No. B 2395
September 2020

Reduce environmental impacts of pharmaceuticals along the value chain

Needs, requirements and use of product-specific environmental information by different actors and for different applications

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In cooperation with The Research-Based Pharmaceutical Industry (LIF)

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Funded by: Foundation of the Institute for Water and Air Research (SIVL) and The Research-Based Pharmaceutical Industry (LIF)
Report number B 2395
ISBN 978-91-7883-216-3
Edition Only available as PDF for individual printing

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This report has been reviewed and approved in accordance with IVL's audited and approved management system.

Table of contents

Summary

In order to reduce the environmental impacts of pharmaceuticals, reliable, comparable and relevant information is needed about the impacts along the value chain as basis for decisions to manage and control the impacts. The objective of this project is to define and evaluate needs, requirements and use of product-specific environmental information by different actors along the pharmaceutical value chain – with the overall aim to reduce environmental impacts. In the context of this report, product-specific environmental information refers to information delivered by the proposed environmental assessment model for pharmaceutical products which has been developed in an earlier project, that includes environmental risks associated with emissions of API (Active Pharmaceutical Ingredient) and carbon footprint in a life cycle perspective.

The evaluation has focused on five main application areas for product-specific environmental information: Assessments in conjunction with product approval, Product and process improvements, Benefit subsidy system, Procurement of pharmaceuticals, and Guidance in product choice and use. Based on these main applications, the study has mapped roles and responsibilities of different actors in the work to reduce environmental impacts along the value chain: Authorities, Regions, Pharmacies and Pharmaceutical companies and supply chains. A review of the policy framework has also been performed. Challenges, drivers and opportunities have been identified – both on a general level, which are shared by all actors, and on application level.

The study shows that there is an increasing focus on environmental impacts of pharmaceuticals and healthcare. All actors stress the need for product-specific environmental information, to enable informed decisions to prioritise and drive improvements in different parts of the value chain. It is also highlighted that there a lot to gain if requirements and standards are shared between actors. This simplifies and harmonises the work for both providers and users of the information. There are, however, still a lack of market incentives to share this information. It is also stressed that any further development should align with other relevant initiatives in this area, to avoid duplication of work and secure synergies. In addition, a combination of regulatory and voluntary initiatives will be needed.

The five application areas are also discussed in terms of which actors are involved in each application, what the current main challenges are, as well as main drivers and opportunities to move forward. The applications Procurement of pharmaceuticals, Product and process improvements and Guidance in product choice and use are all within the responsibilities, frame of action and mandate of the involved actors. Several initiatives have started or is ongoing in these areas, where the possibility to drive environmental improvements would be strengthened by increased availability of product-specific environmental information. The applications Benefit subsidy system and Assessments in conjunction with product approval require policy development and decisions on national or on EU and international level. Experiences gained in the other applications may, however, facilitate such policy development.

Based on the results from the study, key elements for further development and proposed way forward have been defined. To facilitate collaboration and interaction, shared goals should be established between the actors along the value chain. Also, shared requirements and standards need to be established on different levels, both on application level e.g. procurement, and on method and standard level, where the proposed model may form the basis. It is also important that further development of the model is integrated with development of its applications to secure that the information meets the requirements of the applications. This will involve developing and

establishing changed or new way of working and tools for both providers and users of the information. Market incentives is needed to get things moving, and in the short term this can be created through procurement of pharmaceuticals combined with the pharmacies initiative to establish a product eco-label for OTC pharmaceuticals, and in the longer term in the benefit subsidy system, especially within the framework for generic substitution. A "timeline" for further development and implementation is also proposed, indicating a potential order for where to start.

As a next step it is proposed to *"pick the low-hanging fruits"* and start to apply the environmental risk part of the proposed model in procurement of pharmaceuticals. To ensure continued development and maintenance of the model and its application as a whole, it is also recommended to create a *shared strategic roadmap* in collaboration with actors along the pharmaceutical value chain. The roadmap should address the key elements for further development and proposed way forward.

Sammanfattning

För att kunna minska miljöpåverkan från läkemedel krävs tillförlitlig, jämförbar och relevant information om påverkan längs hela värdekedjan, till grund för beslut om att hantera och kontrollera påverkan. Syftet med detta projekt är att definiera och utvärdera behov, krav och användning av produktspecifik miljöinformation av olika aktörer längs läkemedelsvärdekedjan - med det övergripande målet att minska miljöpåverkan. I denna rapport avser produktspecifik miljöinformation den information som levereras av den föreslagna modellen för miljöbedömning av läkemedel, vilken har utvecklats i ett tidigare projekt, som inkluderar miljörisker i samband med utsläpp av API (aktiv läkemedelssubstans) och klimatavtryck ur ett livscykelperspektiv.

Utvärderingen har fokuserat på fem huvudsakliga tillämpningsområden för produktspecifik miljöinformation: Bedömningar i samband med produktgodkännande, Produkt- och processförbättringar, Läkemedelsförmånssystem, Upphandling av läkemedel samt Vägledning vid produktval och användning. Baserat på dessa tillämpningar har studien kartlagt olika aktörers roller och ansvar i arbetet för att minska miljöpåverkan längs värdekedjan - Myndigheter, Regioner, Apotek samt Läkemedelsföretag och leverantörskedjor. En genomgång av policyramverket har också genomförts. Utmaningar, drivkrafter och möjligheter har identifierats - både på generell nivå, som är gemensamma för alla aktörer, och på tillämpningsnivå.

Studien visar att det finns ett ökande fokus på miljöpåverkan av läkemedel och hälso- och sjukvård. Alla aktörer betonar behovet av produktspecifik miljöinformation för att möjliggöra väl underbyggda beslut för att prioritera och driva förbättringsarbete i olika delar av värdekedjan. Det framhålls också att det finns mycket att vinna om krav och standarder delas mellan aktörer. Detta förenklar och harmoniserar arbetet för både leverantörer och användare av informationen. Det saknas dock fortfarande marknadsincitament för att dela denna information. Det betonas också att vidareutveckling bör anpassas med andra relevanta initiativ på detta område för att undvika dubbelarbete och säkra synergier. Dessutom kommer en kombination av lagstiftning och frivilliga initiativ att behövas.

De fem tillämpningsområdena diskuteras också med avseende på vilka aktörer som är involverade i varje tillämpning, vilka de nuvarande huvudutmaningarna är, liksom de viktigaste drivkrafterna och möjligheterna för att gå vidare. Tillämpningarna Upphandling av läkemedel, Produkt- och processförbättringar och Vägledning i produktval och användning ligger inom de involverade aktörernas ansvar, handlingsutrymme och mandat. Flera initiativ har startat eller pågår inom dessa områden, där möjligheten att driva arbete med miljöförbättringar skulle stärkas genom ökad tillgänglighet av produktspecifik miljöinformation. Tillämpningarna Läkemedelsförmånssystem och Utvärderingar i samband med produktgodkännande kräver policyutveckling och beslut på nationell eller på EU-nivå och internationell nivå. Erfarenheter från andra tillämpningar kan dock underlätta sådan policyutveckling.

Baserat på resultaten från studien har nyckelelement definierats för vidareutveckling och en föreslagen väg framåt. För att underlätta samarbete och interaktion bör delade mål upprättas mellan aktörerna längs värdekedjan. Delade krav och standarder bör upprättas på olika nivåer, både på tillämpningsnivå, t.ex. upphandling, samt på metod och standardnivå, där den föreslagna modellen kan ligga till grund. Det är också viktigt att vidareutveckling av modellen integreras med utveckling av dess tillämpningar, för att säkerställa att informationen uppfyller kraven i tillämpningarna. Det innebär utveckling av förändrade eller nya arbetssätt och verktyg för både leverantörer och användare av informationen. Marknadsincitament behövs för att få fart på

arbetet, och på kort sikt kan detta skapas genom upphandling av läkemedel, i kombination med apotekens initiativ för att etablera en produktmiljömärkning för receptfria läkemedel, samt på längre sikt i läkemedelsförmånssystemet, särskilt inom ramen för generisk substitution. En "tidslinje" föreslås också för fortsatt utveckling och implementation, vilken indikerar en potentiell ordningsföljd för var man bör börja.

Som ett nästa steg föreslås att *"plocka de lågt hängande frukterna"* och börja tillämpa miljöriskdelen av den föreslagna modellen vid upphandling av läkemedel. För att säkerställa fortsatt utveckling och förvaltning av modellen och dess tillämpning som helhet rekommenderas också att skapa en *gemensam strategisk färdplan* i samarbete med aktörer längs läkemedelsvärdekedjan. Färdplanen bör adressera nyckelelementen för vidareutveckling och föreslagen väg framåt.

1 Introduction

Pharmaceuticals have an environmental impact along the value chain; from extraction and processing of raw materials, production of API, formulation and packaging to the distribution, use and end-of-life of the product. To manage and control the impacts, environmental considerations need to be integrated in different activities along the chain, such as in product development and innovation, product approval, production development, procurement, distribution, administration and use, where different stakeholders along the value chain have different roles in this work.

Therefore, to enable environmental considerations and decisions for improvements by different stakeholders along the pharmaceutical value chain, there is an increasing need for credible, relevant and comparable information about the environmental impacts of pharmaceuticals in a life cycle perspective.

As a response to this this need of information, a model for environmental assessment of pharmaceutical products was developed and proposed in a collaboration project between IVL and LIF, financed by LIF and SIVL[1]. The model includes environmental risks associated with emissions of Active Pharmaceutical Ingredients (API) and carbon footprint in a life cycle perspective. It is intended to enable evaluation and comparison of environmental impacts of medically equivalent pharmaceutical products. Several potential applications for the model were also identified, where the information may be used to reduce the environmental impact of pharmaceuticals along the value chain. The model and its potential applications are briefly introduced in chapter 2 and chapter 3 in this report.

This continuation project has focused on improving the understanding of different stakeholder needs, as basis for recommendations for how the further development and implementation of the model may be performed. Some further harmonisation and development still remain before the model can be implemented. However, one of the key conclusions from the project was that the actual intended use of the information must be clarified and better understood in order to prioritise and guide further development and implementation of the model.

1.1 Aim of project and study

The objective of the project is to define and evaluate needs, requirements and use of product-specific environmental information by different stakeholders along the pharmaceutical value chain – with the overall aim to reduce environmental impacts along the chain.

In the context of this report, product-specific environmental information refers to information delivered by the proposed model for environmental assessment for pharmaceutical products, which includes environmental risks from emissions of API and carbon footprint in a life cycle perspective[2] . See chapter 2 for a brief introduction to the model.

[1] Pålsson AC., Belleza E., Ryding SO., Örtlund L. Westberg E. (2019) *Environmental assessment model for pharmaceutical products – Environmental risks related to Active Pharmaceutical Ingredients (API) and carbon footprint in a life cycle perspective*, Report B2352, Swedish Environmental Research Institute

[2] Ibid

The project is aimed to:

- Identify and map roles and responsibilities of different actors along the pharmaceutical value chain in the work to reduce environmental impacts, both in terms of current status and potential new/changed responsibilities. This includes where and how product-specific environmental information can be used to prioritize, measure and follow-up environmental improvements, as well as identification of knowledge and competence requirements to use the information in a correct way.
- Identify drivers, incentives and barriers for reporting and using product-specific environmental information in different parts of the value chain, by different actors - both internal and in collaboration with other actors along the chain. This includes an evaluation of policy and regulations that may support or hinder implementation.

Note: This project is a continuation of a jointly funded LIF/SIVL project aimed to develop and propose a model for environmental assessment of pharmaceutical products, that ran between 2017-2019[3].

1.2 Study set-up and limitations

The study has been performed based on the basic premise that product-specific environmental information may be used in different ways to drive improvements along the pharmaceutical value chain. The study has therefore been performed based on the following key aspects:

- *System perspective:* The pharmaceutical value chain consists of a complex system of different actors, where the actors have different roles and responsibilities and where the actors are interdependent and interact in different ways.
- *Environmental information as an enabler for change:* Access to relevant, credible and understandable environmental information enables informed decisions by different actors along the chain - to drive change and improvements.

The study involves an actor and system analysis aimed to define and evaluate needs, requirements and use of product-specific environmental information by different stakeholders along the pharmaceutical value chain. The scope of "product-specific environmental information" in the study is, however, limited to the scope of the proposed model for environmental assessment of pharmaceutical products, i.e. it has primarily focused on evaluating the needs, requirements and use of environmental risk and carbon footprint information specifically delivered by this model (see chapter 2).

In terms of included actors, it has primarily focused on key stakeholders along the pharmaceutical value chain that have or can have an "active" role and responsibility in the work to drive environmental improvements along the chain - by direct or indirect influence on development, approval, production, distribution and use of pharmaceuticals in Sweden. The following key actors

[3] Pålsson AC., Belleza E., Ryding SO., Örtlund L. Westberg E. (2019) *Environmental assessment model for pharmaceutical products – Environmental risks related to Active Pharmaceutical Ingredients (API) and carbon footprint in a life cycle perspective*, Report B2352, Swedish Environmental Research Institute

have been included: pharmaceutical companies and their supply chains, Swedish regions, pharmacies and government agencies.

The study has also focused on evaluating the potential applications that were identified for the proposed model for environmental assessment of pharmaceutical products: Assessments in conjunction with product approval, Process and product improvements, Benefit subsidy system, Procurement and Guidance in product choice and use (see chapter 3).

The collection of information in study has been performed by two multi-stakeholder workshops (in October 2019 and March 2020), combined with interviews with key actors along the pharmaceutical value chain and a literature review. Representatives from the following organisations have contributed in the project: LIF, AstraZeneca, Bayer, Pfizer, Västra Götalandsregionen (VGR), Region Stockholm, The Medical Product Agency (Läkemedelsverket), the National Agency for Public Procurement (Upphandlingsmyndigheten), The Swedish Pharmacy Association (Sveriges Apoteksförening), Apotek Hjärtat and Stockholm International Water Institute (SIWI).

The project was performed from August 2019 to June 2020 and was jointly funded by LIF and SIVL. The team at IVL included persons with competence and experience in sustainability management, sustainable value chains, environmental information management and policy development.

Note: Further development of the proposed model as such was not included within the scope of this project.

2 Product-specific environmental information for pharmaceuticals

The study is aimed to evaluate needs, requirements and use of product-specific environmental information by different stakeholders, where the evaluation is based on the proposed model for environmental assessment of pharmaceuticals developed in a joint LIF/IVL project.

This chapter provides a short overview of the content of the proposed model. As part of the development also several potential applications and use of the model was identified, indicating how the information delivered by the model could be used to drive environmental improvements by different actors along the pharmaceutical value chain. These applications are further described in chapter 3. More information about the model is available in IVL-report B2352[4].

The proposed model for environmental assessment includes two main parts (as indicated in Figure 1 below):

- *Environmental risks related to emissions of API* – which both covers environmental risks in production process steps where API can be/is released to the environment as well as release of API from patient excretion in Swedish water recipients.
- *Product carbon footprint in a life cycle perspective* – which covers greenhouse gas emissions for partial or full life cycle, i.e. from extraction of raw materials, transportation and production steps until finished product ("cradle to gate") or also including distribution, use to final disposal ("cradle to grave")

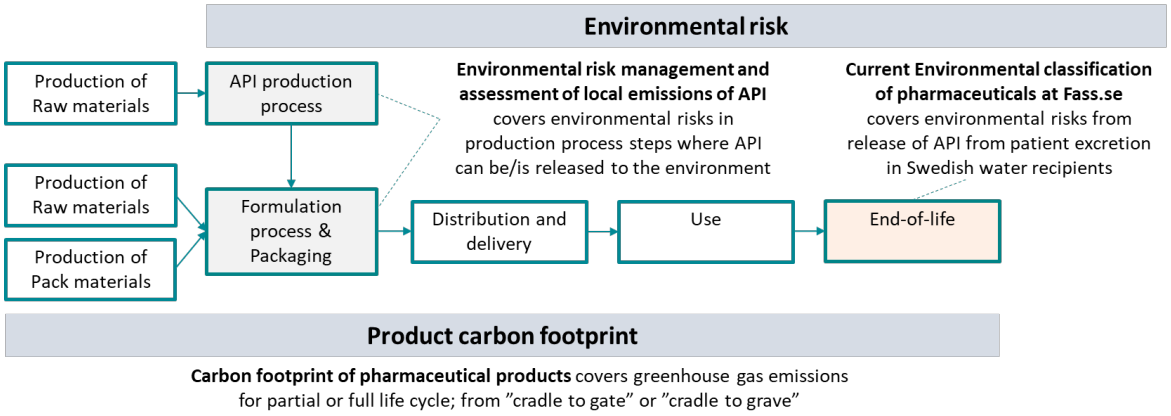


Figure 1. Overview of the parts in the model for environmental assessment of pharmaceutical products

The model is intended to facilitate and enable evaluation and comparisons between performed environmental assessments of pharmaceutical products with the same API. To ensure credibility and quality of reported results, the model should also allow for third party review and validation.

[4] Pålsson AC., Belleza E., Ryding SO., Örtlund L. Westberg E. (2019) *Environmental assessment model for pharmaceutical products – Environmental risks related to Active Pharmaceutical Ingredients (API) and carbon footprint in a life cycle perspective*, Report B2352, Swedish Environmental Research Institute

The two parts of the model are briefly described below.

The environmental risk part of the model covers environmental risks related to emissions of API in both production and end-of-life of pharmaceuticals. It builds on the current environmental classification at Fass.se and includes the following elements:

- *Environmental risk management*, which involves a qualitative evaluation of how the reporting company works with risk management in a systematic way, in terms of policies, procedures and follow-up.
- *Assessment of local emissions of API*, which involves an environmental risk assessment of emissions of API to local water recipients from production process steps where API can be/is released; i.e. from production of the API, and from formulation and packaging of the pharmaceutical products.
- *Current Environmental classification at Fass.se,* which involves an environmental risk assessment of release of API from patient excretion in Swedish water recipients.

Note: This part of the model combines existing elements (evaluation of environmental risk management and the current environmental classification) with a new element (assessment of local emissions of API) which is focused on production, in order to achieve a more complete picture of environmental risks in different parts of the life cycle.

The product carbon footprint part covers greenhouse gas emissions for partial or full life cycle; from "cradle to gate" or "cradle to grave", based on Life Cycle Assessment (LCA) methodology.

To secure comparability and verifiability, we propose to use the framework described in ISO 14025 for environmental product declarations as basis and initiate the development of Product Category Rules (PCR) for pharmaceutical products; building on earlier harmonization efforts and experiences with life cycle assessments and carbon footprints within the pharmaceutical industry. A PCR describes and harmonizes scope and content for what to include in data collection, calculations and reporting for a specific product category.

