment

In Sweden, the main actors dealing with issues concerning pharmaceuticals and the environment are authorities, regions, pharmaceutical companies, pharmacies, and NGOs (non-governmental organizations) such as trade organizations. Among all these different actors there is a sense of a shared environmental vision with common goals. However, the ongoing work with e.g. screenings, campaigns and educational programs are not always coordinated on a regional or national level. This can result in duplication of work or that some parts might be overlooked.

3.1 The Swedish Medical Product Agency

The Swedish Medical Product Agency (MPA) is the national authority responsible for regulations and surveillance of the manufacturing and marketing of pharmaceuticals. They are also responsible for environmental issues connected to pharmaceuticals. MPA is the authority that approves pharmaceuticals and also the environmental assessment included in the applications from the producers. MPA works to identify, calculate and disseminate information on pharmaceuticals in the environment, mainly via their website and in public reports. The knowledge is also spread via university courses led by MPA for specialist doctors concerning pharmaceuticals and environmental issues. This education includes environmental impacts of pharmaceuticals from production, prescription and use, to waste management.

MPA also actively participates in working groups within the EU and conducts work to increase environmental consideration in the EU's pharmaceutical legislation (Läkemedelsverket, 2019B).

3.1.1 Swedish Knowledge Centre on Pharmaceuticals in the Environment

Since 2018, the Swedish government allocates five million SEK annually for a Knowledge Centre on Pharmaceuticals in the Environment. The MPA has been commissioned to establish and be responsible for this Centre. The first step was to bring forth goals and a business plan for the years 2019–2023. The Knowledge Centre is expected to further highlight the knowledge about the effects of pharmaceutical residues in the environment and contribute to an increased environmental concern of pharmaceuticals both in Sweden and in the EU (Läkemedelsverket, 2019B).

However, the main aim of the Knowledge Centre is to develop a platform for dialogue and cooperation amongst Swedish actors dealing with pharmaceuticals i.e. authorities, academia, health care sector, pharmaceutical industry, pharmacies, NGOs and in some part the public. The activities within the Knowledge Centre are divided into three focus areas, *Collaboration and dialogue, Increased knowledge* and *External monitoring/market intelligence.* The focus areas include goals to strengthen knowledge of pharmaceutical substances that potentially impact the environment e.g. by collecting data, and to act as a national information source for pharmaceuticals in the environment (Läkemedelsverket, 2019B).

3.2 The Swedish Environmental Protection Agency

The Swedish Environmental Protection Agency (SWEPA) is the national authority responsible for developing and implementing environmental legislation as well as other instruments and measures in order to achieve non-toxic and resource-efficient material cycles.

SWEPA is also responsible for monitoring the state of the environment. Therefore, the occurrence and levels of various environmental pollutants are measured on a regular basis within the national environmental monitoring programs. Furthermore, screening studies are conducted to investigate the presence of new

environmental pollutants and their effects on the environment. In recent years the measures and screening studies have also included several pharmaceuticals, such as hormones, analgesics, antibiotics, anti-inflammatory agents, sleep agents and antidepressants (Linderoth, M. 2019).

The results from the environmental monitoring studies are regularly spread through newsletters and seminars, which are mainly directed to the County Administrative Boards, other authorities and scientists. The results from the screening studies are also used to determine which substances should be prioritized and included in further activities, follow-up work or discussions in the national and regional marine conventions (Baresel, C. et. al. 2019).

SWEPA also promotes the implementation of advanced technologies to remove pharmaceutical residues and other pollutants from sewage treatment plants, as this is important for mitigating the discharge of pollutants into the environment. Within this work, SWEPA administers state-funded investment grants aimed to upgrade sewage treatment plants with technology for advanced wastewater treatment. In 2018, SWEPA granted the Swedish Water & Wastewater Association funding to start a pre-procurement group consisting of representatives from Swedish sewage treatment plants. The pre-procurement group´s overall aim is to support and facilitate cost-effective procurement and implementation of the advanced treatment technologies in Swedish sewage treatment plants. Activities for the years of 2018–2019 included e.g. gathering and disseminating the knowledge and experience of the implementation of such technologies in Sweden and the EU via workshops and a web page. Further, SWEPA releases the publication "Wastewater treatment in Sweden" every second year, including sections about advanced treatment for the removal of pharmaceutical residues and other environmental pollutants (André, A. et al. 2016).

3.3 The Regions (former County Councils)

Sweden is divided into 21 regions responsible for, among other things, management and operation of health care and hospitals. Every region has a department for environmental issues, which often includes the environmental impacts of pharmaceuticals. However, since the regions work independently from each other, the environmental departments have different priorities and focal points. The regions have a national network to cooperate and share material and experiences about environmental issues and there are some common approaches, such as how personnel shall handle pharmaceutical waste, information to personnel about the environmental impacts of pharmaceuticals, and to some extent information to the public regarding environmental impacts.

One example of the environmental work is in 2018, Region Östergötland focused on sharing information about the environmental impacts of pharmaceuticals with personnel. The personnel were trained via educational films on internal websites, and in order to spread the message among public they also shared the information with patients via the screens in the waiting rooms.

Another example is that Region Stockholm offers an on-line course on pharmaceuticals in the environment on their webpage Janusinfo.se (Region Stockholm, 2019). The target group is prescribers of human medicines and the course is structured according to different types of patient-based cases. The purpose of the course is to increase knowledge about how and why pharmaceuticals have an effect on the environment, how Region Stockholm handles these questions, and how to consider environmental aspects in day-to-day health care.