A modularised set-up for the PCR development is proposed, to allow reporting on different levels. Three potential levels have been identified; Level 1. Cradle to gate - finished API, Level 2. Cradle to gate – finished product, and Level 3. Cradle to grave – product. The modularisation would e.g. allow for API suppliers to report aggregated results that can be used directly as input data in calculations for finished products. This could be one way of handling issues with secrecy and data sharing between business partners.

Results delivered by the model: An example

The model is aimed to deliver product-specific environmental information that enables comparisons of environmental performance between equivalent products delivered by different suppliers. Figure 2 shows an example of how the result from the two parts of the model may look like. The example also illustrates that a supplier that performs well in terms of environmental risk may perform worse in terms of carbon footprint. Thus, it also shows that trade-offs will need to be handled between the two parts of the model.

Result Product A, Supplier A	
Environmental risk	
• Environmental risk management	Medium level
• Local emissions of API from production	Medium risk
• Release of API from patient excretion in Swedish water recipients	Low risk
Product carbon footprint	
• Level 2 Cradle to gate	2 kg CO2e/DDD

Result Product B, Supplier B	
Environmental risk	
• Environmental risk management	Best in class
• Local emissions of API from production	Low risk
• Release of API from patient excretion in Swedish water recipients	Low risk
Product carbon footprint	
• Level 2 Cradle to gate	4 kg CO2e/DDD

Figure 2 Example of potential result from the model, for two suppliers delivering equivalent products

Need for further development

For both parts of the model, further development and harmonisation are needed before implementation can start. Three main areas of further development have been identified:

- *Securing comparability in data collection & assessments;* i.e. agree and harmonise how to collect and compile data in a comparable way. Among issues to be solved are, for example, how to allocate data on production site level to individual products, and how to handle data collection from suppliers. This includes development of supporting guidelines and tools to facilitate data collection, calculations and reporting.
- *Third-party verification:* develop methods and procedures for how to verify underlying data and results, to secure transparency and credibility of results
- *Communication and interpretation of results:* develop how to communicate the results in an understandable manner, to secure that they can be correctly interpreted and used. Guidance for how to handle trade-offs between the two parts of the model, i.e. between environmental risks related emissions of API and climate impacts, may also need to be developed.

For all parts in development, confidentiality in data sharing and reporting will be an important aspect to consider and manage, as well as resources and competence requirements for those involved in the work.

3 Applications for product-specific information to drive environmental improvements

As the proposed model is intended to enable evaluation and comparison of environmental performance between products and suppliers, it may be used as basis to control, manage and reduce impacts along the pharmaceutical value chain, and drive improvement work in different parts of the chain.

Five main application areas for the information have been identified, as indicated in Table 1. The application areas may be considered as key strategies or action areas in the work to reduce the environmental impacts of pharmaceuticals along the value chain.

Table 1. Identified main application areas for product-specific environmental information, to drive environmental improvements along the pharmaceutical value chain

Application	How can this drive environmental improvements?
Assessments in conjunction with product approval	Set a "basic environmental standard" for pharmaceuticals by enabling a broader understanding of the environmental consequences of the product to be approved, as basis for e.g. risk mitigation measures
Product and process improvements	Reduce environmental footprint along the value chain, through research, product development & innovation, operations development and procurement & supply chain management.
Benefit subsidy system	Secure health & safety, environmental and financial performance of products within the system, by including environmental aspects as selection criteria
Procurement of pharmaceuticals	Reduce environmental impacts in supply chain by favouring suppliers and products that perform better in regard to environmental aspects
Guidance in product choice and use	Reduce environmental impacts of pharmaceutical use, by choosing environmentally preferable options among alternatives, and guide use and handling of the product to minimise environmental impacts in use and end-of-life treatment

A common denominator for these main application areas is that they all require environmental information about environmental impacts of products in a life cycle perspective, in order to enable and support actions and decisions to manage and control environmental impacts. They are primarily focused on "upstream" actions, i.e. actions in different parts of the value chain to reduce emissions to the environment. "Downstream" actions to handle emissions once they have entered the environment, such as actions to improve waste management and treatment of wastewater, is therefore not specifically addressed.

The identified applications are aligned with the action areas identified in the EU strategy for Pharmaceuticals in the Environment, especially the parts of the strategy aimed at increasing

awareness and promoting prudent use of pharmaceuticals, supporting development of pharmaceuticals intrinsically less harmful to the environment and promoting greener manufacturing, improving risk assessment, and filling knowledge gaps[5].

The application areas also contribute to several Sustainable Development Goals (SDG) and targets within Agenda 2030, particularly:

- *Goal 6 Ensure availability and sustainable management of water and sanitation for all*, with focus on improving water quality by minimizing release of hazardous substances (target 6.3).
- *Goal 12 Ensure sustainable consumption and production patterns,* with focus on environmentally sound management of chemicals throughout the life cycle (target 12.4), encouraging companies to adopt sustainable practices and integrate sustainability reporting into their reporting cycle (target 12.6), promote sustainable public procurement practices (target 12.7), and ensure that people everywhere have access to relevant information for sustainable development (target 12.8).
- *Goal 13 Take urgent action to combat climate change,* with focus on integrating climate change measures in policies and strategies (target 13.2).
- *Goal 14 Conserve and sustainably use the oceans, seas and marine resources for sustainable development,* with focus on preventing and reduce marine pollution of all kinds (target 14.1).
- *Goal 17 Partnerships for the goals,* with focus on encouraging and promoting public-private partnerships (target 17.17).

The identified main application areas are further described below.

Assessments in conjunction with product approval

An improved and broader environmental assessment of the environmental risks of the product, which cover risks in different parts of the life cycle, can be used in processes for market authorization within EU, and has as such a potential to secure environmental aspects a basic level for all pharmaceuticals in the Swedish and European market. This has been proposed by the Swedish Medical Product Agency (see also Appendix 3).

This does not necessarily imply that environmental aspects should be integrated in the patient product risk/benefit evaluation. In line with current regulation and opinion, the focus for approval should still remain on risk vs. benefits from a medical/clinical human health perspective. However, in the current legislation the measures for mitigating identified environmental risks once the product has been approved and launched is fairly limited (see also Appendix 2). This could be improved by, for example, conditioning the approval with requirements for different actions to control identified risks, such as actions to minimise emissions from manufacturing processes as well as requirements in prescription to optimise use and reduce release of the API to the environment from patient excretion.

[5] European Commission (2019) *European Union Strategic Approach to Pharmaceuticals in the Environment.* COM(2019) 128 final.

Product and process improvements

This includes the pharmaceutical industry's own efforts to reduce impacts along value chain through different actions (see also Appendix 6):

- *Product development and innovation;* focusing on improving the overall environmental performance of products in a life cycle perspective. This can, for example, include integrating environmental assessments in different stages of the research, product development and innovation work to identify and mitigate environmental risks in different parts of the life cycle.
- *Process and production development;* focusing on improving the environmental performance of own operations and manufacturing. This can, for example include technology development, improving emission control, waste, as well as considerations of where to localize production sites.
- *Procurement and supply chain management;* focusing on improving the environmental performance in supply chain, in production of raw materials by suppliers and sub-suppliers. This can, for example, include integrating environmental requirements and follow-up in different parts of the procurement process, such as in evaluation and choice of supplier, in contract agreements, and in continuous supplier improvements.

Product-specific environmental information can be used in a number of different ways to support product and process improvements. For example, it can be used to identify improvement opportunities in different parts of the life cycle (e.g. in supply chain, own operations or in use phase) or within the product portfolio (e.g. products within the portfolio which has a high environmental impact), as well as to prioritize and plan improvement actions, define targets and KPIs, both internally and in collaboration with business partners along the chain, and follow-up results from implemented improvements.

The pharmaceutical industry´s work with product and process improvements are driven both by legal requirements and by the companies´ own proactive environmental ambitions, strategies and targets. In the development of strategies and targets, usually different stakeholder requirements (investors, employees, customers, etc.) are considered.

Benefit subsidy system

Integrating environmental aspects as one selection criteria in the benefit system can secure health & safety, environmental and financial performance of the products within the system. Today, the system is based on "lowest cost", guided by the aim of the whole system to "acquire as much health as possible for the tax-payers money going to medicines"[6]. Environmental aspects are not weighed into the decisions. By integrating environmental considerations, the system could secure the "best value" based on health, environmental and financial aspects. The main potential lies in the part of the benefit system where there is competition, that is, in the generic substitution system ("periodens vara"). See also Appendix 3 and Appendix 4.

In order to weigh in environmental considerations in the system, relevant, comparable and reliable product-specific environmental criteria and information is required, that has been compiled, reported and verified in accordance with commonly accepted methods and tools. Naturally such

[6] TLV, TLV i korthet: https://www.tlv.se/om-oss/om-tlv/tlv-i-korthet.html

criteria and information need to hold for strict review, to secure that the expected environmental benefits are realised.

Since the benefit subsidy system involves substantial volumes of medicines – in 2019 it represented 64 percent of the total sales in Sweden (see also Appendix 1) – the inclusion of environmental aspects as selection criteria in the system can have a substantial effect on the work to drive improvements and reduce environmental impacts along the value chain for pharmaceuticals used in Sweden.

Procurement of pharmaceuticals

Environmental impacts in the pharmaceutical supply chain can be reduced by integrating environmental considerations in procurement of pharmaceuticals, by favouring suppliers and products that perform better in regard to environmental aspects in procurement decisions. This both includes public procurement for inpatient care performed by the regions (see Appendix 4), as well as the pharmacies´ procurement of OTC (over the counter) pharmaceuticals (see Appendix 5). Here, product-specific environmental information can be used to prioritise and follow-up environmental requirements and improvements.

The potential of Green Public Procurement (GPP) as a policy instrument to achieve environmental targets has been increasingly recognised, and over recent years there has been growing political commitment at national, EU and international levels. Sustainable procurement is also a key part in many companies´ sustainability strategies.

In 2019, public procurement of pharmaceuticals for inpatient care represented 19 percent of the total pharmaceutical sales in Sweden, and the pharmacies´ sales of OTC pharmaceuticals represented 10 percent (see also Appendix 1). Thus, inclusion of environmental aspects into procurement decisions could have a considerable effect on the work to reduce environmental impacts of pharmaceutical use in Sweden.

Guidance in product choice and use

Environmental impacts of pharmaceutical use can also be reduced by choosing the environmentally preferable options for medical treatments when there are alternatives, and guide use and handling of the product to minimise environmental impacts in use and end-of-life treatment.

This includes integrating environmental aspects in development and implementation of different types of guidance and recommendations for product choice and use, such as in guidelines and recommendations by the regions´ medicinal products committees (see Appendix 4), or through “eco-labelling” for OTC pharmaceuticals by pharmacies (see Appendix 5). Product-specific environmental information can be used to compare environmental impacts of different options and be used as basis for verifying requirements in product labels. It can also include specific environmental information directed towards healthcare professionals, pharmacy personnel and patients/consumers.

Guidance in product choice and use complements the application areas described above and can as such combine and utilise efforts in the other applications (e.g. information collected in procurement can be used as basis in development of recommendations), as well as secure optimal use and handling of the products, thereby optimising the overall environmental performance along the value chain.

4 Roles and responsibilities of actors along the pharmaceutical value chain

As described in the previous chapter, a number of main application areas have been identified for using product-specific environmental information to drive improvements and reduce impacts along the pharmaceutical value chain. Depending on the application, the different actors along the chain – pharmaceutical companies, authorities, pharmacies, regions and patients/consumers – will have different roles and responsibilities and will be able to use the information in different ways. Also, depending on application the actors interact in the different ways, and consequently collaboration is needed between the actors along the chain.

This chapter presents a mapping of roles and responsibilities of different Swedish actors in the work to reduce impacts along the pharmaceutical value chain, including where and how product-specific environmental information can be used to prioritize, measure and follow-up improvements. We have primarily focused on actors that have or can have an "active" role and responsibility in the work to drive environmental improvements along the chain - by direct or indirect influence on development, approval, production, distribution and use of pharmaceuticals in Sweden. Figure 3 illustrates the key actors that have been included.

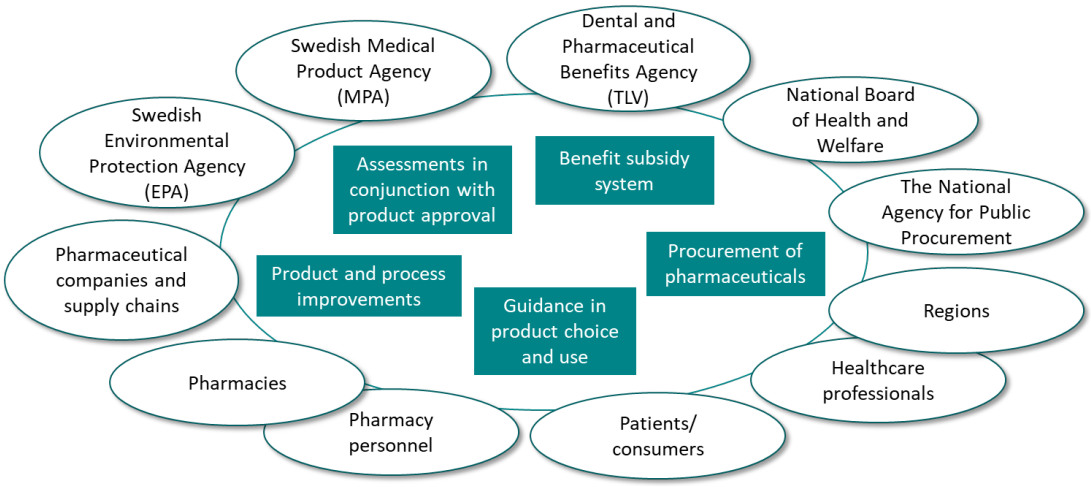


Figure 3. Key actors along the pharmaceutical value chain in Sweden

Each actor is described below in terms of actor structure, governance of environmental priorities and environmental responsibilities. The description of environmental responsibilities starts from the identified applications for product-specific environmental information described in chapter 3. Thus, we have focused on roles and responsibilities where product-specific information specifically is needed to support the work. This means that some environmental responsibilities of the different actors may not be described or captured. The end-user of pharmaceuticals, i.e. the patient/consumer is not specifically described below, except for in the meeting with healthcare professionals in Regions and pharmacy personnel in Pharmacies.

The roles and responsibilities of different actors are influenced by the policy framework in terms of regulations for development, approval, production, distribution and use of pharmaceuticals in Sweden. Therefore, an overview of the policy framework is also given below.

4.1 Policy framework

The description below is a summary of the review of policy and regulations for pharmaceuticals, see Appendix 2 for more information

Pharmaceutical products are strictly regulated by legislation, directives and policy instruments on international and EU level as well as on national level to secure public health protection and the quality, safety and efficacy of the medicines. Regulations cover development, approval, manufacturing, marketing, distribution and use. The environmental regulation for pharmaceuticals on process and product level is limited within the pharmaceutical legislation. However, pharmaceutical manufacturing processes are regulated within general environmental legislation, such as Industrial Emissions Directive (IED) in Europe.

Before a medicine can be marketed and made available to patients, a *product approval through market authorisation* is required. As part of the authorisation, it is since 2006 mandatory to perform an Environmental Risk Assessment (ERA) in accordance to the EMA guideline. The ERA most often includes environmental risks associated with emissions of API from usage of the medicine, i.e. risks in other parts of the life cycle is generally not included. The results from the ERA are not included in the risk-benefit evaluation, which is the basis for the market authorisation decision, i.e. medicines cannot be declined due to significant environmental risks. The possibility to impose regulatory risk management measures to reduce risks once the products has been launched is also fairly limited and is basically restricted to measures to inform health and medical care about the environmental risks. In addition, there is currently no requirements to make the detailed information from the ERA publicly available when the medicine has been approved and launched. Some details can be available in the European Public Assessment Report (EPAR) for approved medicines, but these are generally very limited.

In terms of regulations for manufacturing, the principles and guidelines for *Good Manufacturing Practice (GMP)* apply irrespective of where in the world the ingredient or product is manufactured. GMP focuses on securing safe and effective medicinal products for users. Requirements regarding environmental management is, however, not included in GMP. Within EU, the main regulations governing pharmaceutical manufacturing are the *Industrial Emissions Directive (IED), REACH* and the *Water Framework Directive*. The IED applies to pharmaceutical manufacturing sites, but emissions of APIs are not included in the list of polluting substances. REACH apply to intermediates and other chemicals used in manufacturing, but the API and finished product are exempt. The Water Framework Directive is currently the single EU directive that most explicitly considers issues of pharmaceuticals in the environment. The directive includes a list of substances that shall be monitored in the EU, where a few selected pharmaceutical substances are included on the watchlist.

The overall legal framework for pricing and reimbursement of pharmaceuticals in the *Swedish national subsidy system and generic substitution* does currently not include environmental aspects. Environmental aspects can, however, be included for pharmaceuticals procured in accordance with the Public Procurement Act, where *Green Public Procurement* as a policy instrument to achieve environmental targets are receiving increased attention within the EU and internationally. There is, however, no harmonized environmental criteria for pharmaceuticals with the EU.

A number of policy initiatives have started within the EU with relevance to the pharmaceutical value chain, which most likely will influence future policies and legislation for pharmaceuticals and improve environmental requirements. Two key initiatives are highlighted; *the European Green*

Deal and the *Strategic Approach to Pharmaceuticals in the Environment.* The transformation of regulations and policy frameworks at international and EU level is, however, a long-term and complex process.

4.2 Government agencies

The following is a summary of the review of government agencies, see Appendix 3 for more information. Note: In this study we have focused specifically on agencies that have, or potentially could have, key responsibilities in environmental management of pharmaceuticals along the value chain.

Actor structure

Roles and responsibilities for pharmaceuticals are shared between several ministries and government agencies:

- The Ministry of Health and Social Affairs is responsible for the Swedish Medical Product Agency (MPA), the Dental and Pharmaceutical Benefits Agency (TLV) and the National Board of Health and Welfare (SoS).
- The Ministry of Environment is responsible for the Swedish Environmental Protection Agency (EPA)
- The Ministry of Finance is responsible for the National Agency for Public Procurement (Upphandlingsmyndigheten)

Governance of environmental priorities

Objectives and priorities for the government agencies are governed by appropriation directions issued by the Government. The Government therefore has quite substantial scope for directing the activities of government agencies, but it generally has no powers to interfere with how an agency applies the law or decides in a specific case. The government agencies take these decisions independently and report to the ministries.