3.3.1 Database “Pharmaceuticals and Environment” on Janusinfo

The regions have different ways to consider environmental impacts when making recommendations for the prescription of medications. Region Stockholm has, for example, developed a database containing information about the environmental impacts of more than 800 APIs. The database is freely available on Janusinfo.se and is also translated into English (Region Stockholm, 2020). Since it is difficult to obtain environmental information on pharmaceuticals and APIs, this database is an asset for all regions (Baresel, C. et. al. 2019).

In the database, APIs are classified according to hazard identification (hazard score) and a risk assessment. The work on classifying APIs began in 2001 as a result of increased awareness about pharmaceuticals released into the environment and their environmental impacts. Classification was a collaboration between Region

Stockholm (at that time County Council of Stockholm) and Apoteksbolaget AB (at that time a government-owned pharmacy monopoly). In 2005 the collaboration was expanded to include the Swedish Medical Products Agency (MPA), the Swedish Association of the Pharmaceutical Industry (LIF) and the Swedish Association of Local Authorities and Regions (SALAR). More details about the classification system are available at the website Janusinfo.se (Region Stockholm, 2019B).

The environmental impact information for newly approved APIs is primarily collected from the environmental risk assessment in the European Public Assessment Reports (EPAR), available on the website of the European Medicines Agency (EMA). In 2006, EMAs Scientific Committee, the Committee for Medicinal Products for Human Use (CHMP), issued guidelines for environmental risk assessments prior to the approval of pharmaceuticals. "Pharmaceuticals and Environment" includes also information on risk assessments based on API concentrations in the environment and ecotoxicological data. These risk assessments are important supplementary information to the more theoretical risk assessments from EPAR and FASS.se. The assessments of medically comparable alternatives are also included in "Pharmaceuticals and Environment".

Region Stockholm has developed a list of 25 environmentally harmful pharmaceuticals whose emissions should be reduced (SLLs table of environmentally hazardous drug substances). The list also includes suggestions for the healthcare professionals to reduce the emissions of these pharmaceuticals (see www.janusinfo.se/miljo). The suggestions have been developed in consultation with the Region Stockholm Drug and Therapeutic Committee and its expert panels. However, several of the 25 substances are also recommended on the Wise List (see 3.3.2). Patient safety always comes first with reference to the recommended pharmaceuticals on the Wise List.

3.3.2 The Wise List

Every region has a Drug and Therapeutics Committee that makes recommendations for the prescription of pharmaceuticals based on scientific documentation regarding efficacy and safety, cost-effectiveness and environmental aspects (Gustafsson, LL. et al. 2011). Region Stockholm considers environmental impacts when selecting the recommended pharmaceuticals from the "Wise List". The pharmaceuticals included in the Wise List have been evaluated for environmental aspects such as environmental classification, persistence, bioaccumulation and toxicity to aquatic organisms (in combination with the consumption rate of the drug and how much reaches the nature). Other environmental aspects can be the removal rate in sewage treatment plants, occurrence in water and fish, changes in aquatic organisms and, for antibiotics, the risk of antimicrobial resistance development. The Wise List is also available in English (Andersén- Karlsson, E., Ateva, K. & Gustafsson, LL. 2015).

The compliance to the Wise List is high in Stockholm, which means that many of the pharmaceuticals that are recommended are widely used. Nonetheless, the priority is medical efficacy and safety, environmental assessment is considered second, and the most advantageous alternative is recommended (Eriksen, J., Gustafsson, LL., Ateva, K., et al. 2017).

3.4 The Swedish Association of the Pharmaceutical Industry (LIF)

LIF is the trade association for the research-based pharmaceutical industry in Sweden. It has about 90 members representing approximately 80 percent of the total pharmaceutical sales in Sweden. The association has an important role in the development of good practices concerning environmental aspects of pharmaceuticals and it has actively taken part in and chaired several initiatives over the last 10 to 15 years.

3.4.1 FASS

One of the several well-known initiatives by LIF is the world-unique public database FASS holding a lot of information, including the environmental impact information, of approved pharmaceuticals on the Swedish market (website www.fass.se). The main purpose of FASS is not to provide environmental impact information, but to inform the health care personnel and patients about the dosages, use, side effects, packaging sizes, prices and availability of medications. The information in FASS is continuously updated by pharmaceutical companies responsible for the products on the market and they also finance the administration of the website

and database. It is voluntary for pharmaceutical companies to publish any environmental impact information on APIs or pharmaceutical products in FASS, hence, an API may have various kinds of environmental impact information. The documentation is reviewed by The Swedish Environmental Institute (IVL) before publishing, but this quality review cannot validate the information nor demand any completion of the voluntarily published information (Graae, L., Westberg, E. & Örtlund, L. 2016). Information about the packaging sizes and prices are continuously updated by the authorities Medical Products Agency and Dental and Drug Benefits Agency.

The incentive for the companies to publish their information may be divided in two. Firstly, pharmaceutical companies face an increasing pressure to become more transparent especially about the environmental impacts data of their products. The program was presented as a "voluntary requirement" in public procurement by Region Stockholm together with Apoteket (the government-owned pharmacy monopoly) in 2003. Secondly, LIF saw this initiative as a potential competitive advantage, given the demand on transparency from consumers and the assumed willingness of the procurers to pay more for "green alternatives".

Since 2001, FASS is web-based but FASS was an established platform for pharmaceutical information long before this website was launched. FASS was previously an annually published book with the first edition in 1966. FASS was used by prescribers and health care personnel, but in 1990 an additional edition was released for patients. The prelude to including environmental impact information was that the government commissioned the MPA to investigate the possibilities for environmental risk classification of pharmaceuticals in the Swedish market in 2002. This resulted in suggestions of environmental parameters for classification. LIF undertook the responsibility of developing a classification model and the first environmental impact documents were published in FASS in 2005.