Environmental responsibilities are clearly articulated in the directions and mandate for the Swedish Medical Product Agency, the Environmental Protection Agency and the National Agency for Public Procurement. For some authorities, however, environmental responsibility is not clearly articulated in the mandate – this concerns the Dental and Pharmaceutical Benefits Agency and National Board of Health and Welfare

Environmental responsibilities

Based on the identified applications in chapter 3 different government agencies have, or could have, different roles - indicated in Figure 4. Responsibilities for some applications are, or could be, shared between different agencies.

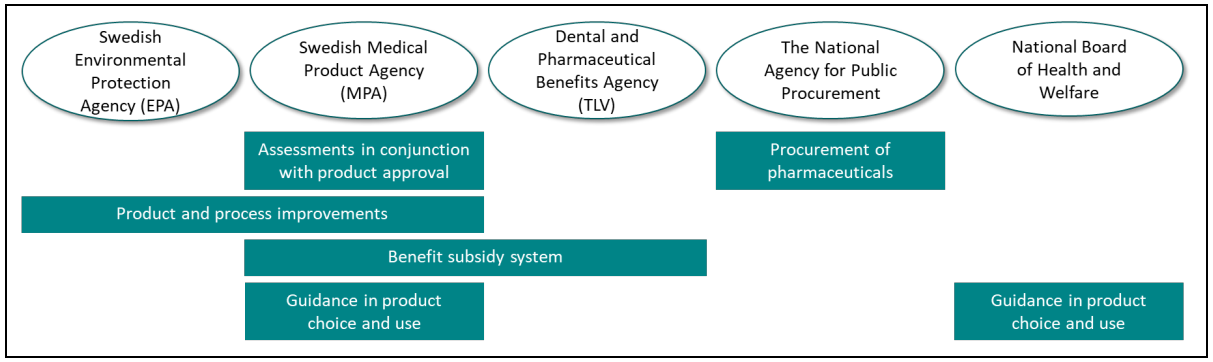


Figure 4. Overview of environmental roles and responsibilities of different government agencies.

The Swedish Medical Product Agency is responsible for regulation and surveillance of the development, manufacturing and sale of drugs and other medicinal products[7]. The MPA has a sector responsibility to coordinate environmental issues for pharmaceuticals in Sweden[8], and is responsible for the environmental milestone target *"Greater environmental consideration in EU pharmaceuticals legislation and internationally"* within the Swedish environmental quality objective *"A Non-Toxic Environment"*[9].

As indicated in Figure 4, the MPA is responsible for evaluating the environmental risk assessments (ERA) in conjunction with product approval as part of market authorisation, as well as for supporting guidance in product choice and use by providing information and increasing knowledge about the environmental effects of pharmaceuticals. The MPA also has a shared responsibility with the EPA concerning environmental legislation for e.g. emission limits for pharmaceutical manufacturing (indicated as product and process improvements in the figure). In addition, the MPA performs the medical evaluation in the benefit subsidy system. Within the current regulations for pharmaceuticals (see chapter 4.1 and Appendix 2), the MPAs mandate and frame of action are, however, somewhat limited (see Appendix 3).

The MPA works actively with promoting issues of pharmaceuticals and the environment on national, EU and international level. Since the regulations for pharmaceuticals are harmonised on EU level, an important task is to influence the development of the policy framework, regulations and measures within EU and internationally. For example, the MPA works to increase environmental considerations in permitting licences for pharmaceuticals, promote availability of environmental information for pharmaceuticals in a concerted manner, reduce discharges of environmentally harmful substances from production of pharmaceuticals, reduce environmental impacts in use of pharmaceuticals, as well as stimulate development of pharmaceutical products with low overall environmental impact[10] (see also Appendix 3 for more information). In this, the MPA seek coalitions with other countries and collaborate with other stakeholders and government agencies. The agency can, however, only act within the framework of its own mandate and major changes require political initiatives.

[7] Government Offices of Sweden, Medical Products Agency: https://www.government.se/government-agencies/medical-products-agency-lakemedelsverket-lv/
[8] Läkemedelsverket (2018) *Miljöutredning 2018.*
[9] Sveriges miljömål, Etappmål, Ökad miljöhänsyn i EU:s läkemedelslagstiftning och internationellt: http://www.sverigesmiljomal.se/etappmalen/okad-miljohansyn-i-eus-lakemedelslagstiftning-och-internationellt/
[10] Läkemedelsverket (2018) *Handlingsplan för hur Läkemedelsverket fram till 2020 ska verka för att nå miljömålen (reviderad).*

The Dental and Pharmaceutical Benefits Agency (TLV) is responsible for the national pharmaceutical subsidy system and generic substitution and determines whether a pharmaceutical product, medical device or dental care procedure shall be subsidized by the state[11]. In the generic substitution system, the MPA is responsible for assessing which medicines are interchangeable and the TLV is responsible for deciding and providing a monthly list of which interchangeable products are least expensive and shall be provided by pharmacies. Environmental aspects are not weighed into the decisions today, as the current regulation for the system the current mandate of TLV do not include or enable explicit environmental considerations.

Thus, TLV could potentially have an important role in weighing in environmental aspects as part of the benefit subsidy system. However, as this is not within the current scope and mandate for the agency, they need a government assignment to do this.

The National Board of Health and Welfare works to ensure good health, social welfare and high-quality health and social care on equal terms for the whole Swedish population[12]. As part of this, the agency develops national guidelines to support decision makers and personnel in health and medical care[13]. At present, the National Board of Health and Welfare does not include environmental considerations in development of the national guidelines. The work with the guidelines and support in the field of equal healthcare could, however, provide a model also for implementing environmental aspects into guidance for choice and use of pharmaceuticals for different medical treatments (as indicated in Figure 4).

The Swedish Environmental Protection Agency is responsible for coordinating Sweden´s environmental work – nationally, within EU and internationally[14]: For example, the EPA ensures that environmental legislation is applied in an appropriate and correct manner, e.g. concerning use of best available techniques (BAT), monitors the state of the environment work as well as work together with other Swedish agencies and organizations on international level and within the EU to promote policy development for emission limits in the manufacture of pharmaceuticals. Also, the Agency can initiate, coordinate, finance and participate in projects, assignments and research that contribute to development and dissemination of knowledge, in collaboration with other actors.

The EPA has a shared responsibility with the MPA concerning environmental legislation for pharmaceuticals (indicated as Product and process improvements in Figure 4). The division of responsibility between the MPA and the EPA is not clear-cut. Based on the review, it seems that the MPA is responsible for pharmaceutical specific environmental impacts and legislation, e.g. impacts related to emissions of APIs, whereas the EPA is responsible for general environmental impacts and legislation which is valid for most industries, e.g. climate impacts. The EPA is also responsible for coordinating monitoring of substances in the environment, which includes several pharmaceutical substances.

The National Agency for Public Procurement has an overall responsibility for developing and supporting the procurement carried out by contracting authorities and entities in Sweden, e.g. by regions and municipalities[15]. They shall work for a legally secure, efficient and socially and

[11] Government Offices of Sweden, Dental and Pharmaceutical Benefits Agency (TLV): https://www.government.se/government-agencies/dental-and-pharmaceutical-benefits-agency-tandvards--och-lakemedelsformansverket-tlv/
[12] Government Offices of Sweden, National Board of Health and Welfare: https://www.government.se/government-agencies/national-board-of-health-and-welfare--socialstyrelsen/
[13] Socialstyrelsen, Nationella riktlinjer: https://www.socialstyrelsen.se/regler-och-riktlinjer/nationella-riktlinjer/
[14] Swedish EPA, About the Swedish Environmental Protection Agency: http://www.swedishepa.se/About-us/
[15] The National Agency for Public Procurement, About us: https://www.upphandlingsmyndigheten.se/en/omossmeny/about-us/

environmentally sustainable procurement for the benefit of citizens and business development. The sustainability criteria library is a central tool in the Agency´s work in supporting contracting authorities in their sustainable procurement[16]. As part of this, updated sustainability criteria for procurement of pharmaceuticals for inpatient care was launched in 2019[17].

Implementation of the sustainability criteria, however, lies with the contracting authorities and the criteria are voluntary to use. Based on the current overall responsibility of the agency, the agency thus has no mandate enforce the implementation of sustainability criteria in procurement on a national level.

4.3 Regions

The following is a summary of the review of the regions, see Appendix 4 for more information.

Actor structure

The 21 regions in Sweden are self-governing local authorities responsible for providing regional health care.

Governance of environmental priorities

Environmental management in the regions are governed by regionally adopted environmental goals, strategies and programs, and consequently the scope and focus for the work vary depending on the political ambitions in the region. The importance of clear political priorities and mandate are stressed, to enable and support the strategic and operational work to manage environmental impacts of pharmaceuticals within the regions. The scope for ambitions and targets usually covers the entire value chain - from manufacture, distribution and prescription to waste.

Environmental responsibilities

As indicated in Figure 5, the regions have a role in promoting environmentally sound pharmaceutical supply chains by using and implementing environmental requirements in *procurement of pharmaceuticals for inpatient care*. The regions also have an important role in promoting sound and sustainable use of pharmaceuticals through *guidance in product choice and use*, where the healthcare professionals working within the regions have a key role as they in the meeting with patients prescribe and recommend pharmaceuticals for different medical treatments.

Figure 5. Overview of environmental roles and responsibilities of regions

[16] Upphandlingsmyndigheten, Ställ hållbarhetskrav: https://www.upphandlingsmyndigheten.se/hallbarhet/stall-hallbarhetskrav/
[17] Upphandlingsmyndigheten, Enklare att upphandla hållbart tillverkade läkemedel: https://www.upphandlingsmyndigheten.se/aktuellt/enklare-att-upphandla-hallbart-tillverkade-lakemedel/

In terms of *procurement of pharmaceutical*s for inpatient care, the 21 regions in Sweden are independent contracting authorities. Within the framework of national coordination for sustainable procurement, there is an established collaboration between the regions, in which pharmaceuticals have been identified as a risk area from an environmental perspective[18]. The regions are using environmental criteria in procurement processes to a varying extent, see Appendix 4, chapter "Public procurement for inpatient care" for more information.

Work with *guidance in product choice and use* includes integrating environmental considerations in the work of the medicinal products committees when developing guidelines and recommendations for healthcare professionals, as well as training and raising awareness among healthcare personnel about the environmental impacts of pharmaceuticals. The recommendation lists prepared by the committees are important tools for healthcare professionals in their work with prescribing and recommending pharmaceuticals for different medical treatments. Also, it can include monitoring of pharmaceutical residues in the environment and specific actions for specific substances that have been identified as hazardous to the environment. See Appendix 4, chapter "Guidance in product choice and use" for more information.

4.4 Pharmacies

The following is a summary of the review of the pharmacies, see Appendix 5 for more information.

Actor structure

The Swedish pharmacy market consists of five major chains, three purely e-commerce players and around forty individually operated pharmacies. In total, there are more than 1,400 outpatient pharmacies, ten distance or internet pharmacies and 36 hospital pharmacies that provide medical care to inpatients[19].

Governance of environmental priorities

Environmental management in pharmacies are in general governed by company specific sustainability strategies, targets and programs, usually decided by the company management team and/or board. The scope and ambition level consequently vary between different pharmacies. Most pharmacy chains have developed and implemented sustainability programs, with targets and strategies related to environmental aspects of pharmaceuticals.

Environmental responsibilities

As indicated in Figure 6, the pharmacies have a role in promoting sound and sustainable use of pharmaceuticals by informing and *guiding consumers in product choice and use*. This is in line with the basic responsibility of pharmacies to promote good and safe pharmaceutical use. Here, the pharmacy personnel have a key role as they in the dialogue with the patients/consumers can guide and inform about all aspects of pharmaceutical use, including raising consumer awareness about environmental aspects. The pharmacies also have a central role in the *benefit subsidy system*, where they are obliged to provide all medicines products covered by the system, including implementing and informing about the generic substitution of drugs when there are cheaper alternatives.

[18] Hållbar Upphandling - Ett samarbete mellan Sveriges regioner: http://www.hållbarupphandling.se/
[19] Sveriges Apoteksförening, Om apoteksbranschen: http://www.sverigesapoteksforening.se/om-apoteksbranschen/

The pharmacies can also promote environmentally sound supply chains by using and implementing environmental requirements in *procurement of pharmaceuticals*. In addition, the pharmacies have a role in reducing pharmaceutical waste, e.g. by advice on packaging size, selling doses instead of packages, as well as receive and handle unused drugs from consumers.

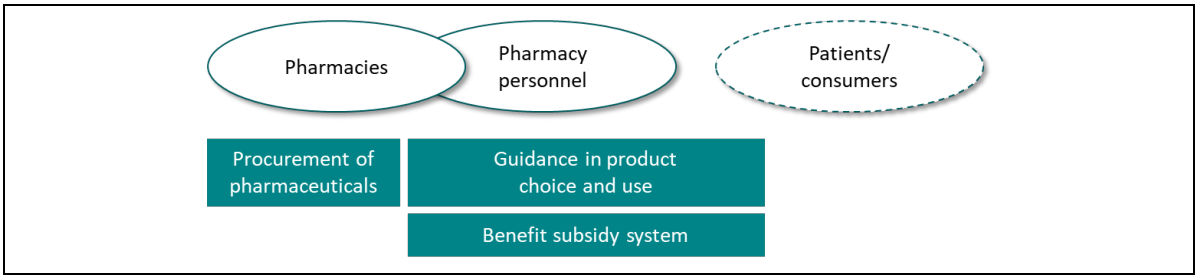


Figure 6. Overview of environmental roles and responsibilities of pharmacies

Depending on the type of pharmaceutical; prescription drugs within the benefit system or OTC (over the counter) drugs; the pharmacies do, however, have different possibilities to influence the environmental impacts along the value chain. Due to the regulations of the *benefit subsidy system* (see Appendix 3 and Appendix 4), the pharmacies currently have no or very limited possibility to influence environmental aspects for prescription products, both in terms of procurement and guidance for product choice and use. For the *OTC part of the assortment*, however, the pharmacies can both work with sustainable procurement and guide consumers towards more environmentally sustainable products through e.g. product eco-labels. See Appendix 5 for more information.

4.5 Pharmaceutical companies and supply chains

The following is a summary of the review of pharmaceutical companies and supply chains, see Appendix 6 for more information.

Actor structure

Pharmaceutical companies can be divided into three main types; *Research-based pharmaceutical companies* that develop, produce and market original patented drugs under a brand name; *Generic pharmaceutical companies* that produce and market copies of drugs for which the patent has expired and *Parallel importers* that buy drugs in countries where the price is low, in order to repackage and resell them where the price is higher. In practice the distinction into these types is, however, not as clear-cut.The supply chains of pharmaceutical companies consist of *API subcontractors* i.e. companies producing active pharmaceutical ingredients (API) and *Other raw material and packaging suppliers* i.e. companies producing raw materials (other than API) which is needed in production of API and in the formulation of products, as well as companies producing packaging materials. The supply chains for pharmaceutical products are often long and complex, located in different parts of the world.

Governance of environmental priorities

Environmental management in pharmaceutical companies and supply chains are in general governed by company specific sustainability strategies, targets and programs, usually decided by the company management team and/or board, as well as by efforts to secure legal compliance in countries of operations. The level of maturity, scope and ambitions for the sustainability and

environmental work varies between different pharmaceutical companies and companies in their supply chains.

Many pharmaceutical companies have well established sustainability programs that covers the whole value chain. Company environmental targets and programs are usually set on corporate or group level and are then broken down on different levels within the company, in business units and functions such as research & development, sourcing, operations and marketing & sales.

Environmental responsibilities

The pharmaceutical companies and their supply chains have a central role in the pharmaceutical value chain, as they are responsible for development, manufacturing, marketing and sales of pharmaceuticals. Environmental responsibilities of the pharmaceutical industry therefore cover the entire value chain, from selection and sourcing of raw materials, development of substances, manufacturing, distribution, to the use and end-of-life of the products.

As indicated in Figure 7 this responsibility includes efforts with overall *product and process improvements,* by promoting environmentally sustainable production and use of products in a life cycle perspective. The responsibility also includes environmental reporting and communication to different stakeholders, such as environmental risk *assessments in conjunction with product approval*, providing information for *procurement tenders* as well as for *guidance in product choice and use.* It could also include providing information in the *benefit subsidy systems*, if environmental aspects are integrated in the system.

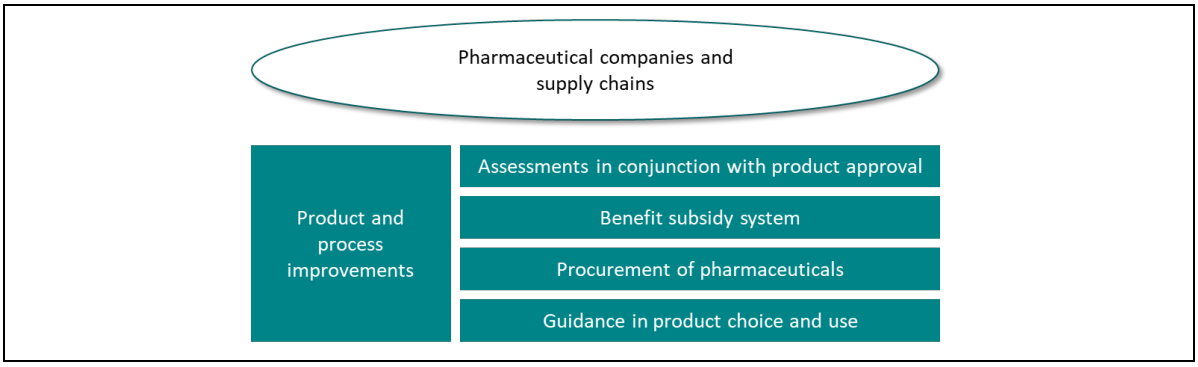


Figure 7. Overview or environmental roles and responsibilities of pharmaceutical companies and supply chains

The companies´ work with *product and process improvements* can in general be divided into three main parts: Product development and innovation; Process and production development; Procurement and supply chain management. This requires collaboration with different partners along the chain, such as suppliers and sub-suppliers, customers and industry peers. There are several voluntary industry initiatives to address specific joint challenges and drive collective change and sustainability improvements, for example, the Pharmaceutical Supply Chain Initiative (PSCI) focused on "building responsible supply chains together" and the AMR Industry Alliance focused on "uniting to act on antimicrobial resistance". See Appendix 6, chapter "Product and process improvements" for more information.

Pharmaceutical companies also *report and communicate* different types of environmental information to several different stakeholders. Thus, companies need to collect, manage and compile environmental data and information for both processes and products in different ways and formats, based on different stakeholder requirements. See Appendix 6, chapter "Environmental reporting and communication to different stakeholders" for more information.