LIF works actively to ensure they have the most relevant and updated information about the environmental issues regarding APIs and pharmaceuticals. For this purpose, LIF is part of an expert network for sustainable development of pharmaceuticals. The network has an advisory role and serves as a forum for feedback from the European Federation of Pharmaceutical Industries and Associations (LIF, 2019B). LIF has already gathered a lot of environmental information about pharmaceuticals and continuously communicates the information to the members and other stakeholders such as the Swedish Pharmacy Association, the Procurement Office and Dental and Pharmaceutical Benefits Agency, mainly through their website (LIF, 2019)

LIF has environmental assignments within the Swedish National Pharmaceutical Strategy. For example, in cooperation with other stakeholders they have developed a model for an extensive environmental assessment of pharmaceuticals including not just the environmental classification of the APIs but also the environmental impacts during manufacturing, including exploitation of natural resources. The model can form the basis for an environmental declaration of a product, and LIF encourages their members to also use the model for assessing manufacturing plants (Government Offices of Sweden, 2017).

3.5 The Swedish Environmental Research Institute

The Swedish Environmental Research Institute (IVL Svenska Miljöinstitutet) is an independent research institute with the mission to work with environmental issues and the interaction between ecological, economic and social perspectives. IVL is working on in-depth studies with the primary aim of improving and strengthening environmental risk assessments. As mentioned above, IVL is also an independent reviewer of the environmental information published in FASS (Graae, L., Westberg, E., & Örtlund, L. 2016).

IVL works in several projects that are linked to the dissemination of information on pharmaceuticals in the environment. For example, IVL has, on behalf of the Swedish Water Development (Svenskt Vatten Utveckling, SVU), conducted a study on the environmental benefits of the upstream measures to reduce the amount of pharmaceuticals that are spread to the environment. One study analyzed if reintroduction of prescriptions for environmentally harmful pharmaceuticals (that previously have been non-prescribed pharmaceuticals) would decrease the emission from these pharmaceuticals to the environment. Other measures were to prescribe

physical activity and other health-promoting efforts and to make the public procurement more effective (Graae, L. et al. 2017).

In 2019, IVL in cooperation with LIF published a report on the Environmental assessment model for pharmaceutical products (Pålsson, A-C. et al. 2019). The model was developed to estimate how to determine the local environmental risks of API emissions from manufacturing and the carbon footprint of the cycle. The model included verification of data and was reported at the level of medication or pharmaceutical products, enabling comparison of products with the same API. The results showed that the local environmental risk can be implemented within the existing framework for environmental classification at FASS.

IVL and the Royal Institute of Technology (KTH) own and operate the Hammarby Sjöstadsverk (IVL, 2019), a facility for research, development and demonstration of wastewater treatment technologies. Hammarby Sjöstadsverk promotes cooperation among companies, experts, researchers and municipal sewage works to meet future challenges in the water and wastewater sector and to increase the export of Swedish knowledge and technology. The facility and projects have been used for knowledge building and transfer in Sweden to master students, PhD students, visitors and engineers at municipalities (Baresel, C. 2019).

3.6 The Swedish Pharmacy Association

The Swedish Pharmacy Association is the trade association representing all pharmacies in Sweden. The association was founded in 2009 when the government monopoly was lifted, allowing private pharmacies to open in Sweden. The members consist of pharmacy retailers with multiple stores, online pharmacies, hospitals and dose dispensing pharmacies. The mission is to create and enable the best possible conditions for members concerning regulatory issues, supply of competence and economic conditions.

The association and the individual pharmacy companies have worked for a long time to increase awareness among citizens concerning return systems for unused or leftover pharmaceuticals. According to the law, the pharmacies must accept returned pharmaceuticals, even if this is a big cost for the pharmacies. In 2018 the pharmacies altogether took back 1 400 tons of unused pharmaceuticals.

In 2020 the pharmacies in Sweden plan to introduce a joint sustainability guideline for over the counter medicines sold at pharmacies. Since it is not possible for pharmacies to obtain information about where and how the medicines are manufactured from the pharmaceutical industry, the guide will show which pharmaceutical companies conduct good and long-term environmental and sustainability work. They will also include if the companies report their work according to “the standards for sustainability reporting” in Global Reporting Initiatives. In the long run, the guide will hopefully be able to show which products are more sustainably produced than others.The public’s questions about the environmental impacts of medicines are increasing and pharmacies feel an increasing need to be able to answer these questions, although today it is impossible.

The Dental and Pharmaceutical Benefits Agency (Tandvårds- och läkemedelsförmånsverket, TLV is a Swedish authority that is responsible for which pharmaceuticals should be granted from the government and which price margins the pharmacies can have on pharmaceuticals. Therefore, the Pharmacy Association wants TVL) to add environmental impacts as a criterion for the generic substitution system that the pharmacies are responsible for carrying out. Further the Pharmacy Association wants to include environmental requirements into good manufacturing practices and introduce more starter packages (Swedish stakeholder meeting in CWPharma, 2019 & Sveriges Apoteksförening, 2019).

3.7 The National Agency for Public Procurement (Upphandlingsmyndigheten)

The National agency for public procurement gives recommendations for criteria to use in the public procurement of pharmaceuticals. The criteria were updated in 2019 and can be applied together with the criteria on social and labor law conditions. The recommended criteria include the availability of aquatic environmental impact information and the environmental procedures in the supply chain. The first criterion requires the supplier to provide similar, third party-verified environmental information as presented in e.g.