5 Challenges, drivers and opportunities – shared by all actors

Based on the review of the main actors along the pharmaceutical value chain, we have identified a number of challenges, drivers, opportunities and that are shared between all actors, and that apply for all applications. They are further described below and can be summarised as:

- Increased focus on environmental impacts of pharmaceuticals and health care
- Clear need for product-specific environmental information - to enable informed decisions to drive improvement in different parts of the value chain
- Shared requirements and standards between actors along the value chain
- Market incentives and equal conditions on the market
- Align with, utilise and support ongoing initiatives
- Combine regulatory and voluntary initiatives

Increased focus on environmental impacts of pharmaceuticals and healthcare

The societal and political focus on climate and environmental issues are constantly increasing and are gaining global momentum. In 2015, all UN Member States adopted the Sustainable Development Goals (SDGs) as part of Agenda 2030. With just under ten years left to achieve the Sustainable Development Goals, world leaders at the SDG Summit in September 2019 called for *a Decade of Action* and delivery for sustainable development[20]. Action is required in all sectors of society, where healthcare and the pharmaceutical industry is no exception.

Healthcare is a large and important sector and its impact on the environment are receiving increased attention in different levels of society. For example, concerning risks for antimicrobial resistance in the environment, pollution from manufacturing of pharmaceuticals, and detection of pharmaceutical substances in water bodies around the world.

There is also an important connection to human health risks at a global scale and a global justice perspective. Pharmaceuticals contribute to improving health and saving lives, but this should not be on the expense of risking the environment and people´s health and lives in countries of manufacturing.

Clear need for product-specific environmental information - to enable informed decisions to prioritise and drive improvements

The scope for environmental management of all actors cover the full pharmaceutical value chain. Therefore, all actors stress the need for increased availability of environmental information for pharmaceuticals in a life cycle perspective. Access to relevant and comparable information enables informed decisions to manage and control environmental impacts within the frame of responsibility of each actor. Actions should be prioritised to where it matters the most from an environmental perspective, where knowledge and information of course is key to be able to set the right priorities.

[20] United Nations, Sustainable Development Goals: https://www.un.org/sustainabledevelopment/development-agenda/

Today, this is hampered by the lack of transparency and the lack of information about environmental consequences of pharmaceuticals. The lack of information makes it difficult for actors along the chain to prioritise and drive different types of environmental improvement activities, in e.g. procurement or guidance for product choice and use.

Thus, all actors see an urgent need to increase availability of environmental information for pharmaceuticals in a life cycle perspective. The proposed model for environmental assessment for pharmaceutical products (see chapter 2) can play an important role in this.

In terms of scope and content of needed information, all actors highlight the necessity to address environmental risks in production and formulation of API and improve availability of environmental risk information in general, including for substances that were authorised before 2006 when ERA became mandatory in the authorisation and the EMA published its ERA guidance. The environmental risk assessment must also be expanded to include risks for antimicrobial resistance in the environment, as this is a key challenge for society. The need and demand for addressing climate impact for pharmaceuticals is not on the same level as environmental risk, but the demand is growing. In general, the climate impacts need to be better understood – does the pharmaceutical industry contribute to significant climate impacts? Since all actors have climate targets or are working on developing such targets and programmes, the demand is expected to rise.

The actors do see some challenges in achieving comparability in results, both between different suppliers of the same API, and between different APIs that can be used for a specific treatment. This as supply chains are long and complex, and it is difficult to have detailed insights in every step of the chain. It should also be recognised that collecting, compiling and reporting environmental information on product level for an entire product portfolio is a resource demanding and complex undertaking, especially in global companies with operations and suppliers all over the world. It will be a challenge to keep the data up to date, due to e.g. changes in production, suppliers, etc. For most companies this will require investments and changes in ways of working and information systems.

Shared requirements and standards between actors along the value chain

The need for reliable, robust and transparent standards, tools and systems for collecting, compiling and reporting environmental information are highlighted by all actors, and they think that there is a lot to gain if requirements and standards are shared between different actors along the value chain. This is especially highlighted for applications with high demands on reliability and comparability of information, such as use in benefit subsidy system and in public procurement. The proposed model (see chapter 2) could form a basis for establishing such shared requirements and standards.

The availability of information is more likely to increase if information requirements are shared by different actors and the same basic information can be used in different applications for different purposes, as indicated in Figure 8. This requires harmonisation, agreement and standardisation across application areas and between different actors along the chain. This also opens for possibilities in shared development of methods and tools, where development costs can also be shared. Ideally such harmonisation should be done on a European or international level, such as within ISO.

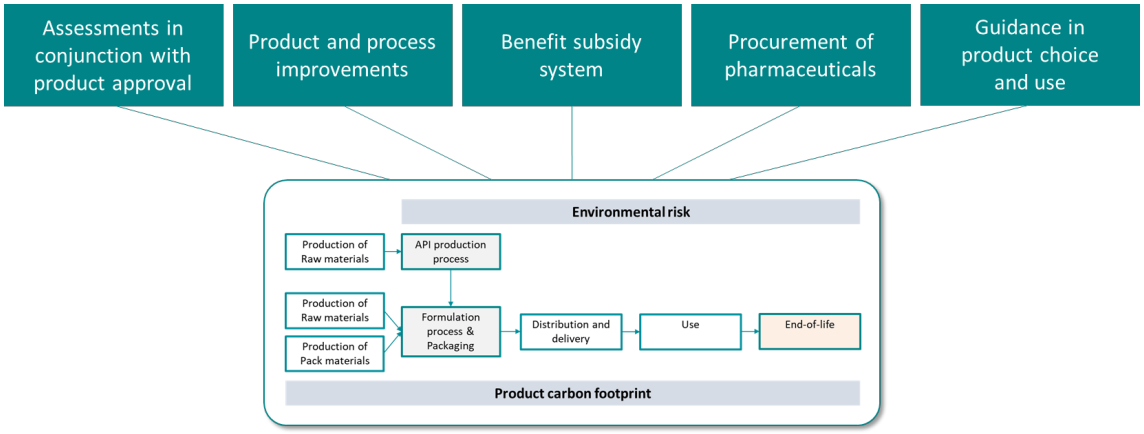


Figure 8. Shared requirements enable use of the same basic information in different applications

Shared requirements and standards will greatly facilitate for companies that are expected to report, as reporting routines and systems can be efficiently developed and maintained. It will be easier to motivate investments in reporting systems. This may lead to both increased availability and quality of reported information, as resources and reporting efforts can be directed to one way of compiling and reporting information, rather than several, which is the case when different actors and applications requires information to be compiled and reported in different ways.

Shared requirements and standards also facilitate the use of information by different actors, both through the potential for increased availability and quality of information (discussed above), but also as training, guidelines, tools etc. for how to interpret and use the information may be developed and shared between actors. In the same way as for the companies expected to report information, also the organisations that will use the information may need to develop or change their ways of working and information systems to integrate the information into e.g. procurement processes and the work of medicinal products committees.

It should be noted that it could be a challenge to develop an environmental assessment model that delivers results which is adapted to all purposes and applications. Also, shared requirements and standards requires different actors to commit to the same standard/model which may require compromises, and this in itself can be a challenge.

The target groups for the information are also quite diverse, and includes different types of organisations, e.g. government agencies, regions, pharmacies, where different functions are involved e.g. environmental experts, procurers, medical experts, healthcare professionals, pharmacy personnel, etc., and where the level of expertise and knowledge regarding environmental issues varies. This naturally poses specific challenges in how to communicate the information to make it easy to interpret and use, and this therefore needs to be addressed in the development of communication formats for the information.

Market incentives and equal conditions on the market

Although there is a clear need for information and shared requirements and standards, the market incentives for sharing information is still lacking. There is a growing demand, for example several regions have integrated environmental aspects in procurement, but so far this has primarily been used as contract terms and not as award criteria in the decision. Thus, there is no real competition today in regard to environmental performance within the pharmaceutical industry.

All actors do agree that incentives are needed to get things moving. If actors truly want to promote better performing alternatives in terms of environmental performance, this should be clear also in the overall business relationships. Market incentives can, for example, be created in the seller-buyer relationship in procurement, by clearly defining the weight of environmental aspects in the procurement decisions or by creating a premium for environmentally preferable alternatives. Figure 9 shows the Swedish pharmaceutical market and indicates how the identified application areas could be used to create incentives in each market segment.

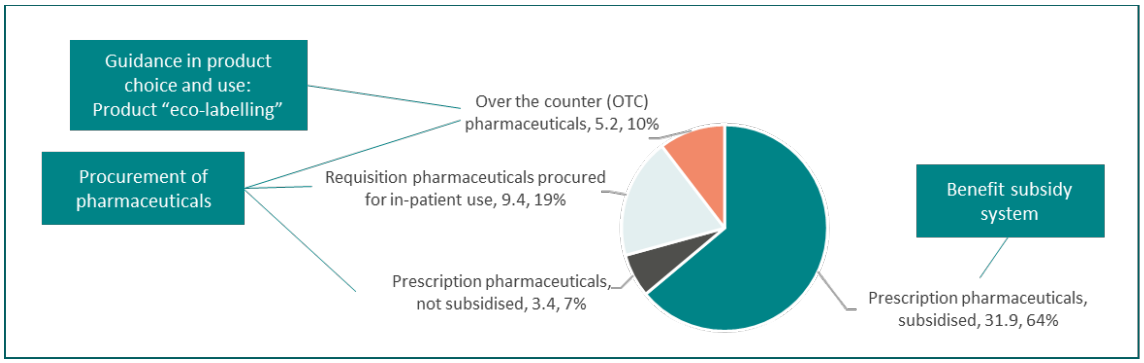


Figure 9. The pharmaceutical market in Sweden in 2019, by segment (value in billion SEK, share in percent) mapped with the identified applications.

Based on the study all actors seem to agree that in the short term, procurement is the application which is closest to creating market incentives for reporting environmental information and improvements (see also Appendix 4), combined with the pharmacies initiative to establish a product eco-label for OTC pharmaceuticals (see also Appendix 5). These applications are within the current frame of action of the actors that are involved, policy development is not needed. They do, however, require clear priority and action from the actors, supported by harmonised and shared requirements and standards (as discussed above).

Most actors also think that environmental considerations should be included in the benefit subsidy system – especially within the framework of generic substitution - as this represent a major share of the pharmaceutical sales in Sweden. This requires policy decisions and a clear mandate for TLV (see also Appendix 3). However, if it can be demonstrated that it "works" in procurement, it could lead the way for development also in this area.

In terms of creating market incentives in procurement, it is of course important that all companies can participate on an equal market. It cannot be excluding and designed so that only a few are able to participate. This may of course pose a challenge since different companies are at different level of maturity in respect to their environmental work and thus some companies will be in a better position, where the needed information may already be collected and compiled, whereas other may need to start implementation and thus may have a longer development curve.

It should be noted that there are also other market incentives for the companies, such as competition for investments where investors may choose not to invest in companies that does not fulfil requirements, as well as competition for talent where sustainability can be an important factor to both attract and keep employees. See also Appendix 6.

Align with and build on other relevant initiatives

There are a number of different ongoing initiatives in this area, on national, Nordic, Baltic, EU and international level, concerning e.g. procurement and supply chain management, antimicrobial resistance, policy development, etc. It is important that we do not start another parallel initiative, but instead find ways for how to align with, build on and collaborate with relevant initiatives; to join forces in the development, utilise synergies and avoid duplication of work.

Combine regulatory and voluntary initiatives

In order to reduce the environmental impacts of pharmaceuticals along the value chain, the actors agree that a combination of both regulatory and voluntary initiatives will be needed:

- *Regulatory initiatives* can secure a basic "minimum environmental level" that the industry need to meet, in terms of e.g. emission levels, or specific risk mitigation actions that needs to be implemented.
- *Voluntary initiatives* can promote and reward better performing alternatives, and should as such go beyond the "minimum level". This can for example include procurement and different efforts to guide product choice and use. In such voluntary initiatives, regulations and political decisions can also play an important role to facilitate and support the initiatives.

The proposed model (see chapter 2) could have a role in both types of initiatives through harmonization and standardisation of assessment methods. For example, the ERA methodology used in product approval within EU is used as basis for the voluntary environmental classification at Fass.se, as well as in the new proposed part for local emissions of API.

There seem to fairly wide consensus among the actors that the environmental legislation for pharmaceuticals is weak and needs to be improved, and also that such legislation needs to be harmonised on EU-level to have any effect. The proposals on how to move forward in this area, however, differs between the actors, where the product approval process and GMP has been put forward as potential options.

6 Challenges, drivers and opportunities – for each identified application

The actors outlined in chapter 4, i.e. government agencies, regions, pharmacies and pharmaceutical companies and supply chains, interact in different ways in the different applications identified in chapter 3:

- Assessments in conjunction with product approval,
- Product and process improvements,
- Procurement of pharmaceuticals,
- Benefit subsidy system and,
- Guidance for product choice and use.

In each application the actors have different roles and responsibilities, where also governance and incentives differ between the actors. For example, public actors are primarily governed by political decisions whereas private actors are governed by decisions by company owners, shareholders, board and management teams.

This chapter includes a discussion of each identified application for the product-specific environmental information in terms of which actors are involved, the current main challenges as well as main drivers and opportunities to move forward. Each application is introduced by a table that provides an overview of the main actors involved as well as main challenges, drivers and opportunities that have been identified through the review of involved actors (see Appendix 3-6).

6.1 Assessments in conjunction with product approval

Overview

Table 2. Overview for the application area "Assessments in conjunction with product approval".

Main actors involved	
Pharmaceutical companies and supply chains; Swedish Medical Product Agency (MPA)	
Main challenges	**Main drivers and opportunities**
• EU-legislation - complex policy process • Lack of political ambitions and priority • Trade-off between health and environmental aspects	• Broader acceptance of the need for stronger environmental legislation for pharma manufacturing – product approval is proposed as one option • ERA information from approval process could be used also in other applications, e.g. guidance in product choice and use

Main actors involved

In assessments in conjunction with product approval, the pharmaceutical companies are responsible the environmental risk assessment for the product for which authorisation is sought, and the national and central medical product agencies are responsible for evaluating and approving the product.

Main challenges

EU-legislation - complex policy process: As regulations for pharmaceuticals are harmonised within EU, any improvements of environmental management in product approval as of market authorisation must be done on EU level. This is a highly complex policy process. Sweden have no possibilities to set own environmental criteria for product approval for the Swedish market.

Lack of political ambitions and priority: The Swedish Medical Product Agency are actively promoting updates of the EU regulations to improve management of environmental risks in all phases of product approval, including post-authorisation. This is done within the framework of the milestone target "Greater environmental consideration in EU pharmaceuticals legislation and internationally" in the Swedish environmental quality objectives. However, on EU level there is still a lack of political ambitions and priority in this area.

Trade-off between health and environmental aspects: The key principle guiding the evaluation as basis for product approval is that the benefits of medicine shall outweigh the risks from a medical/health perspective. Environmental risks are not included in the evaluation. If environmental aspects were to be included it would be a very difficult trade-off.

Main drivers and opportunities

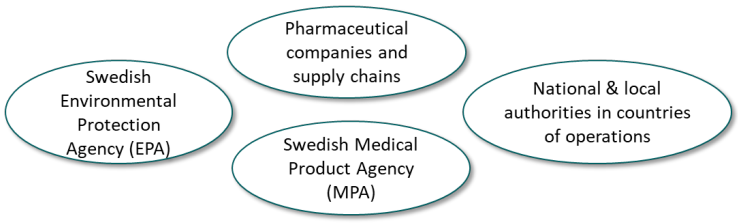
Broader acceptance of the need for stronger environmental legislation for pharma manufacturing – product approval is proposed as one option: Most actors call for strengthened environmental legislation for the pharmaceutical industry, that can secure minimum environmental standards and that can apply irrespective of where in the world the pharmaceutical is manufactured. The Swedish MPA has identified that integrating environmental aspects in product approval could be a key regulatory mean for achieving common environmental requirements for manufacturing and use of pharmaceuticals consumed within the EU. If Swedish actors along the value chain can develop and agree on a feasible proposal on how this may be implemented, it could open the way for policy development within EU.

ERA information from approval process could be used also in other applications, e.g. guidance in product choice and use: In the product approval process, there is currently no requirements to make the detailed information from the ERA publicly available when the medicine has been approved and launched, and the information that are made available are generally limited. However, if the detailed information is made publicly available, it can be used in other applications such as in procurement and guidance in product choice and use, to prioritise and support actions for mitigation of risks in different parts of the value chain.

6.2 Product and process improvements

Overview

Table 3. Overview for the application area "Product and process improvements".

Main actors involved	
	
Main challenges	**Main drivers and opportunities**
• Complex and long supply chains • Different level of maturity, ambitions & resources - in different companies and in their supply chains; API and other raw material and packaging suppliers • Secrecy and trust between business partners • Weak market incentives • Weak environmental legislation and/or enforcement	• Increased requirements and demand from different stakeholders; owners, investors, employees • Additional market incentives can be created via other applications; procurement, benefit subsidy system, etc. • Several voluntary industry initiatives established, e.g. PSCI, AMR Alliance • Broader acceptance of the need for stronger environmental legislation and/or enforcement

Main actors involved

The pharmaceutical companies and supply chains are responsible for environmental improvements of their products and processes along the value chain. In addition, different authorities are responsible for development and supervision of environmental legislation governing products and manufacturing processes. This includes the Swedish MPA, EPA as well as national & local authorities in countries of operations.

Main challenges

Complex and long supply chains: The pharmaceutical industry consists of different types of companies operating on many different markets, and where their supply chains often are long and complex. In terms of driving environmental improvements along the value chain, this of course poses many challenges such as differences in requirements on different markets and countries of operations, and possibilities to have insights to and manage different steps in supply chain. For example, main environmental impacts may occur in 2nd tier or further upstream in the supply chain, which often is difficult to influence.

Different level of maturity, ambitions & resources - in different companies and in their supply chains; API and other raw material and packaging suppliers: Environmental management in pharmaceutical companies and supply chains are in general governed by efforts to secure legal compliance and by company specific sustainability strategies, targets and programs. Consequently, and quite naturally, the level of maturity, ambitions and resources for environmental work varies between different companies and within their supply chains.

Secrecy and trust between business partners: A value chain perspective in sustainability and environmental work requires collaboration with different partners along the chain, such as

suppliers and sub-suppliers, customers and industry peers. To make progress, this implies that information needs to be shared between business partners, where issues with secrecy and confidentiality of information as well as trust are key challenges. So far, the pharmaceutical industry has lacked transparency in this regard, although some improvements have been made in recent years, demonstrated through e.g. different industry initiatives.