FASS for all products covered by the procurement agreement. The second, requires the supplier to implement procedures aiming at minimizing the environmental impacts caused by the use and handling of the active substances and other raw materials during the manufacturing of the products.

The criteria drive the development for increased openness about where and how the manufacturing of pharmaceuticals takes place. This gives the contracting authorities better capabilities to identify and prioritize environmental and social risks and possible follow-up measures (Upphandlingsmyndigheten, 2019).

3.8 National Veterinary Institute

The National Veterinary Institute (Statens veterinärmedicinska anstalt, SVA) is a Swedish national expert authority that strives for good animal and human health, a good environment and sustainable food production. SVA supports the Swedish Board of Agriculture (Jordbruksverket, 2020) in case of e.g. contagious animal diseases, zoonoses and risk evaluation during an eradication of a contagious disease.

When it comes to veterinary pharmaceuticals, the issue with antibiotic resistance dominates the discussions about the environmental and health aspects. SVA is a partner in the Swedish strategic program against antibiotic resistance (Strama) and its subgroup Strama VL which is specialized on issues concerning the use of antibiotics for companion animals and animal husbandry (SVA, 2019).

Apart from SVA and the Swedish Board of Agriculture there are several associations, networks and organizations for veterinarians. One example is the Swedish Veterinary Association where approximately 90 percent of all the Swedish veterinarians are members.

4. Dissemination of information regarding environmental impacts of pharmaceuticals

4.1 The MPA and SWEPA

Authorities like the MPA and SWEPA disseminate information on how households should handle their medical waste on their websites and in publications. For example, on MPA's website there is a list which advises how to minimize pharmaceuticals in the environment (Läkemedelsverket, 2018):

- *Do not pick up more medicines than you need.*
- *Never flush the medication down the sink or toilet.*
- *Always deliver your redundant medicines to the pharmacy.*
- *Packages containing visible medicinal residues should be delivered to the pharmacy.*
- *Return the medicine patches, such as hormone patches, both used and unused to the pharmacy.*
- *Sort and discard empty pharmaceutical packaging into the packaging waste.*

Occasionally, the unit for Environmental Toxins at SWEPA publishes reports directed to the public called "Toxins and Environment" (Gifter och miljö). These reports contain information on pharmaceutical residues in the environment. SWEPA's website presents further information on the pharmaceutical residues in the environment and information on the entire life cycle of a product from production, through consumption to the waste management. SWEPA has also linked the website to other authorities and organizations which work with pharmaceuticals in various ways (Linderoth, M. 2019).

4.2 The Swedish Pharmacy Association

On the Swedish Pharmacy Association website there is information about the impacts of the pharmaceuticals on the environment, as well as instructions about actions every person can take to reduce the environmental impacts.

4.3 The Regions

Since the main mission of the regions is to provide and coordinate the public health, their main target groups are pharmacists, doctors and other personnel working in the health care sector. The regions have no mission to raise the public awareness. However, e.g. Region Östergötland and Region Stockholm use the screens in the waiting rooms at the hospitals and health care centers to spread information about the pharmaceutical management and return practices to the patients. They have also published booklets and put them in the waiting rooms.

4.4 Pharmacies and households

Pharmacies also work to increase awareness among citizens concerning return systems for unused pharmaceuticals. All the pharmaceutical chains have information concerning the environmental impacts of pharmaceuticals and the acceptance of unused pharmaceuticals on their websites. An incentive for the users to return their leftover pharmaceuticals is to offer bonus credits for handing in unused pharmaceuticals. In addition, some of the pharmacies have conducted campaigns for the return of pharmaceuticals.

The fact that households sort their waste is important for the whole return system and for minimizing the amount of pharmaceuticals that end up in the environment. Therefore, it is regulated by law stating that: *Households are obliged to comply with the rules for waste management in the municipality*. However, there is no specific description of how pharmaceutical waste should be managed. Instead the citizens are encouraged by authorities, organizations and the regions to return their left-over pharmaceuticals to pharmacies.

5. Good practices in Sweden

The overall summary of the good practices concerning the sharing of information about the impacts of pharmaceuticals on the environment in Sweden is that there is a lot of ongoing work, such as refining the legislation, education of health care staff, pharmacy campaigns, collecting and validating environmental impact data, workshops involving different actors and recommendation for prescribers. Further, it is positive that so many different actors are involved in publishing and disseminating environmental impact information for pharmaceuticals (e.g. authorities, regions, industry, trade associations, pharmacies, universities, NGOs). However, although the actors have a shared vision and concern about the environmental impact of pharmaceuticals, they often perform activities separately (MistraPharma, 2011). There is no national agreement concerning environmental impact information and contradictory interests also occur.

The dissemination of information about pharmaceutical impacts on the environment is, in this report, divided into:

- Education and training
- Databases and guidelines
- Dissemination of information to the public
- Collaboration among stakeholders

5.1 Education and training

There are several ongoing trainings and workshops concerning pharmaceuticals and the environment conducted for different target groups. Two examples of the good practices are education at university level and training of health care and pharmacy personnel.

Education about the environmental impacts of pharmaceuticals is included in university courses for physicians, nurses and pharmacists. This training teaches them to consider the environmental impacts when deciding what medicines to prescribe, when handling medications, and when giving instructions to patients. The education in pharmacology and toxicology for veterinary students is partly focused on environmental consequences of the use of pharmaceuticals. Responsible parties for the education are the universities, the MPA, and the regions, which in turn collaborate with research centres such as IVL and authorities like the SWEPA.

In order to continuously increase and update knowledge on the environmental impacts, health care sector personnel are trained via e.g. broadly accessible online courses. The regions are mainly responsible for the continual training of health care sector personnel and often provide information and training via their internal websites. Also, the MPA and other authorities have updated information on their websites.