Weak market incentives: As discussed in chapter 5, true market incentives for sharing environmental information and show environmental improvements is currently lacking. Customer requirements regarding sustainability and environmental issues are still fairly limited, and there is no competition in regard to sustainability.

Weak environmental legislation and/or enforcement: As discussed in chapter 4.1 and Appendix 2, the environmental legislation for pharmaceuticals is limited. Also, the environmental legislation that are in place are not always fully enforced. For example, according to EU environmental legislation, requirements regarding emissions of API should be set as part of the environmental permits but in practice this is seldom done[21]. The same is true for legislation outside of EU.

Main drivers and opportunities

Increased requirements and demand from different stakeholders; owners, investors, employees: Among the driving forces and reasons as to why pharmaceutical companies are working strategically and operationally with sustainability are; to protect and strengthen brand and competitiveness, requirements and demands from investors and other stakeholders, to attract and keep employees, manage and reduce risks, and to take responsibility for the company´s sustainability impacts based on corporate visions and policies. According to the companies, sustainability is increasingly becoming a requirement to attract both investors and talent.

Additional market incentives can be created via other applications; procurement, benefit subsidy system, etc.: If a market demand is created through, for example, integrating environmental requirements in procurement and the benefit subsidy system, this would provide even stronger incentives for companies to drive environmental development and improvements. Such incentives can provide competitive advantages for companies that perform well in regard to environmental management.

Several voluntary industry initiatives established, e.g. PSCI, AMR Industry Alliance: Work and collaboration with business partners are very much facilitated by common methods and standards for e.g. collecting and sharing environmental information. The pharmaceutical industry has started several voluntary initiatives to address specific joint challenges and drive collective change and sustainability improvements, such as the Pharmaceutical Supply Chain Initiative (PSCI) and the AMR Industry Alliance focused on antimicrobial resistance. Such initiatives are key for both knowledge building and for development of industry standards.

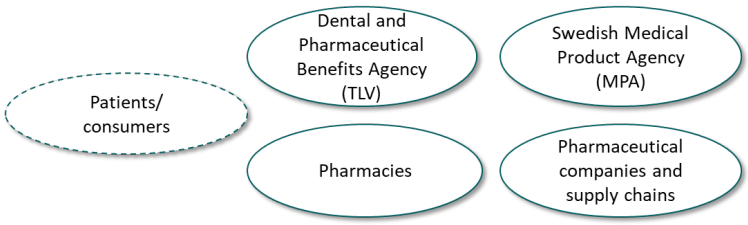
Broader acceptance of the need for stronger environmental legislation and/or enforcement: As discussed in chapter 6.1, all actors including the pharmaceutical companies, agree on the need for stronger environmental legislation.

[21] Läkemedelsverket (2018) *Miljöutredning 2018.*

6.3 Benefit subsidy system

Overview

Table 4. Overview for the application area "Benefit subsidy system"

Main actors involved	
	
Main challenges	**Main drivers and opportunities**
• Lack of political ambitions and priority • Fear of increasing costs for the system • Trade-off between the requirements in the system	• Can create major market incentives for suppliers, main potential in generic substitution • Several actors are actively promoting this • Progress in other applications (procurement) could lead the way, by testing and establishing criteria and by experiences in consequences on costs • Cost for pharmaceuticals is a minor part of the total cost for healthcare

Main actors involved

The *Dental and Pharmaceutical Benefits Agency (TLV)* are responsible for the benefits subsidy system, and for making decisions of which products to include in the system. The *Swedish MPA* also have a role in the system by performing the medical evaluation for products within the system. The *pharmacies* are responsible for implementing decisions in the system, including informing about generic substitution. The *pharmaceutical companies* as suppliers are responsible for applying to TLV for inclusion of products in the benefit system and for delivering products in the system. And finally, *patients/consumers* use the system in their medical care by access to subsidised medicines.

Main challenges

Lack of political ambitions and priority: Currently, there seem to be a lack of political ambitions and priority for introducing environmental criteria within this field. Already in 2013, a governmental review has suggested how environmental criteria could be included in the benefit system, but these proposals have not yet had a political impact.

Fear of increasing costs for the system: The societal cost of pharmaceuticals in the healthcare system is constantly increasing and puts pressure on public budgets. Financing the welfare and care needs of an aging population is one of the major challenges facing the state and regions over the coming years and decades. Weighing in environmental aspects in decisions for the subsidy system may potentially lead to increased costs. Consequently, changing the benefit system in a way that could lead to increasing the cost of pharmaceuticals poses a clear challenge to integrate environmental aspects in the system. At the same time, there is a lack of knowledge on the actual consequences on

costs. Also, comparative studies show that the price of pharmaceuticals in this part of the benefit system is relatively low in Sweden compared to other European countries[22].

Trade-off between the requirements in the system: The benefit system aims at securing access to pharmaceuticals at the lowest socio-economic cost. Integrating environmental aspects means balancing environmental, health and financial performance of products within the system, and this will naturally mean that trade-offs between the different requirements will need to be handled. For example, what should improvements in environmental performance be worth in the system?

Main drivers and opportunities

Can create major market incentives for suppliers, main potential in generic substitution: As the benefit subsidy system constitute the main part of the pharmaceutical market in Sweden (see also Appendix 1), the system has a potential to create major market incentives for pharmaceutical suppliers. The main potential lies in the part of the benefit system where there is competition, that is, in the generic substitution system ("periodens vara").

Several actors are actively promoting this: Several actors along the pharmaceutical value chain – pharmacies, Swedish MPA, pharmaceutical companies, and to some extent regions – are actively promoting that environmental considerations should be integrated in the benefit subsidy system. If this would be implemented, it could probably also facilitate work in other applications, as it also has a potential to increase availability of environmental information for pharmaceutical products in general.

Progress in other applications (procurement) could lead the way, by testing and establishing criteria and by experiences in consequences on costs: As discussed above, there are today two key challenges for integrating environmental aspects in the system - lack of commonly accepted requirements and reliable, robust and transparent standards for product-specific environmental information as well as fears of increasing costs of the system. Progress in other applications such as procurement could, however, lead the way to make progress in this area. This can both include testing and establishing relevant environmental criteria that could be used as basis for the system, as well as build-up of knowledge and experiences concerning the potential consequence on costs.

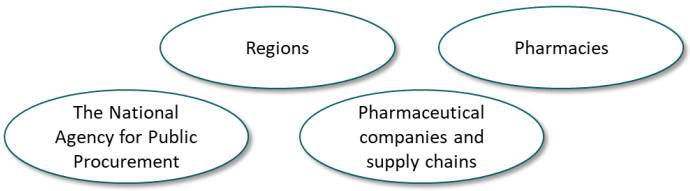
Cost for pharmaceuticals is a minor part of the total cost for healthcare: In 2018, the cost of medicines accounted for approximately 12 per cent of total fixed healthcare expenditure in Sweden. Thus, although the cost for pharmaceuticals is substantial, it still constitutes a minor part of the total cost for healthcare.

[22] TLV (2019) *Internationell prisjämförelse 2019 - En analys av svenska läkemedelspriser i förhållande till 19 andra europeiska länder.*

6.4 Procurement of pharmaceuticals

Overview

Table 5. Overview for the application area "Procurement of pharmaceuticals"

Main actors involved	
	
Main challenges	**Main drivers and opportunities**
• Governed by regional environmental targets and programs, varies between regions • Market fragmentation; the regions are 21 independent contracting authorities • Availability of resources and environmental expertise in the procurement process • Ensuring all principles in the procurement Act, e.g. equal conditions on the market – parallel import a challenge • Handling trade-offs with other requirements in the evaluation	• Can create market incentives for suppliers • Increasing political support and attention for procurement as a tool to achieve environmental targets • Harmonisation of environmental criteria in Sweden by the National Procurement Authority • National collaboration in place – opens for shared requirements between regions • Nordic collaboration in place – opens for shared requirements with other Nordic countries

Main actors involved

The *Swedish regions* are contracting authorities, responsible for procurement of pharmaceuticals for inpatient care. The *National Agency for Public Procurement* is responsible for supporting the contracting authorities in their procurement, e.g. through development of environmental criteria. The pharmaceutical companies as suppliers are responsible for responding to procurement tenders and for complying with agreed terms of the contract.

The *pharmacies* also procure pharmaceuticals. For pharmaceuticals within the benefit subsidy system they, however, have limited possibility to influence suppliers through procurement, due to the regulations of the system. They can however work with sustainable procurement for the OTC assortment.

Note: In the overview and below we have chosen to focus on the procurement of pharmaceuticals for inpatient care which is performed by the regions. Several of the challenges, drivers and opportunities do, however, apply also for procurement performed by the pharmacies.

Main challenges

Governed by regional environmental targets and programs, varies between regions: Environmental management in the regions are governed by regionally adopted environmental goals, strategies and programs, and consequently the scope, focus and priority for driving environmental improvements through procurement vary depending on the political ambitions in the region.

Market fragmentation; the regions are 21 independent contracting authorities: There are 21 regions in Sweden, and each region is an independent contracting authority in procurement of pharmaceuticals for inpatient care. This contributes to market fragmentation in Sweden and can

hamper the potential for regions to encourage and push suppliers towards more environmentally sustainable supply chains, both due to limited purchasing power (smaller contracts) and due to differing environmental criteria between the regions depending on the scope and focus of environmental work in the regions. Differing criteria may be difficult to handle for both the contracting organisation and the companies responding to the tenders. It may also lead to duplication of work.

Availability of resources and environmental expertise in the procurement process: Resources and environmental competence is needed in different parts of the procurement process, to effectively manage formulation of environmental criteria, follow-up etc. In general, availability of resources and environmental competence is a major challenge for the regions and especially for smaller regions that do not have dedicated internal expertise similar to that of the larger regions (see also Appendix 4, Public procurement). Availability of resources and expertise can also be a challenge for companies responding to procurement tenders. For example, can be a challenge for Swedish and Nordic marketing and sales companies to collect and report environmental information in tenders, even if it available within the group, as they often do not have direct access to the information but must go to the right unit or person within the group (see also Appendix 6, Environmental reporting and communication).

Ensuring all principles in the procurement Act, e.g. equal conditions on the market – parallel import a challenge: A general challenge in defining and using environmental criteria is of course to secure that all requirements related to the Public Procurement Act are met. For example, the Act requires equal conditions on the market. Here, parallel import companies have been identified as a specific challenge, as such companies generally have limited insight into the supply chains of the imported products and may therefore have difficulties to respond.

Handling trade-offs with other requirements in the procurement evaluation: Integrating environmental aspects into procurement usually also means that trade-offs need to be handled with other business objectives in the procurement. It can be difficult to balance environmental requirements with other requirements in the tender evaluation, such as price, quality, supply reliability, etc.

Main drivers and opportunities

Can create market incentives for suppliers: As procurement of pharmaceuticals for inpatient care represents almost 20 percent of the Swedish market (see also Appendix 1), it has a clear potential to create market incentives for pharmaceutical suppliers. The regions themselves have the scope for action today within existing regulatory frameworks. Additional policy development is not needed. This market potential would be greatly enhanced if requirements can be harmonised across procuring organisations within Sweden and Nordic countries, but ideally on EU or international level.

Increasing political support and attention for procurement as a tool to achieve environmental targets: Public procurement as an instrument and tool to achieve environmental targets and create incentives for environmental (and other) measures are receiving increased political support and attention. There is a clear momentum in the area, where several initiatives are underway in Sweden, EU and internationally. There is also increased political support and priorities at regional level in the form of politically determined environmental goals, strategies and programs.

Harmonisation of environmental criteria in Sweden by the National Procurement Authority: The environmental criteria used by the regions are to a large extent harmonised through the sustainability criteria developed and maintained by the National Agency for Public Procurement. In 2019, the agency launched updated environmental criteria for pharmaceuticals that includes

both contract terms and award criteria, which enable flexibility for contracting authorities in using relevant requirements in the specific procurement situation. They also enable for authorities to provide incentives for suppliers through use of award criteria.

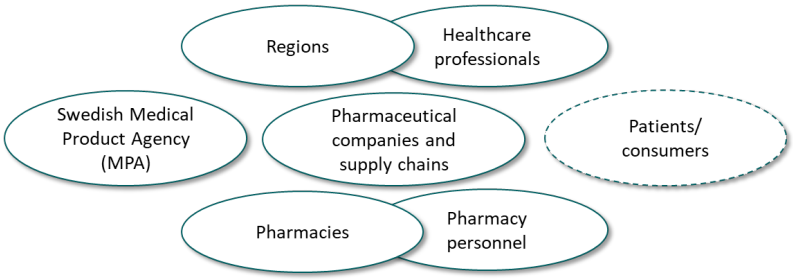
National collaboration in place – opens for shared requirements between regions: The regions have an established collaboration within the framework of national coordination for sustainable procurement, where pharmaceuticals have been identified as a risk area from both a social and environmental perspective[23]. This opens for and can facilitate shared requirements between the regions. In general, there is a great desire in the regions to further harmonise environmental requirements and their application nationally.

Nordic collaboration in place – opens for shared requirements with other Nordic countries: There is also an established Nordic network for joint development and sharing of experiences related to sustainable procurement with contracting organizations in Norway, Denmark and Iceland, where the Västra Götaland region is responsible for representing Sweden. These countries are all working on developing and implementing environmental criteria in procurement, and thus the network could open for shared requirements also with other Nordic countries. Naturally, the work would be greatly facilitated if criteria, follow-up etc. would be harmonised on EU level, but of course this is a bigger undertaking and it is unclear who can and should take the initiative in to get this in place.

6.5 Guidance in product choice and use

Overview

Table 6. Overview for the application area "Guidance in product choice and use"

Main actors involved


Main challenges	Main drivers and opportunities
• Risk that patients/consumers refuse treatment due to environmental concerns, could increase problem of poor adherence • Broad target group – different levels of environmental knowledge and experience • Trade-off between health and environmental aspects	• Increasing patient/consumer requirements and demand • Increasing interest among healthcare professionals and pharmacy personnel • Environmental considerations in recommendation lists by medicinal products committees • Pharmacies has started product eco-label for OTC pharmaceuticals

[23] Hållbar Upphandling - Ett samarbete mellan Sveriges regioner: http://www.hållbarupphandling.se/

Main actors involved

The *Swedish regions* are responsible for prescription and recommendations of pharmaceuticals for medical treatments, where *healthcare professionals* have a key role in the meeting with patients. In a similar way, the *pharmacies* and *pharmacy personnel* are responsible for providing advice and guidance to patients/consumers regarding pharmaceuticals. The *Swedish MPA* have a general role in providing guidance to both medical and health care and the general public. The *pharmaceutical companies* are responsible for acquiring and communicating information to enable and support guidance in product choice and use. The *patients/consumers,* that use medicines for medical treatment, have a responsibility to follow prescriptions and handle medicines as advised.

Main challenges

Risk that patients/consumers refuse treatment due to environmental concerns, could increase problem of poor adherence: There are clear challenges and complexities in mixing health and environmental information for substances and products. For example, it is difficult to communicate that something that is "good for health" is "bad for the environment". If patients/consumers can make their own environmental choices, there is a risk that some may refuse treatment due to environmental concerns, which in turn could increase the problem of poor adherence to prescribed treatments.

Broad target group – different levels of environmental knowledge and experience: This application basically includes everyone that are involved in the choice and use of pharmaceuticals. Thus, the target group is broad and includes e.g. environmental experts, medical experts, healthcare professionals, pharmacy personnel as well as patients/consumers. The level of knowledge and experience regarding environmental issues varies greatly. This poses several challenges in communication of environmental information to enable correct interpretation and use.

Trade-off between health and environmental aspects: The health aspect is most important when assessing which pharmaceutical to use for a medical treatment. But in some cases, trade-offs can be needed between environmental and health aspect for patient and people in the supply chain.

Main drivers and opportunities

Increasing patient/consumer requirements and demand: Pharmacies and regions are experiencing increasing interest and demands from patients/consumers regarding sustainability and environmental aspects. They are asking questions about the environmental impacts of products, and patient/consumer environmental awareness, knowledge and expectations is increasing.

Increasing interest among healthcare professionals and pharmacy personnel: There is also an increased awareness and interest among healthcare professionals and pharmacy personnel, where they expect their employers to take responsibility and where they want to know how they can and should contribute to environmental improvements in their role.

Environmental considerations in recommendation lists by medicinal products committees: The medicinal products committees have a central role in the work with harmonizing the prescription of drugs within the regions. Several regions have integrated environmental aspects in the work of the committees, and there is also an established collaboration regarding compilation of information used as basis for the evaluation (see also Appendix 4, Guidance in product choice and use).

Pharmacies has started product eco-label for OTC pharmaceuticals: To guide consumers towards sustainable alternatives, the pharmacies are currently developing a common product label for OTC pharmaceuticals, named "choose sustainable", thereby harmonizing such labelling within Sweden. See also Appendix 5.

7 Conclusions and proposed way forward

This study has aimed to define and evaluate needs, requirements and use of product-specific environmental information by different stakeholders along the pharmaceutical value chain – with the overall aim to reduce environmental impacts along the chain.

The results clearly show that there is a substantial need and demand for product-specific environmental information by different actors, and for different applications. During the course of the study, we have experienced that there is a strong engagement, interest and will among all actors along the value chain to collaborate constructively in order to make progress. In general, there seem to be a sense of urgency to move from "talking" to "action". There is also a strong momentum. Several initiatives are moving in the same direction, and thus there is a great potential to utilise synergies and join forces. The proposed model for environmental assessment of pharmaceuticals (see chapter 2) could play a key role in this and has a potential to form the basis for further development and implementation in this area.

Below we have summarised five key elements for further development and proposed way forward:

- Establish shared goals between the actors along the value chain
- Establish shared requirements and standards
- Integrate further development of the model with development of its applications – establish way of working and tools
- Create market incentives
- Get started! And develop step by step

Establish shared goals between actors

Collaboration and interaction between actors along the pharmaceutical value chain would be greatly facilitated by goals and target that are shared by the actors. This also enables and support joint prioritisation and action plans for development and implementation. On a general level, all actors seem to share the overall ambition and goal to reduce environmental impacts along the value chain. However, currently the routes and strategies vary slightly between actors. By establishing shared goals, efforts by different actors can be better aligned and coordinated.

Establish shared requirements and standards

Based on the study, development and establishment of shared requirements and standards have been identified as a key element to make progress (see also chapter 5). This would greatly facilitate for both information providers and information users. The development should be performed on two levels (as indicated in Figure 11):

- *Application level*, i.e. requirements and means of communication are shared by different actors working with a specific application, such as procurement or guidance in product choice and use.
- *Method and standard level,* i.e. a common foundation in terms methods, models and data, which can be used as basis in all applications, but where of course the results are

used in different ways. The proposed model could form the basis for such common standards.

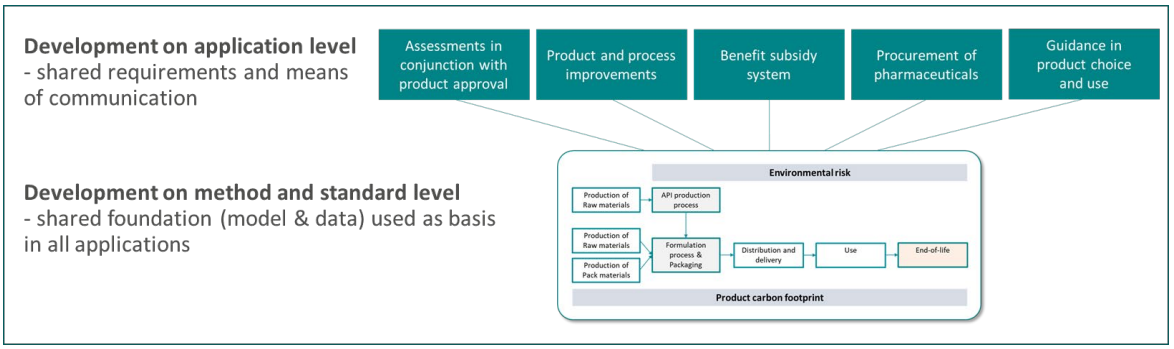


Figure 10. Development of shared requirements and standards on different levels.

Division of the development into two levels, enables more dedicated and focused development work, where harmonisation and collaboration on application level can be performed by the actors involved in that specific application. At the same time, development of methods and standards may be shared between applications and actors. The shared development of methods and standards will also coordinate, align and harmonise requirements between applications and actors.

Integrate further development of the model with development of its applications – establish way of working and tools

The proposed model could play a key role in further development and implementation of environmental improvement work in different applications. Further development of the model should be integrated with development of its applications to secure that the model fulfils and meets the specific needs and requirements of the applications, This will require development of way of working and supporting tools for both information providers and users (illustrated in Figure 10 below). This in turn will require multi-stakeholder collaboration, harmonisation and agreement, between different actors along the chain as well as internally between different internal functions/roles within organisations.

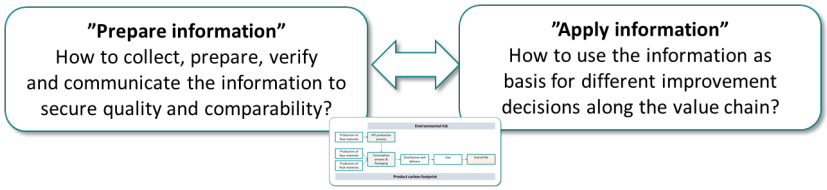


Figure 11. Integrate development of how to prepare information with development of how to apply the information

For information providers, the development will involve how to collect, prepare, verify and communicate the information to secure quality and comparability, where challenges regarding confidentiality and transparency in data sharing must be addressed and managed.

For information users, the development will involve how to use the information as basis for different improvement decisions along the value chain, such as in procurement, benefit subsidy system or guidance in product choice.

The development will also include interaction and collaboration between information providers and information users, through development of shared requirements and standards.

Create market incentives

As discussed in chapter 5, all actors agree that market incentives are needed to get things moving. In general, clear customer expectations and requirements is one of the most important driving forces for companies in advancing their sustainability efforts. In the Swedish pharmaceutical market, there are basically three main "customer groups"; the regions, pharmacies and the benefit subsidy system, that all have important roles to play in creating a demand for environmentally sound products and processes.

In the short term, market incentives can be created through procurement of pharmaceuticals, combined with the pharmacies initiative to establish a product eco-label for OTC pharmaceuticals. These represent around 30 percent of the Swedish pharmaceutical market and can be done within the frame of action and mandate of involved actors. There are several initiatives underway, and there is a clear will and ambition in both regions and pharmacies to move forward. The greatest impact will be achieved if tender requirements can be aligned and harmonised on a wider scale – on Swedish national, Nordic, Baltic, EU or even international level.

In the longer term, market incentives can be created in the benefit subsidy system, especially within the framework of generic substitution ("periodens vara"). Here lies the biggest potential for creating market incentives in Sweden, as it represents more than 60 percent of the Swedish pharmaceutical market. This require policy development and decisions. Joint efforts will be needed to make progress in this area. However, development and practical experiences from procurement and product eco-labelling, in terms of environmental criteria, methods and tools as well as experiences in terms of costs, may lead the way for political decisions in this area.

Get started! And develop step by step

As noted above, there is a sense of urgency among the different actors along the value chain to move forward and make progress. Sweden is often seen as a forerunner in terms of pharmaceuticals and the environment, and there are clear opportunities for Sweden to lead the way also in this area, within EU and internationally. Thus, we just need to get started! And then take the development and implementation step by step. This of course also requires pioneers among the actors, that dare to move forward.

Based on the current status, challenges, drivers and opportunities for the identified applications, there is a "timeline" for further development and implementation, where Figure 12 below indicate an overall potential order for where to start.

Figure 12. "Timeline" and order of further development and implementation of the different applications

Three of the identified applications – *Procurement of pharmaceuticals, Product and process improvement* and *Guidance in product choice and use* - are within the responsibilities, frame of action and mandate of the involved actors. The possibility to drive environmental improvements through these applications would be strengthened by increased availability of product-specific environmental information. Thus, further development and implementation may start straight away.

Procurement of pharmaceuticals can create market incentives for reporting product-specific environmental information and has as such a potential to both reduce environmental impacts and increase the availability of environmental information for pharmaceutical products.

Product and process improvements are partly self-driven; proactive companies are already doing this, whereas others may start when they see the need and incentives to show environmental improvements in e.g. procurement tenders. This application area also includes the pharmaceutical industry´s own work with sustainable procurement, where further harmonisation of methods and tools within the industry has a potential to strengthen also such activities.

When the information has been made available through efforts in procurement, it can be used also as input to other applications to *guide product choice and use*, in e.g. the work of the medicinal products committees in the regions and work with developing sustainability labelling for OTC pharmaceuticals in pharmacies.

Two of the identified applications require policy development and decisions, either on national level as is the case with the *Benefit subsidy system* or on EU and international level as is the case with *Assessments in conjunction with product approval*. Policy development may, however, be facilitated if experiences are first gained in the other applications. When the model for environmental assessment of pharmaceuticals and relevant environmental criteria is sufficiently robust, it can potentially also be used as basis for further development and implementation in these applications.

8 Recommendations for next steps

Based on the results from the study, we propose the following next steps, briefly described below:

- "Pick the low-hanging fruits" - Start to apply the environmental risk part of the proposed model in procurement of pharmaceuticals
- Create a shared strategic roadmap in collaboration with actors along the pharmaceutical value chain - to broaden the application and scope

"Pick the low-hanging fruits" – Start to apply the environmental risk part in procurement

Public procurement is the application where there seem to be the best conditions to start using the model. Several initiatives are underway to strengthen environmental requirements in the procurement of medicines, where the proposed model for environmental assessment of pharmaceutical product may have a role.

Thus, it is recommended to develop and pilot test how the information may be used as basis for procurement decisions, with focus on the environmental risk part of the model. This part of the model is closer to being finalised and possible to use, since environmental risk assessments are well established in the pharmaceutical industry, compared to the product carbon footprint part which requires significantly more development and harmonization in the industry in order to be completed. To secure relevance, the risk part of the model should also be expanded to include risks for antimicrobial resistance in the environment.

Create a shared strategic roadmap – to broaden the application and scope

To ensure continued development and maintenance of the model and its application as a whole, a shared strategic roadmap should be created in collaboration with actors along the pharmaceutical value chain. The roadmap should address the identified key elements outlined in chapter 7 and should include how both parts of the model (environmental risk and product carbon footprint), can be further developed and maintained as well as how it can reach a broad application by different actors for different purposes. For example, to reduce the environmental impacts of medicines through product choice, product and process improvements or via the benefit subsidy system.

The creation of the roadmap will include defining:

- common visions and goals,
- what development steps are required and in what order they should be implemented,
- how the development should be coordinated and maintained,
- which actors should have active roles in different parts of the development,
- forms of financing the different parts,
- how to utilise synergies with other ongoing relevant initiatives, as well as
- conditions and opportunities for Nordic, European and international collaboration and implementation.

Appendix

Appendix 1. The Swedish pharmaceutical market

The Swedish market for pharmaceuticals consists of several different sub-markets, each with different rules and conditions for competition. The Swedish Competition Authority identifies five different submarkets:[24]

- Prescription pharmaceuticals *without* competition in the benefit system
- Prescription pharmaceuticals *with* competition in the benefit system (generic substitution)
- Prescription pharmaceuticals not included in the benefit system
- Requisition pharmaceuticals procured for inpatient care in Regions
- Prescription-free pharmaceuticals (OTC - over the counter pharmaceuticals)

In 2019, the Swedish pharmaceutical market had total sales of SEK 49.9 billion[25]. The cost of medicines has increased every year in recent years, to a large extent due to the introduction of new more expensive drugs. The cost of medicines constitutes a small but substantial part of the total health care costs in Sweden. In 2018, the cost of medicines accounted for approximately 12 per cent of total fixed healthcare expenditure in Sweden. The cost of medicines in the benefit subsidy system (prescription pharmaceuticals with or without competition) amounted to approximately SEK 31.9 billion including patient own payments in 2019. In addition, prescription pharmaceuticals not included in the benefit system amounted to SEK 3.4 billion (including pharmaceuticals for infectious diseases). Requisition pharmaceuticals procured by the regions for inpatient care amounted SEK 9.4 billion. Prescription-free pharmaceuticals (OTC) amounted to SEK 5.2 billion.

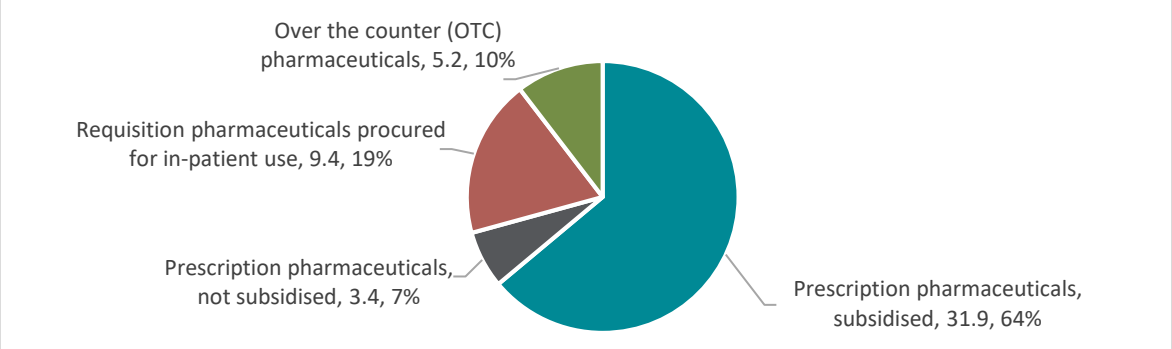


Figure 13. The pharmaceutical market in Sweden in 2019, by segment (value in billion SEK, share %)[26]

[24] Konkurrensverket (2017) *Prismodeller och prispress på läkemedelsmarknaden*. Rapport 2017:9.
[25] Socialstyrelsen (2020) *Läkemedelsförsäljning i Sverige – analys och prognos 2020–2023*.
[26] Ibid

Table 7 below presents an overview of the conditions for competition in the different Swedish submarkets for pharmaceuticals, in terms of entry requirements to the market, pricing, possibilities for exchange at pharmacies, the options available for the patient, who pays for the drug, who earns on exchange, and the margins for the pharmacies. Further details on the different submarkets are given in the following sub-chapters.

Table 7. Overview of market conditions for the different Swedish submarkets for pharmaceuticals[27]

Conditions for competition	Prescription pharmaceuticals without competition	Prescription pharmaceuticals with competition	Prescription pharmaceuticals not included in the benefit system	Requisition pharmaceuticals	Prescription-free pharmaceuticals (OTC)
Entry requirements	Companies apply for price and subsidy at TLV	The MPA approves pharmaceuticals that are interchangeable	Approval by MPA	Public procurement	Approval by MPA
Pricing	TLV makes value-basecx d assessment and decides on price	"Periodens vara" - monthly auctions conducted by TLV.	Free pricing	Determined through public procurement	Free pricing
Possibility of exchange at pharmacies	Parallel imports: pharmacies can import original medicines, get fully paid and retain profits	Pharmacies are obliged to change to "periodens vara" (generic substitution)	Unlimited	Not applicable – procured by regions	Unlimited
Options for the patient	Doctor's prescription	"Periodens vara" or doctor's prescription	Doctor's prescription	Doctor's prescription	Unlimited
Who pays	The regions via the drug benefit system	The regions via the drug benefit system	The patient	The regions	The patient (The region pays for medicines for infectious diseases)
The pharmacy's margin	TLV determines margins, pharmacies can earn more from parallel imports	TLV determines margins	Free pricing	Not applicable	Free pricing

Prescription pharmaceuticals without competition

This market segment includes products included in the drug benefit system where no competition has arisen. These may be both products covered by patents (also referred to as original pharmaceuticals) and products whose patents have expired, but where competition between two interchangeable drugs has not arisen. For these products, TLV decides on price on the suggestion of pharmaceutical companies, if it is deemed to be a reasonable price. Once an original drug has been approved by the Swedish Medical Product Agency, the company can apply to TLV for the drug to be included in the drug benefit system at a certain price. TLV's assessment on which drugs

[27] Konkurrensverket (2017) *Prismodeller och prispress på läkemedelsmarknaden*. Rapport 2017:9.

and prices should be approved is based on the eligibility criteria for reimbursement that are laid out in the Act on Pharmaceutical Benefit.

Prescription pharmaceuticals with competition

The market segment consists of generic medicines included in the drug benefit system, i.e. medicines where the patent for an original drug has expired and other companies can manufacture and sell the drug. For off-patent products, generic substitution is mandatory between medically equivalent pharmaceuticals subject to competition from more than one manufacturer. These can be sold at lower prices than the original drugs. The Swedish MPA performs the assessment and decides on which drugs that are interchangeable and TLV decide on price within the benefit system.

In the generic substitution system ("periodens vara") TLV carries out an auction every month for each group of interchangeable medicines, whereby the drug with the lowest price is selected for the product of the period. The pharmacies are obliged, upon delivery of medicines, to exchange the prescribed drug for the equivalent that has been designated the product of the period. The pharmaceutical company must ensure availability of the pharmaceutical during the entire price period and that the expiry date of the product meets the minimum requirements. TLV also appoints two back-up products that pharmacies can switch to if it is not possible to obtain the cheapest alternative.

The purpose of the substitution system of pharmaceuticals in pharmacies is to keep the society's cost down for pharmaceuticals whose patent protection has expired. In a study, the Swedish Competition Authority concluded that a combination of generic exchange and the period's goods system gives low prices in an international comparison.[28]

Prescription pharmaceuticals not included in the benefit system

The market segment consists of medicines that are not included in the drug benefit system. For these drugs, including prescription-only drugs, free pricing applies where the patient pays the full cost. However, in some cases, including for drugs for infectious diseases, the regions are responsible for the cost even for medicines outside the benefit system.

Pharmaceuticals fall outside the benefit system either following a decision by TLV or on the initiative of pharmaceutical companies. If a drug does not meet the criteria in the Benefits Act, TLV will reject the application and the product will not be included in the benefit. This may be, for example, because the cost of the drug is judged to be too high in relation to the benefit the treatment provides. Pharmaceutical companies can also themselves request that a drug no longer be included in the benefit scheme. This can have several causes, such as decisions from TLV such as a review, roof price decisions or decisions about no price increase. It can also be about purely business strategic decisions from the companies.

[28] TLV (2019) *Internationell prisjämförelse 2019 - En analys av svenska läkemedelspriser i förhållande till 19 andra europeiska länder.*

Requisition pharmaceuticals

The market segment consists of pharmaceuticals used within health and medical care that is not dispensed by a pharmacy. Requisition pharmaceuticals are financed and procured by the regions. Requisition drugs are financed through the budget of the health care institution, and in the extension of the region.

Requisition drugs are procured in accordance with the Public Procurement Act (LOU). The price paid by the region is often calculated based on the purchase price for pharmacies (the so-called list price at TLV). In some cases, the regions pay the list price while in other cases they pay a lower price. The lower price is often described as the region received a discount on the Pharmacies purchasing price ("Apotekens inköpspris" - AIP). The size of the discounts varies between regions and depending on which drug is procured. When there are several companies competing to sell products to regions, the discounts are higher compared to, for example, the case of original medicines without generic competition, where there are usually small discounts or sometimes none[29].

Virtually all Swedish regions do collaborative contracts with one or some other region. Those who do not do so are the three metropolitan regions. Centralized drug procurement for inpatient care is carried out by the Swedish Association of Local Authorities and Regions (SKR) purchasing center Commentus in areas where there are coordination benefits that are able to limit the cost increases. Work is underway on coordination and streamlining of the region's drug procurement. SKR Commentus does not have the same formal position, mandate and assignments as Amgros in Denmark and Sykehusinnkjøp LIS in Norway. Analyses show that centralized drug procurement in neighbouring countries gives lower prices and higher discounts than in Sweden where the responsibility is regional. [30]

Prescription-free pharmaceuticals

This market segment includes pharmaceuticals that can be purchased without prescription for self-care, i.e. over the counter (OTC) pharmaceuticals. Pricing of OTC pharmaceuticals is unrestricted; the patient pays the entire cost, i.e., a regular competitive market. Sales take place at both pharmacies and at other retailers such as in supermarkets. Which non-prescription drugs that can be sold on the Swedish market are determined by the Swedish Medical Product Agency.

All approved non-prescription drugs can be sold at pharmacies. For sales outside of pharmacies, i.e. in other retail stores, the following criteria need to be fulfilled; the drug is suitable for self-care, that serious side effects are rare and that it is appropriate for patient safety and public health protection. The Swedish Medical Product Agency provides a list of medicines that are allowed for sale in other retail stores outside pharmacies.

[29] SOU 2012:75 (2012) *Pris, tillgång och service - fortsatt utveckling av läkemedels- och apoteksmarknaden.* Delbetänkande av Läkemedels- och apoteksutredningen.
[30] Swedish Competition Authority (2016) *Olika pris för samma läkemedel - En kartläggning av landstingens priser vid upphandlingar av rekvisitionsläkemedel*. Rapport 2016:5.