5.2 Databases and guidelines

There are several databases of the environmental impacts of pharmaceuticals in Sweden. The collected data can be used to develop guidelines on how to consider the environmental impacts during prescription, or for other purposes such as waste handling.

5.2.1 Databases

Two examples of databases with environmental information on APIs are “Pharmaceuticals and environment” (Janusinfo, 2019) and FASS. Although the data in Janusinfo and FASS are not complete, they provide valuable information and are important platforms where different criteria are gathered. This facilitates decision making from an environmental point of view.

Responsible parties for these easily accessible and versatile databases are Region Stockholm for "Pharmaceuticals and environment" (Janusinfo) and LIF for FASS. Currently, these Swedish databases contains only API-specific information, which makes it impossible to perform comparisons between different pharmaceutical products containing the same API. In addition, it should be noted that these databases may contain some incorrect or unrepresentative information.

According to a Finnish study, where experts from LIF, IVL and Region Stockholm were interviewed, the classification system itself is poorly known among Swedish citizens. However, they are considered to have helped increase public discussion about the adverse environmental impacts of pharmaceuticals, making the issue common knowledge. The interviews also indicated that it is not completely clear whether the classification system has helped reduce these impacts significantly. However, according to the interviewees from Region Stockholm, in some cases substances have been replaced by the less environmentally harmful ones on the Wise List. An example of such case was the replacement of felodipine with amlodipine. (Vieno et al. 2019)

5.2.2 Guidelines

If the environmental aspects are to be considered when prescribing a medicine, they need to be integrated in the medical recommendations. It is not possible for the healthcare professionals to follow parallel recommendations for therapeutically and environmentally good choices. Evaluation of environmental information requires expertise just as the evaluation of medical studies does (Borgendahl, J., Ramström, H. & Håkansson Ovesjö, M-L. 2019). However, the lack of transparency from the pharmaceutical industry regarding where and how the contents of pharmaceuticals are manufactured makes it hard to formulate proper recommendations regarding environmental impacts and develop the environmental considerations (Baresel, C. et al. 2019). The Wise List as well as other regional recommendations are good practices based on expert assessments and a step towards making prescriptions where environmental aspects are considered.

The recommendation lists in Sweden are mainly produced by the regions and have high compliance with local healthcare professionals.

5.2.3 Public procurement

One benefit of listing and collecting data in databases is that they can be used in public procurement. In 2019 new procurement regulations were introduced, providing more possibilities to consider environmental benefits. All the regions in Sweden have demands for the working conditions and certain environmental considerations during the pharmaceutical production in their procurements. Some regions place additional requirements specifically for environmental aspects (Borgendahl, J., Ramström, H. & Håkansson Ovesjö, M-L. 2019).

5.2.4 Potential for development

The environmental information in the Swedish databases concentrates on the risk to the aquatic environment. This should be accompanied by an assessment of the risks to the soil environment. The data necessary for assessing chemical risks contains intrinsic variability. For instance, the results from ecotoxicity studies depend not only on the species used, but also on several other variables and their interactions. Therefore, the existing databases may give different values for the same parameters. In these cases, it would be important that e.g. an independent third-party reviewer compares the presented data with other data and the more in-depth assessments, such as the ones carried out within the EU Water Framework Directive.

Digital medical records would enable tracking each patient's consumption of pharmaceuticals, even if they e.g. move to another city (Thorsén, G. et al. 2018). The development of such records is on-going in Sweden. The benefit of the records would be the optimization of the medication, i.e. the patient gets the correct medication

and the correct amount of medication which may result in less waste, thus less emissions of pharmaceuticals to the environment.

5.3 Dissemination of information to the public[1]

There are several channels for the dissemination of environmental impact information to the public in Sweden. The pharmacies have a natural role to disseminate information to the citizens while selling medications. The regions, including the prescribers, also have an important role, as well as the national authorities and the pharmaceutical industry.

The pharmacies' role as trainers and consultants is important in order to sustain the correct management of pharmaceuticals. Among other things, pharmacies can help increase awareness of the impacts of pharmaceuticals on the environment and minimize the amounts of pharmaceuticals ending up in the wrong places and thus spreading into the environment. The pharmacies' campaigns for the return of unused pharmaceuticals and leaflets with environmental impact information have proven efficient in disseminating information and raising awareness. In Sweden, several pharmacy chains offer their customers bonus credit for handing in unused medications, which has increased both the return rate of left-over medicines and public awareness (Baresel, C. et al. 2019). Another good practice from Sweden is the campaign "The big collection day" introduced by one pharmacy in 2017. The objective was to raise public awareness concerning unused medications in Sweden. During the four-week campaign, the number of customers handing in unused medications tripled (Frisk, M. 2018).

The prescribers and the pharmacists can also counsel on alternative self-care treatments that are less harmful for the environment. In the absence of any ecolabelling of medications, one pharmacy chain in Sweden developed their own eco-label "Välj med hjärtat" (Choose with the heart). In 2019 this labelling was handed over to the other pharmacy trade chains in Sweden. The ecolabelling requires that the pharmaceutical supplier must conduct good, long-term environmental and sustainability work and report the work according to "the standards for sustainability reporting" in Global Reporting Initiatives (Global Reporting Initiative, 2020). The labelling also requires the pharmaceutical companies to be members of the Pharmaceutical Supply Chain Initiative (a global trade organization that works with environmental, sustainability and societal issues in the pharmaceutical industry) and share their knowledge and expertise with other companies in the industry in order to impose similar environmental requirements on subcontractors in the manufacturing chain.