Appendix 2 Policy and regulations

Development, approval, manufacturing, marketing, distribution and use of pharmaceutical products are strictly regulated by legislation, directives and policy instruments on international and EU level as well as on national level. This chapter is aimed to introduce key regulations and policy initiatives with relevance for the pharmaceutical value chain and the identified applications for product-specific environmental information, with focus on:

- Product approval through market authorisation
- Manufacturing of pharmaceuticals
- The Swedish national subsidy system and generic substitution
- Public procurement and GPP (Green Public Procurement)
- Current policy initiatives in the EU – the Green Deal and the Strategic Approach to Pharmaceuticals in the Environment, both launched in 2019

The application of these regulations is also further described in the chapter describing roles and responsibilities of government agencies (see Appendix 3).

Product approval through market authorisation

All medicines must be authorized before they can be marketed and made available to patients. The requirements and procedures for marketing authorisation, as well as the rules for monitoring authorised products is common for all member states within EU and are primarily laid down in Directive 2001/83/EC and in Regulation (EC) No 726/2004[31].

As part of the market authorisation procedure, a scientific assessment is made of the medicine, where the key principle guiding the assessment is the balance between the benefits and risks. A medicine can only be authorised if its benefits outweigh the risks[32].

Main routes for market authorisation within EU

In the EU, there are two main routes for authorizing medicines: a centralized route and a national route.[33]

Under the centralized authorisation procedure, pharmaceutical companies submit a single marketing-authorisation application to EMA. This allows the marketing-authorisation holder to market the medicine and make it available to patients and healthcare professionals throughout the EU based on a single marketing authorisation. The European Commission is the authorizing body for all centrally authorized product, who takes a legally binding decision based on EMA's recommendation. Once granted by the European Commission, the centralized marketing authorisation is valid in all EU Member States as well as in the European Economic Area (EEA) countries Iceland, Liechtenstein and Norway. The centralized authorisation procedure is

[31] European Commission, Legal framework governing medicinal products for human use in the EU: https://ec.europa.eu/health/human-use/legal-framework_en
[32] European Medicines Agency, How EMA evaluates medicines for human use: https://www.ema.europa.eu/en/about-us/what-we-do/authorisation-medicines/how-ema-evaluates-medicines
[33] European Medicines Agency, Authorisation of medicines: https://www.ema.europa.eu/en/about-us/what-we-do/authorisation-medicines

compulsory for several specific medicines and optional for others. Today, the majority of new, innovative medicines pass through the centralized authorisation procedure in order to be marketed in the EU.

Most generic medicines and medicines that does not require a prescription are, however, assessed and authorized at national level in the EU. Each EU Member State has its own national authorisation procedures. The Swedish Medical Product Agency is responsible for decisions concerning market authorisation in Sweden (see also Appendix 3). The legislative framework for pharmaceuticals in Sweden is the Medicinal Products Act (Läkemedelslagen 2015:315) which is complemented by the Medicinal Products Ordinance (SFS 2015:458) and by numerous other provisions.

When a company wishes to request marketing authorisation in several EU Member States for a medicine that is outside the scope of the centralized procedure, it may use one of the following routes:

- mutual-recognition procedure (MRP), whereby a marketing authorisation granted in one Member State can be recognized in other EU countries;
- decentralized procedure (DCP), whereby a medicine that has not yet been authorized in the EU can be simultaneously authorized in several EU Member States.

Of the medicines entering the EU market, 90% are nationally authorised. These are mainly generics which reach the market through the mutual recognition procedure and the decentralized procedure.[34]

As a result of these procedures, new pharmaceutical products are authorized to be produced at industrial scale and placed on the market. The number of new pharmaceutical products reaching consumers per year has nearly doubled in the last decade, both for human and veterinary products.[35]

Environmental Risk Assessment (ERA) in market authorisation

Since 2006, performing an ERA is mandatory for any pharmaceutical company submitting a marketing authorisation application for a medicine. It is described in specific EMA guidelines for human and veterinary pharmaceuticals, respectively. The guidelines define how the ERA shall be conducted when applying for market authorisation in the EU.[36] The ERA is reviewed by national medicines or environment agencies and/or the Scientific Committees of the EMA, depending on the selected authorisation procedure (centralised, decentralised, mutual recognition).

The ERA requirement only includes environmental risks associated with emissions of API from usage of the medicine, based on expected sales figures on the markets for which authorisation is sought. Thus, the ERA does not include environmental risks related to emissions of API from production processes, or emissions of other substances than API. The ERA guideline for human medicines are currently being revised to facilitate the work for both applicants and regulators, as well as use more relevant test methods to evaluate environmental impacts, e.g. for endocrine

[34] EMA (2020) *Annual report 2019*.
[35] European Commission (2018) *Options for a strategic approach to pharmaceuticals in the environment - Final Report*.
[36] EMA (2006) *Guideline on the environmental risk assessment of medicinal products for human use*.

disruptive properties[37]. It is, however, not within the scope of the revision to expand the ERA to include risks in other parts of the life cycle. A draft of the revised guideline was made available in December 2018, but at the time of writing the final revised version of the guideline is still not published.

According to the EU regulations, results from the ERA shall not be included in the risk-benefit evaluation which is the basis for the market authorisation decision for human medicines. Thus, medicines cannot be declined due to significant environmental risks. Identified risks should according to the EMA guideline for ERA be handled through different precautionary and measures, which includes different types of information such as labelling and leaflets for patient use, product storage and disposal[38]. However, there are no requirements to include identified environmental risks in the Risk Management Plan that among other things include different measures to minimise risks. In addition, there is no requirements to review or update the ERA once the medicine has been approved and launched.

For veterinary products, however, a legislative change was made in 2018 that stipulates that environmental risks can be taken into consideration in the approval. Pharmaceuticals assessed as "posing a significant risk" to the environment at the time of the assessment can be placed on the market provided Risk Mitigation Measures (RMMs) are identified and/or implemented.[39]

Also, there is currently no requirements to make the detailed information from the ERA publicly available when the medicine has been approved and launched. Access to the information is often restricted due to proprietary or confidentiality reasons. This implies that it is not available for use in other applications, such as e.g. in procurement or guidance in product choice and use. Appropriate details from the ERA can be included in the European Public Assessment Report (EPAR) of approved medicines, but these are generally very limited. In the draft revised EMA guideline for ERA, however, applicants are encouraged to share data generated for the ERA in accordance with Directive 2010/63/EU to avoid unnecessary repetition of studies[40].

The Swedish Medical Product Agency are actively promoting updates of the EU regulations to improve management of environmental risks as a part of the market authorisation (see also Appendix 3).

Manufacturing of pharmaceuticals

Manufacturing of pharmaceutical ingredients and products are strictly regulated to secure patient safety and quality through the principles and guidelines for *Good Manufacturing Practice (GMP)*. This apply irrespective of where in the world the ingredient or product is manufactured.

The environmental regulations governing manufacturing of products and APIs are, however, in general regional, national or local. As the pharmaceutical industry is global and a major share of the pharmaceutical products and ingredients consumed within the EU are manufactured in countries outside of EU, this consequently implies that environmental regulations in countries of

[37] European Medicines Agency, Revised guideline to assess risk of human medicines for the environment: https://www.ema.europa.eu/en/news/revised-guideline-assess-risk-human-medicines-environment
[38] EMA (2006) *Guideline on the environmental risk assessment of medicinal products for human use.*
[39] European Commission (2018) *Options for a strategic approach to pharmaceuticals in the environment - Final Report*.
[40] European Medicines Agency, Revised guideline to assess risk of human medicines for the environment: https://www.ema.europa.eu/en/news/revised-guideline-assess-risk-human-medicines-environment

manufacturing varies. Within EU, the main regulations governing pharmaceutical manufacturing are the *Industrial Emissions Directive, REACH* and the *Water Framework Directive*.

In general, emissions of pharmaceutical specific substances (i.e. APIs) are not adequately addressed in current regulations for manufacturing. According to EU environmental legislation, requirements should be set as part of the environmental permits but in practice this is seldom done, and the legislation only covers manufacturing within the EU[41]. The Swedish government has therefore actively lobbied for the establishment of emission limits on active substances, and the Swedish Medical Products Agency promotes EU regulations for emissions of APIs from manufacturing that can also include production outside of the EU.[42]

In the following, some of the EU legislation governing manufacturing practices and emissions from pharmaceutical manufacturing are briefly described.

Good Manufacturing Practice (GMP)

The EU Guidelines for Good Manufacturing Practice (GMP) focuses on securing safe and effective medicinal products for users through a monitoring system and regular controls conducted by countries' medical product agencies (MPAs). GMP describes the minimum standard that a medicines manufacturer must meet in their production processes. Manufacturers of medicines intended for the EU market, no matter where in the world it is located, must comply with GMP.[43] In Sweden, the Swedish MPA is responsible for GMP inspections, and for issuing permits for manufacturing of pharmaceutical products.

GMP does not include environmental management of pharmaceutical manufacturing, and it is not within the scope of the GMP inspections to make observations regarding environmental aspects at the pharmaceutical production sites.[44]

As manufacturing of pharmaceuticals takes place all over the world, with varying local environmental legislation, the Swedish Medical Product Agency (MPA)[45] and other actors such as the Swedish Pharmacy Association[46] and the industry association for generic pharmaceuticals and biosimilars (FGL) [47] has suggested to include emission limits in GMP as one way achieving basic environmental standards for manufacturing that apply irrespective of location. LIF have highlighted some of the challenges with making such a change. GMP is a global standard where the same requirements apply irrespective of location to secure product quality, whereas environmental impacts are local depending on the specific conditions at the manufacturing location. Also, if additional aspects are added into GMP, there is a risk that focus can be diverted from the key purpose of GMP, i.e. to secure safe and effective medicinal products[48].

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[41] Läkemedelsverket (2018) *Miljöutredning 2018.*
[42] Läkemedelsverket (2018) *Handlingsplan för hur Läkemedelsverket fram till 2020 ska verka för att nå miljömålen.*
[43] European Medicines Agency, Good manufacturing practice: https://www.ema.europa.eu/en/human-regulatory/research-development/compliance/good-manufacturing-practice
[44] Changing Markets/Ecostorm for Nordea (2016) *Impacts of pharmaceutical pollution on communities and environment in India.*
[45] Läkemedelsverket (2018) *Miljöutredning 2018.*
[46] Sveriges Apoteksförening, Läkemedel och miljö: http://www.sverigesapoteksforening.se/lakemedel-och-miljo/
[47] FGL - ställningstaganden, Miljökonsekvenser vid läkemedelstillverkning: https://www.generikaforeningen.se/wp-content/uploads/2014/02/Miljokonsekvenser-vid-lakemedelstillverkning.pdf
[48] LIF, Skärpta miljökrav vid upphandling av läkemedel kan införas redan idag: https://www.lif.se/nyheter/skarpta-miljokrav-vid-upphandling-av-lakemedel-kan-inforas-redan-idag/

The Industrial Emissions Directive

The Industrial Emissions Directive (IED, 2010/75/EU) aims to achieve a high level of protection of human health and the environment taken as a whole by reducing harmful industrial emissions across the EU)[49]. The IED requires manufacturing industries to annually report their emissions of certain substances. The Directive is implemented in Swedish law by general binding rules, mainly in the Ordinance on Industrial Emissions (2013:250) and the Swedish Environmental Code (Miljöbalken). The Swedish Environmental Protection Agency is responsible for supporting implementation of the IED in Sweden (see also Appendix 3).

The Directive applies to pharmaceutical manufacturing sites and regulates e.g. emissions of solvents. Emissions of APIs are, however, not included in the list of polluting substances. The EU Strategic Approach for Pharmaceuticals in the Environment, however, states the Commission will *"Ensure that the emission of pharmaceuticals to water is considered as a possible Key Environmental Issue when reviewing Best Available Techniques Reference Documents under the Industrial Emissions Directive for relevant sectors"*.[50]

During the years 2020-2023, the IED will be revised, as part of the European Green Deal (see also below). This could provide an opportunity to integrate APIs in the list of polluting substances.

REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals)

The REACH regulation (EC 1907/2006) concerns the Registration, Evaluation, Authorisation and Restriction of Chemicals. It entered into force in 2007 and aims to ensure a high level of protection of human health and the environment. The basic principle of REACH is that producers, importers, and downstream users assume responsibility for their chemicals. There is an exemption in the REACH regulation for Active Pharmaceutical Ingredients (APIs) and final pharmaceuticals products. Other compounds such as intermediates and other chemicals used in manufacturing and development of pharmaceuticals are, however, covered by REACH.

The Water Framework Directive

The Water Framework Directive (2000/60/EC) aims to protect and improve all waters in the EU. It includes water quality standards and is currently the single EU directive that most explicitly considers issues of pharmaceuticals in the environment. The directive includes a list of prioritised substances (2013/39/EU) that may cause risk to the water environment and that shall be monitored in the EU, where a few selected pharmaceutical substances are included on the watchlist. Member states can also adopt own lists and limits for particularly polluting substances.

In the EU Strategic Approach for Pharmaceuticals in the Environment, the directive is highlighted where one of the actions is *"Under the Water Framework Directive, consider specific pharmaceuticals, and groups of pharmaceuticals with similar effects, in the work supporting the regular review of the list of substances posing a risk at Union level, and work with Member States on environmental quality standards for pharmaceuticals posing a risk at national level"*[51].

In Sweden, the responsibility for implementation of water management lies with the five county administrative boards, which are water authorities. The Swedish Agency for Marine and Water Management (HaV) supports the water authorities through guidance and regulations for surface

[49] European Commission, Industrial Emissions Directive: https://ec.europa.eu/environment/industry/stationary/ied/legislation.htm
[50] European Commission (2019) *European Union Strategic Approach to Pharmaceuticals in the Environment.* COM (2019) 128 final.
[51] European Commission (2019) *European Union Strategic Approach to Pharmaceuticals in the Environment.* COM (2019) 128 final.

water[52]. HaV:s regulations includes environmental quality standards for the pharmaceuticals substances included on the watchlist of the water framework directive[53]. In the development of environmental quality standards, the Swedish Medical Product Agency contributes with knowledge about which pharmaceutical substances that may be relevant to limit[54].

The Swedish national subsidy system and generic substitution

In the Swedish healthcare system, patients pay a maximum sum per year for pharmaceuticals that are included in the benefits scheme. In the so-called high-cost threshold system, a medicine is tax-subsidised, and the state pays a portion of the costs[55]. Sweden also follows a generic substitution system, which means that pharmacies substitute a prescription medicine given with another medicine with the same formula, whenever a generic or different version of the original medicine is available[56].

This is regulated in the Act on Pharmaceutical Benefits (Lag (2002:160) om läkemedelsförmåner m.m.), which builds the overall legal framework for the pricing and reimbursement of pharmaceuticals. The Act can be summarised in three principles (SFS 2002:160):

- The *human value principle*; underlines the respect for equality of all human beings and the integrity of every individual. It is not allowed to discriminate based on sex, race, age etc., when making reimbursement decisions.
- The *need and solidarity principle*; states that those in greatest need take precedence when it comes to reimbursing pharmaceuticals. In other words, patients with more severe diseases are prioritized over patients with less severe conditions.
- The *cost-effectiveness principle*; states that the cost for using a medicine should be reasonable from a medical, humanitarian and social-economic perspective.

In addition, the government has adopted an ordinance on Pharmaceutical Benefits etc. (2002:687).

The Dental and Pharmaceutical Benefits Agency (TLV) is the government agency responsible for implementation of pharmaceutical benefits in Sweden (see also Appendix 3). TLV issues provisions that provide rules on the application of the legal framework and published general guidelines for economic evaluations submitted with applications for the inclusion of a medicine in the Pharmaceutical Benefits Scheme and for price increases of pharmaceuticals.

Today the pharmaceutical subsidy system is purely based on medical aspects and cost, guided by the aim of the whole system to "acquire as much health as possible for the tax-payers money going to medicines"[57] Environmental aspects are not weighed into the decisions. However, already in 2013, a State White Paper[58] (SOU 2013:23) stated that it would in principle be possible to take

[52] HaV, Vattenförvaltning: https://www.havochvatten.se/hav/vagledning--lagar/vagledningar/vattenforvaltning/om-vattenforvaltning.html
[53] HaV (2019) *Havs- och vattenmyndighetens föreskrifter om klassificering och miljökvalitetsnormer avseende ytvatten* (HVMFS 2019:25).
[54] Läkemedelsverket (2018) *Handlingsplan för hur Läkemedelsverket fram till 2020 ska verka för att nå miljömålen.*
[55] TLV, What is the high cost threshold?: https://tlv.se/in-english/medicines/what-is-the-high-cost-threshold.html
[56] TLV, Substituting medicines at the pharmacy: https://tlv.se/in-english/pharmacy/substituting-medicines-at-the-pharmacy.html
[57] TLV, TLV i korthet: https://www.tlv.se/om-oss/om-tlv/tlv-i-korthet.html
[58] SOU 2013:23 (2013) *Ersättning vid läkemedelsskador och miljöhänsyn i läkemedelsförmånerna*. Delbetänkande av Läkemedels- och apoteksutredningen.

environmental aspects into consideration. The report proposed a system of voluntary environmental classifications and environmental premium as a way forward. To date, however, the proposals have not been further developed or implemented in the system.

Public Procurement and GPP (Green Public Procurement)

In addition to pharmaceuticals dispensed through pharmacies, Swedish regions procure pharmaceuticals for inpatient care within healthcare institutions in accordance with the Public Procurement Act (LOU (2016:1145)). The Public Procurement Act is based on the EU Directive on Public Procurement. The Directive was updated in 2014, followed by several initiatives in the Members States to establish national Public Procurement strategies and legislation. Probably the most important new feature in the updated EU Public Procurement Directive is that the evaluation and assignment of a winning bid can be based on the use of *award* criteria focusing on "the best economic advantageous tender" (also referred to as Best value for money). This approach adds other components to the principle of "lowest price", which can include environmental considerations.

The potential of Green Public Procurement (GPP) as a policy instrument has been increasingly recognised, and over recent years there has been growing political commitment at national, EU and international levels. It has been highlighted internationally by the OECD and was established as a policy instrument within the EU in 2004. GPP is defined as "a process whereby public authorities seek to procure goods, services and works with a reduced environmental impact throughout their life cycle when compared to goods, services and works with the same primary function that would otherwise be procured". The European Commission and a number of European countries have developed guidance in this area, in the form of national GPP criteria. EU GPP is a voluntary instrument, which means that Member States and public authorities can determine the extent to which they implement it.