Though the regions have no official mission to raise the public awareness, in practice the regions, including hospitals, health care units and prescribers play an important role in disseminating information to the public. The regions have for instance published booklets on the subject and displayed the information on the screens in the waiting rooms. Both examples are recognized as good ways to raise public awareness.

5.4 Collaboration among stakeholders

In Sweden various actors, such as authorities, regions, pharmacies and industries, share the same vision of how the pharmaceutical business should look in the long term. Even if there is still a lot of work to be done, the collaboration in Sweden is one of the reasons for the progress that has been made regarding pharmaceuticals in the environment (MistraPharma,2011).

There are several on-going collaborations and MPA's newly started "Knowledge Centre for Pharmaceuticals" is a good platform for different actors to discuss environmental issues connected to pharmaceuticals. The MPA also works actively in different EU groups in order to improve the EU legislation according to environmental aspects of pharmaceuticals.

1 https://dictionary.cambridge.org/dictionary/english/public?q=the+public

6. Practices in other countries in the Baltic Sea region

The countries in the BSR are at different levels when it comes to management of pharmaceutical residues. The public awareness differs on the subject, as do the systems for returning leftover medications. This chapter is written by partners from each country participating in work package 4, group activity 4.2 in the CWPharma project. In the sections below, the authors describe the current situation in each country within the categories presented in chapter 5; *Education and training, Databases and guidelines, Dissemination of information to the public* and *Collaboration among stakeholders.*

6.1 Finland

Terhi Lehtinen (Fimea)

The curriculum for pharmacists and veterinarians in Finland includes basic education on the environmental impacts of pharmaceuticals. The curriculum of medical doctors and dentists does not include any specific courses on the environmental issues of pharmaceuticals. During recent years, seminars on medicines and the environment have been arranged by the universities and the Pharmaceutical Information Centre, but the attendance is mostly limited to those with specific interest in environmental aspects.

The Finnish Medical Society, Duodecim, publishes the national Current Care Guidelines which are independent, evidence-based clinical practice guidelines including recommendations on medical treatment where relevant. There are also "smart to avoid" recommendations which include out of date practices or practices that are not evidence-based. Currently there are 105 clinical practice guidelines and 97 "smart to avoid" recommendations. At present these guidelines do not consider environmental aspects of medicines when guiding the prescription. To be considered in the guidelines, evidence-based data and information on environmental impacts of pharmaceuticals should be publicly available.

Information on the environmental impacts of pharmaceuticals for professionals (doctors, veterinarians, dentists, pharmacists) or citizens is not currently available in any of the databases used in Finland. These databases (Duodecim database, Pharmaca Fennica, Pharmaca Fennica Veterinaria, Fimea database) include the approved summaries of product characteristics and patient information leaflets, where only seldomly is environmental impact information available. The environmental information is usually data on proper disposal of e.g. hormonal pharmaceuticals (e.g. used hormonal replacement or contraceptive plasters or contraceptive rings).

Finnish pharmacies have made information available for their customers on the proper treatment (e.g. return) of unused medications, and several customer and trade magazines have published articles on pharmaceuticals in the environment. NGOs, trade organizations and water companies have also carried out information campaigns on these topics, directed at the general public.

In conclusion, specific information on environmental aspects of medicines is not currently available from the Finnish sources. However, there are widely used national pharmaceutical and treatment guideline databases which could be explored for the dissemination of this information. In the basic education and training of professionals prescribing and dispensing pharmaceuticals the environmental aspects are currently limited. The situation is better in the education for pharmacists and veterinarians. Hence, the first step to increase awareness of the environmental effects of pharmaceuticals would be to make such information available to professionals and to incorporate this information in the education and training of professionals responsible for prescribing (e.g. doctors) and distributing the pharmaceuticals.

6.2 Denmark

Jeppe Bregendahl (Kalundborg Utility)

In Denmark there is no direct education on environmental issues connected to pharmaceuticals. The education at the universities and in the health care sector takes toxicity to humans into account and mostly antimicrobial resistance. At present there are no existing lists of recommendations in Denmark similar to the ones mentioned for the Swedish and Finish systems.

When it comes to pharmaceuticals in the environment, the main discussion in Denmark is regarding the flow of pharmaceuticals and how to develop end-of pipe solutions. Linked to that work there are some collaborations in Denmark e.g. between utilities, hospitals and industries. The primary purpose of this collaboration is to develop central systems to first find the point-sources of pharmaceutical emissions, such as hospitals, and second manage these sources.

6.3 Poland

Marlena Szumska (IOS), Aleksandra Bogusz (IOS), Radosław Kalinowski (IOS, Radikal)

In Poland, there is generally low public awareness regarding the environmental aspects of pharmaceuticals and handling of pharmaceutical waste. Public awareness is closely related to the media message, but in Poland there is no media coverage on this subject.

There are no databases about the environmental impacts of pharmaceuticals in Poland, except the environmental risk assessment data required in the marketing authorization applications, which was included in the EU legislation in 2006.

Medical students have pharmaceutical toxicology as part of their studies, but there are no guidelines nor practices for taking environmental aspects into consideration when prescribing pharmaceuticals.

6.4 Estonia

Ülle Leisk (EERC), Egge Haiba (EVEL)

To raise the awareness among doctors, pharmacists and the public of the impacts of pharmaceuticals on the environment, many lectures and seminars have been held during recent years. Pharmaceutical toxicology is a part of the healthcare studies in Tartu University and Tallinn Health Care College, but no environmental aspects are taken into consideration in prescribing pharmaceuticals.

In Estonia, public awareness on the environmental impacts of pharmaceuticals is low. As in Poland, the public awareness is closely related to the media message and the subjects that are disseminated via media. However, there have been a few public media campaigns with the purpose to increase awareness concerning the collection of outdated medications as a hazardous waste. Additionally, studies have been performed on pharmaceutical substances in drinking water and these results have been disseminated in the media.

6.5. Latvia

Anete Kublina (LEGMC)

In Latvia, the awareness of the environmental impacts of pharmaceuticals and the management of pharmaceutical products is not extensive. As an example, a study about the return of unused medicines in 2014 showed that only 10 percent of the public return their unused medications to pharmacies or discard them in suitable containers (Prola, 2017).

The scientific research and projects about pharmaceuticals in the environment focus mainly on the aquatic environment and antimicrobial resistance. Some press releases on a base of scientific articles have been disseminated in mass media of Latvia. The press releases have considered antibiotic resistance and

pharmaceuticals in drinking water (interview with Bartkevičs V. by Čudare A., 2018), or pharmaceuticals in aquatic biota (Sondare, 2018).

The following courses for the pharmacy personnel and veterinary students include aspects related to the environmental impacts of pharmaceuticals:

- In Latvian University the curriculum of pharmacy in Faculty of Medicine for Bachelor Pharmacy program includes 107 academic hours (1 academic hour – 90 minutes) devoted to environmental impacts of pharmaceuticals:
    - Environmental biochemistry and toxicology (80 academic contact hours, including laboratory works),
    - Medical Microbiology and Immunology (2 academic hours on mechanisms of antibiotic resistance development, including environmental pollution by antimicrobial agents),
    - Clinical Pharmacy (some information on antimicrobial environmental pollution, 1 academic hour),
    - Drug metabolism (4 academic hours on the environmental impacts of the medicinal products, including the report UNESCO & HELCOM 2017),
    - Environmental Protection (obligatory study course for all students of the Latvian University, 20 academic hours).
- In Riga Stradins University the curriculum of pharmacy includes a course *Environmental health and environmental protection* without specific lectures on pharmaceuticals (Riga Stradins University, 2018).
- There is no information about this topic in the veterinary study programme of the Latvia University of Life Sciences and Technologies.

6.6 Germany

Jan Schütz (KWB), Michael Stapf (KWB)

Since the detection of pharmaceuticals in groundwater (clofibric acid) in the early 1990s, the topic of pharmaceuticals in the environment has increasingly been in the focus of science, authorities and media. 150 active substances could be detected in different environmental compartments, based on research programs and investigations (UBA 2018). However, in Germany there is no systematic monitoring of active pharmaceutical ingredients in the environment. Active pharmaceutical ingredients are not yet included in regular monitoring programs under the EU Water Framework Directive or the National Surface Waters Ordinance.

In order to inform people from all pharmaceutical-related areas (doctors, pharmacists and patients) of the sustainable use of pharmaceuticals, a corresponding training module for doctors and pharmacists was developed and implemented through the program UFOPLAN funded by the Federal Environmental Agency (UBA, 2018).

In the last years, there have been public campaigns to increase the awareness amongst the population regarding the disposal of outdated medications. Information for a correct disposal behaviour of unused medicines is available for public (e.g. https://arzneimittelentsorgung.de/home). In addition, API-related topics, such as their occurrence in the water cycle, need for advanced wastewater treatment, and the impact of APIs on the (aquatic) environment, are discussed in the mass media.

7. Conclusions and recommendations for the Baltic Sea Countries

This report summarizes some good practices for disseminating environmental information on pharmaceuticals in Sweden. Additionally, it recommends what could be done in the other BSR countries. The recommendations are divided in four main areas i.e. education, databases and guidelines, dissemination of information to public, and collaboration among stakeholders. Some recommendations might be performed without any large challenges or financial efforts while other recommendations require e.g. economic investments and changes in regulation.

7.1 Education and training

The first recommendation is to introduce the topic *pharmaceuticals in the environment* in the education for doctors, pharmacists, veterinarians and nurses. This must be done in a practical and carefully planned way in order to ensure that environmental impacts of pharmaceuticals are connected to the daily working methods of the above-mentioned health care professionals. The responsible actor and party for developing and performing such education may vary in different countries depending on the education system. In Sweden, it is the universities in collaboration with both the MPA and regions that are responsible for this kind of education. It might also be possible for the other Baltic Sea countries to use the educational materials already used in Sweden.

The second recommendation is to arrange training courses for the health care personnel already working in the sector. The training could cover practical issues concerning e.g. pharmaceutical waste (including unused medicines) and management in the local hospital or health care center. Personnel working in pharmacies also need continuous training to be able to answer questions and guide citizens about the environmental aspects of pharmaceuticals.

7.2 Databases and guidelines

The third recommendation is that environmental information on APIs should be compiled in a national or, ideally, EU level database. Preferably, the database would be owned by an authority or a research institute, and the data stored in the database would be assessed by independent third-party experts. When feasible, the database can be extended to cover not only API-specific environmental impact information but also product-specific information such as emissions and impacts of their whole life cycle (Baresel et. al. 2019).

Connected to the database there would, ideally, be a nationally or European unified classification system that covers some drawbacks identified in this report and in previously published reports (e.g. Vieno et al. 2019). To this end, hazard classification used for other chemicals, biocides and plant protection products (CLP Regulation, (EC) 1272/2008) can also be investigated and considered for the environmental classification of APIs and pharmaceuticals.

To enable these kinds of comparisons, the pharmaceutical industry must publish more information on the manufacturing process as well as the contents of the pharmaceutical products.

As a first step, the Baltic Sea countries might investigate the possibility to establish national interfaces to the Swedish databases FASS or “Pharmaceuticals and Environement” (Janusinfo). Norway already has an interface and uses the Swedish database FASS (LMI 2015) amended with Norwegian national information on the use of pharmaceuticals (e.g. amounts used).

The fourth recommendation is that the BSR countries establish similar guidelines for the prescription of pharmaceuticals taking into account the environmental considerations as in Sweden. Further, the recommendation is that the environmental impact data and the guidelines are public to increase

transparency and accessibility. However, in Sweden there are several guidelines for prescription and none of them is nationally agreed. For Sweden as well as for the other BSR countries, it would be valuable if international or European medical doctor associations would consider the environmental aspects of medicines in their treatment guidelines. The international instructions could then be incorporated into the national guidelines. However, there are contradictory interests and different aspects to consider when the focus of using the pharmaceuticals is human health and therapeutic treatment.

A future option may be to include an LCA-perspective[2] in databases and guidelines. This would strengthen information about the environmental impacts of the complete pharmaceutical product, not only the API. It could also decrease the adverse environmental impacts of manufacturing in other countries, such as in India. However, this is an extensive undertaking. APIs and pharmaceutical intermediates are fabricated in many different countries and the production chain is not publicly traceable. A further difficulty is that the LCAs must be carried out in a similar way, using similar system boundaries throughout the pharmaceutical industry, in order for the results to be interpreted in a conclusive way and to enable realistic comparisons.

Another future vision is to clarify the needs, requirements and uses of product-specific environmental impact information of pharmaceuticals by different stakeholders and applications. This is stated by IVL in their report for the environmental assessment model, since there are differences in the requirements, e.g if the information is used only to improve general environmental awareness, or if it shall be used as a selection and award criterion in the public procurements and the generic substitution system (Pålsson et al. 2019).

7.3 Dissemination of information to public

Since there are several channels to disseminate information, **the fifth recommendation,** for how to disseminate information to the public, **is that the national authorities, pharmacies (i.e. pharmacists) and prescribers (mainly physicians but also nurses) are the main source of information for citizens**. This will make the information trustworthy for the public. Pharmacies especially can improve the adherence to recommendations and reduce incorrect use of medications since they are the ones who meet the citizens in everyday life (MistraPharma, 2011).

In order to further expand the information from authorities and pharmacies, more environmental information could be added onto package leaflets, but it may be difficult due to strict regulations on their contents. Creating national legislation on the issue might not be feasible, since individual BSR countries are relatively small markets. Therefore, the requirements for additional environmental impact information to be given in the package leaflets should be issued at the EU level.

Campaigns, booklets and information in the waiting rooms at the Swedish hospitals have shown to be efficient as an upstream measure to decrease the amount of unused medicines.

7.4 Collaboration among stakeholders

It is highly feasible to develop the collaboration between actors with different responsibilities and interests. In most countries, collaboration already exists in some form between the personnel working in the health care sector, the authorities, sewage treatment plants and pharmaceutical industries. In the current situation, these collaborations mainly address questions about end-of-pipe solutions, or how to minimize antimicrobial resistance. **The sixth recommendation is to use the existing networks as a starting point to also involve other environmental concerns related to pharmaceuticals and to find new collaboration possibilities**.

2 Life-cycle Analysis, a technique to assess environmental impacts associated with all the stages of a product's life from raw material extraction through materials processing, manufacture, distribution, use, repair and maintenance, and finally disposal or recycling.

Common campaigns have been conducted in Finland between hospitals, pharmacies and authorities. There is also some other collaboration between the partners in the pharmaceutical business, mostly concerning issues other than the environmental impacts. However, the European Federation of Pharmaceutical Industries and Associations (EFPIA) has activities concerning pharmaceuticals and the environment. For example, they have participated in the development of a holistic environmental risk management program Eco-Pharmaco-Stewardship.

There are existing collaboration networks between different countries within the BSR (e.g. Baltic Sea Pharma Platform under EU Strategy for the Baltic Sea Region and CG PHARMA under HELCOM). This type of collaboration network could be used for continuous transfer of the best practices within the BSR and preferably also to export these outside the BSR.

National collaboration groups should be established in some form in each Baltic Sea country. The national groups can consist of actors from the pharmaceutical industry, medicine and environmental authorities, veterinarians and agriculture and professionals from pharmacies and hospitals. **The seventh recommendation is that the Baltic Sea countries should invest in establishing national knowledge centres for pharmaceuticals and the environment within their national medicine agencies** like has been done in Sweden.

The eighth recommendation is to establish a national pharmaceutical strategy that includes environmental issues related to pharmaceuticals. Sweden has already established a National pharmaceutical strategy, which of course demands politically entrenched goals and strategies. The report MistraPharma also concluded that a national strategy is important as it increases the incentives for partnerships among different stakeholders (MistraPharma, 2011).

The identified recommendations discussed in this report facilitate the development and implementation of harmonized legislation concerning pharmaceuticals. They provide more opportunities and resources for national medical agencies in the Baltic Sea countries to work with environmental aspects.

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Länsstyrelsen skapar samhällsnytta genom rådgivning, samordning, tillstånd, tillsyn, prövning, stöd och bidrag.Vi skyddar miljön, ser till att viktiga natur- och kulturvärden bevaras och skapar förutsättningar för att utveckla landsbygden och näringslivet i länet. Vi har även samhällsviktiga uppdrag inom bland annat krisberedskap, sociala frågor, djurskydd och samhällsplanering.
På så sätt bidrar vi till Länsstyrelsens vision om ett livskraftigt Östergötland

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