GPP require clear and verifiable selection criteria. Depending on the level of ambition of public procurement authorities, GPP criteria can be classified as "core" (focusing on the key areas of environmental performance of a product and aimed at keeping administrative costs for companies to a minimum) or "comprehensive" (criteria take into account more aspects or higher levels of environmental performance, for use by authorities that want to go further in supporting environmental and innovation goals). Both core and comprehensive criteria set the minimum performance levels that products must fulfil. *Award criteria* can also be provided in GPP for the evaluation and selection of tenderers. Compliance checks of the criteria is part of the tendering procedure conducted by the procurer. This could also imply third party verification.[59]

In Sweden, the National Agency for Public Procurement is responsible for supporting procurement authorities in their procurement, including green public procurement (see also Appendix 3). Procurement of pharmaceuticals for inpatient care is performed by the Swedish regions (see also Appendix 4).

[59] European Commission (2008) *Public procurement for a better environment.* COM (2008) 400 final.

Current policy initiatives in the EU

In addition to the regulations and initiatives described above, a number of policy initiatives has started within the EU with relevance to the pharmaceutical value chain. Two key initiatives are highlighted below; *the Green Deal* and the *Strategic Approach to Pharmaceuticals in the Environment*. It is likely that both these initiatives will influence future policies and legislation for pharmaceuticals.

The European Green Deal

In December 2019, the European Green Deal for the EU and its citizens was launched, which aims to "making Europe climate neutral by 2050, boosting the economy through green technology, creating sustainable industry and transport, cutting pollution"[60] It is at the same time a new growth strategy that aims to transform the EU into a fair and prosperous society, with a modern, resource-efficient and competitive economy where there are no net emissions of greenhouse gases in 2050 and where economic growth is decoupled from resource use. It also aims to protect, conserve and enhance the EU's natural capital, and protect the health and well-being of citizens from environment-related risks and impacts.[61] The Green Deal is an integral part of the Commission's strategy to implement the United Nation's 2030 Agenda and the sustainable development goals.

The Green Deal includes several elements and initiatives that will or can have an influence on the environmental impacts along the pharmaceutical value chain, including climate impacts and emissions of APIs, as well as on the different identified applications to drive improvement along the chain, such as procurement.

For example, in *"A zero pollution ambition for a toxic-free environment"* the Commission will propose measures to address pollution from urban runoff and from new or particularly harmful sources of pollution such as micro plastics and chemicals, including pharmaceuticals. Also, in "*Mobilising industry for a clean and circular economy"*, reliable, comparable and verifiable information are highlighted as an important part to enable buyers to make more sustainable decisions. It is also stated that public authorities, including the EU institutions, should lead by example and ensure that their procurement is green. The Commission will propose further legislation and guidance on green public purchasing[62].

The Green Deal includes a roadmap with actions[63]. At the time of writing, several actions have been launched such as a proposal for a European Climate Law, adoption of the European Industrial Strategy as well as a proposal of a Circular Economy Action plan.

The *European Climate Law* proposes a legally binding target of net zero greenhouse gas emissions by 2050[64]. As part of the Law, the Commission will propose a new EU target for 2030 greenhouse gas emissions reductions. By June 2021, the Commission will review, and where necessary propose to revise, all relevant policy instruments to deliver the additional emissions reductions for 2030.

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[60] European Commission, A European Green Deal - Actions being taken by the EU: https://ec.europa.eu/info/strategy/priorities-2019-2024/european-green-deal/actions-being-taken-eu_en

[61] European Commission (2019) *The European Green Deal*. COM (2019) 640 final.

[62] European Commission (2019) *The European Green Deal*. COM (2019) 640 final.

[63] European Commission (2019) *Annex to The European Green Deal*. COM (2019) 640 final.

[64] European Commission (2020) *Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL establishing the framework for achieving climate neutrality and amending Regulation (EU) 2018/1999 (European Climate Law)*. COM (2020) 80 final, 2020/0036 (COD).

Thus, in the coming years the law is expected to have a large influence on the work with managing and reducing climate impacts in all sectors of society.

In the *European Industrial Strategy*, the EU will support the development of key enabling technologies that are strategically important for Europe's industrial future, where pharmaceuticals are included as one of the key technologies. A new EU pharmaceutical strategy will be put forward, focusing on the availability, affordability, sustainability and security of supply of pharmaceuticals[65].

In the *Circular Economy Action Plan*[66] a key feature is to empower consumers and public buyers. The action plan points out several areas of action and potential measures. Public authorities' purchasing power is highlighted as a powerful driver for sustainable products. To further enhance this policy tool the Commission will propose minimum mandatory green public procurement (GPP) criteria and targets in sectoral legislation and phase in compulsory reporting to monitor the uptake of Green Public Procurement (GPP). Furthermore, the Commission will continue to support capacity building with guidance, training and dissemination of good practices and encouraging public buyers to take part in a "Public Buyers for Climate and Environment" initiative, which will facilitate exchanges among buyers committed to GPP implementation. The action plan also states that the Commission will propose that companies substantiate their environmental claims using Product and Organisation Environmental Footprint methods (PEF and OEF).

The EU Strategic Approach to Pharmaceuticals in the Environment

In 2019, the EU presented a Strategic Approach to Pharmaceuticals in the Environment with six focus areas of actions, that cover all stages of the life cycle of pharmaceuticals where improvements can be made. The six identified areas are:

- Increase awareness and promoting prudent use of pharmaceuticals
- Support the development of pharmaceuticals intrinsically less harmful for the environment and promote greener manufacturing
- Improve environmental risk assessment and its review
- Reduce wastage and improve the management of waste
- Expand environmental monitoring of concentrations of pharmaceuticals in the environment
- Fill other knowledge gaps, such as the links between presence of antimicrobials in the environment and the development and spread of antimicrobial resistance.

Concrete actions related to manufacturing include e.g. aiming to fund research and innovation for greener pharmaceuticals; engaging with pharmaceutical industry to among other things explore the potential of extended producer responsibility; discussing public procurement as a way to promote greener pharmaceutical design and manufacturing; and encouraging action in third countries considering anti-microbial resistance (AMR).[67]

The Commission will follow up the actions set in the Communication and invites Member States and other stakeholders to take action as well.

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[65] European Commission (2020) A *New Industrial Strategy for Europe.* COM (2020) 102 final.
[66] European Commission (2020) *Circular Economy Action Plan For a cleaner and more competitive Europe.* COM (2020) 98 final.
[67] European Commission (2019) *European Union Strategic Approach to Pharmaceuticals in the Environment.* COM (2019) 128 final.

Appendix 3. Government agencies

The description is primarily based on literature review and analysis, combined with discussions and interviews with representatives of the Swedish Medical Product Agency and the National Agency for Public Procurement.

Roles and responsibilities regarding pharmaceuticals are shared between several Swedish agencies. In this study we have focused specifically on agencies that have, or potentially could have, key responsibilities in environmental management of pharmaceuticals along the value chain:

- the Swedish Medical Product Agency (MPA) - Läkemedelsverket,
- the Dental and Pharmaceutical Benefits Agency (TLV) - Tandvårds- och Läkemedelsförmånsverket,
- the National Board for Health and Welfare (SoS) - Socialstyrelsen,
- the Swedish Environmental Protection Agency (EPA)- Naturvårdsverket and
- the National Agency for Public Procurement (UHM) - Upphandlingsmyndigheten.

Governance of the Swedish national government agencies

In the Swedish Government, each Ministry is responsible for several government agencies tasked with applying the laws and carrying out the activities decided on by the parliament and the government. Every year the Government issues appropriation directions for the government agencies. These set out the objectives of the agencies' activities and how much money they have available to them. The Government therefore has quite substantial scope for directing the activities of government agencies, but it generally has no powers to interfere with how an agency applies the law or decides in a specific case. The government agencies take these decisions independently and report to the ministries.

The *Ministry of Health and Social Affairs* has the overall responsibility for social welfare and health issues, including issues concerning pharmaceuticals[68]. The Ministry is responsible for submitting legislative proposals regarding changes to the healthcare and social systems, and later decided by the Swedish Parliament. The Ministry is responsible for the Swedish Medical Product Agency, the Dental and Pharmaceutical Benefits Agency (TLV) and the National Board for Health and Welfare.

The *Ministry of the Environment* is responsible for environmental and climate policy. The Ministry works on issues related to reduced climate emissions, a non-toxic environment, to strengthen biodiversity on land and in water, waste, radiation safety, protection and management of valuable nature, and international environmental cooperation. The 16 national environmental quality objectives form the basis for the government's environmental policy and the environmental goals system is the central, common platform for actors in Swedish environmental work[69]. The Ministry is responsible for the Swedish Environmental Protection Agency.

The roles and responsibilities of pharmaceuticals and the environment is therefore somewhat shared between these two ministries and their respective government agencies. In addition, the *Ministry of Finance* is responsible for the National Agency for Public Procurement.

[68] Government Offices of Sweden, Ministry of Health and Social Affairs: https://www.government.se/government-of-sweden/ministry-of-health-and-social-affairs/
[69] Government Offices of Sweden, Ministry of the Environment: https://www.government.se/government-of-sweden/ministry-of-the-environment/

Swedish Medical Products Agency (MPA)

The Swedish Medical Products Agency (MPA)/Läkemedelsverket is responsible for regulation and surveillance of the development, manufacturing and sale of drugs and other medicinal products. The agency's task is to ensure that both the individual patient and healthcare professionals have access to safe and effective medicinal products and that these are used in a rational and cost-effective manner[70].

The MPA is among other things responsible for:

- Market authorisation of pharmaceutical products in Sweden, including evaluation of the environmental risk assessment (ERA) as part of the authorisation procedure,
- Inspections in manufacturing of pharmaceutical ingredients and products in Sweden in accordance with good manufacturing practice (GMP), and for issuing permits for manufacturing of pharmaceutical products
- Performing the medical evaluation within the pharmaceutical benefit subsidy system
- Information about pharmaceuticals to professionals in medical and health care and the general public, to e.g. guide product choice and use

Since 2007, the MPA has an overall responsibility for environmental issues related to the agency's area of activity, a so-called *"sector responsibility"*[71]. Within the framework of the sector responsibility, the agency shall gather, support and drive activities in relation to other interested parties.

Based on the responsibilities listed above, the MPAs mandate and frame of action are, however, limited due to the current regulations (described in Appendix 2). In market authorisation of human medicines, environmental risks are not included in the risk/benefit evaluation, i.e. products cannot be declined due to identified significant environmental risks, and the possibility to impose risk management measures to the reduce risks once the products has been launched is fairly limited and is basically restricted to measures to inform health and medical care about the environmental risks. Environmental aspects are not included in GMP or the benefit subsidy systems, and therefore the MPA has no possibility to include environmental concerns in GMP inspections or substitution evaluations.

The MPA is since 2013 responsible for the environmental milestone target *"Greater environmental consideration in EU pharmaceuticals legislation and internationally"* within the Swedish environmental quality objective *"A Non-Toxic Environment"*[72]. The target is formulated as follows; *"Decisions are made within the EU or internationally by 2020 at the latest that involve existing and any new regulations for medicinal products for human or veterinary use taking greater environmental consideration."*. As the target has 2020 as end-year, the MPA has requested a prolongation of the government assignment within the environmental objectives system. Within the milestone target, the MPA are actively promoting updates of the EU regulations to improve environmental management of pharmaceuticals and are in this collaborating with the pharmaceutical industry, other government agencies and stakeholders.

[70] Government Offices of Sweden, Medical Products Agency: https://www.government.se/government-agencies/medical-products-agency-lakemedelsverket-lv/
[71] Läkemedelsverket (2018) *Miljöutredning 2018.*
[72] Sveriges miljömål, Etappmål, Ökad miljöhänsyn i EU:s läkemedelslagstiftning och internationellt: http://www.sverigesmiljomal.se/etappmalen/okad-miljohansyn-i-eus-lakemedelslagstiftning-och-internationellt/

The agency´s action plan to improve environmental management of pharmaceuticals

In June 2018, the MPA published an updated action plan for how it will work until 2020 to achieve the environmental targets and contribute to Agenda 2030.[73] The action plan has a life cycle perspective, where the main measures in the plan are:

- Increase environmental considerations in permitting licenses for pharmaceuticals
- Improve knowledge and reduce the exposure of substances that are harmful to the environment
- Promote availability of environmental information for pharmaceuticals in a concerted manner
- Reduce discharges of environmentally harmful substances from production of pharmaceuticals
- Reduce environmental impacts in use of pharmaceuticals, medical/technical products and cosmetic products
- Stimulate development of pharmaceutical products with low overall environmental impact

Regarding the measure to *increase environmental considerations in permitting licenses for pharmaceuticals,* the MPA is working for changes in the EU regulations for pharmaceuticals for human use to introduce requirements such as environmental considerations in the risk/benefit evaluation in the approval process, risk mitigation measures, making environmental data available in an concerted manner, as well as emission limits for active substances from manufacturing. As the legislation for product approval is common within the EU (see also Appendix 2), Sweden have limited opportunities to set specific national environmental requirements. Sweden cannot have regulations that differ from EU regulations to a large extent, although it is in some cases possible to have complementing national requirements.[74] Therefore, the work is done in collaboration between the government, authorities and companies on both national and international level. The MPA notes that Sweden already had a key role in improving environmental considerations to the updated legislation on veterinary medicine products.

In relation to the measures to *improve knowledge and reduce the exposure of environmentally harmful substances* and *promote availability of environmental information for pharmaceuticals in a concerted manner*, the MPA for example works for improved test requirements and availability of information by participating in the development of updated guidelines for the Environmental Risk Assessments (ERA) that companies need to establish as part of the approval process. The update takes place by a working group within EMA. In collaboration with The Swedish Agency for Marine and Water Management (HaV), the MPA also works to identify pharmaceutical substances with potential environmental risks by participating in formulation of the EU regulation for priority hazardous substances within the Water Framework Directive.

Regarding the measure to *Reduce discharges of environmentally harmful substances from production of pharmaceuticals* the MPA works for emissions limits for antibiotics to reduce risks for antimicrobial resistance in the environment, as well as improved international legislation to regulate emissions of API:s in manufacturing where, for example, introduction of emission limits in Good manufacturing practice (GMP) has been proposed (see also Appendix 2).

[73] Läkemedelsverket (2018) *Handlingsplan för hur Läkemedelsverket fram till 2020 ska verka för att nå miljömålen (reviderad).*
[74] Läkemedelsverket (2018) *Miljöutredning 2018.*

In terms of the measure to *reduce environmental impacts in use of pharmaceuticals* the MPA for example works for integrating environmental considerations in recommendations for medical treatments, as well as contribute in development of environmental criteria that can be used to guide product choice and use in e.g. the benefit subsidy system, environmental labels for OTC products, and public procurement.

Within the measure to *stimulate development of pharmaceutical products with low overall environmental impact* the MPA works to identify needs for research on risk minimising measures and to inform and educate about environmental issues of pharmaceuticals, for example to increase substitution of hazardous substances to substances that are less harmful to the environment.

As part of this, the MPA is responsible for a knowledge centre on pharmaceuticals in the environment (Kunskapscentrum för Läkemedel i Miljön). The centre was established in August 2019 with the mission to be a national platform for dialogue and cooperation and to increase knowledge sharing on pharmaceuticals in the environment. Its focus areas are; Knowledge on substances that are potentially harmful to the environment; Strengthen the knowledge on sustainable production; and Promote development and use of environmental criteria for pharmaceuticals[75].

Dental and Pharmaceutical Benefits Agency (TLV)

The Dental and Pharmaceutical Benefits Agency (TLV)/Tandvårds- och läkemedelsförmånsverket is responsible for the national pharmaceutical subsidy system and generic substitution (see also Appendix 2). TLV´s remit is to determine whether a pharmaceutical product, medical device or dental care procedure shall be subsidized by the state[76]. The Agency also contribute to quality service and accessibility of pharmacies, which includes regulating the generic substitution of medicines and the retail margin for pharmacies, as well as monitoring and supervising some areas of the pharmaceutical market.

Pharmaceuticals included within the benefit system are tax-subsidised, where the state pays a portion of the costs and where the patients pay a maximum sum per year, the so called high-cost threshold. In addition to deciding which products shall be subsidised by the state, TLV also decides how much a medicine or a medical device in the system should cost.[77] To include its product in the system, a pharmaceutical company needs to send an application to TLV, who then decides if the product will be included and sets its price in the system.[78] See also Appendix 1 for more information.

Sweden also follows a generic substitution system, which means that pharmacies are obliged to substitute a prescription medicine with an equivalent cheaper medicine, whenever a generic or different version of the original medicine is available. In the generic substitution system, the MPA is responsible for assessing which medicines are interchangeable and the TLV decides and

[75] Läkemedelsverket - Kunskapscentrum för läkemedel i miljön, Fokusområden: https://www.lakemedelsverket.se/sv/miljoarbete/kunskapscentrum-for-lakemedel-i-miljon/fokusomraden
[76] Government Offices of Sweden, Dental and Pharmaceutical Benefits Agency (TLV): https://www.government.se/government-agencies/dental-and-pharmaceutical-benefits-agency-tandvards--och-lakemedelsformansverket-tlv/
[77] TLV, Our mission: https://tlv.se/in-english/organisation/our-mission.html
[78] TLV, Pricing and reimbursement of medicines: https://www.tlv.se/in-english/medicines/pricing-and-reimbursement-of-medicines.html

provides a monthly list of which interchangeable products are least expensive and shall be provided by pharmacies.[79]

The current regulation for the benefit system and generic substitution and the current mandate of TLV do not include or enable explicit environmental considerations. The annual appropriation directions from the Government for TLV for 2019 also lacks any mentions of sustainability or environmental issues.

Thus, it is currently not within TLVs mandate to include environmental considerations in the benefit system. Based on the review there seem to be two main challenges for TLV to weigh in environmental aspects into decisions in the subsidy system and generic substitution:

Lack of political support for potential increase in costs. Weighing in environmental aspects in decisions for the subsidy system may potentially lead to increased costs for the system. Financing the welfare and care needs of an aging population is one of the major challenges facing the state and regions over the coming years and decades. Changing the benefit system in a way that could lead to increasing the cost of pharmaceuticals poses a significant obstacle to integrating environmental aspects in the system. At the same time, there is a lack of knowledge on the actual consequences on costs. Also, comparative studies show that the price of pharmaceuticals in this part of the benefit system is relatively low in Sweden compared to other European countries[80].

Lack of environmental criteria that can ensure fair and equal evaluation of products within the system, including commonly accepted methods, tools and verification systems for compiling and reporting environmental information for pharmaceutical products. Such criteria are of course central to enable TLV to weigh in environmental considerations in its decisions, and naturally such criteria and information need to hold for strict review to secure that the expected environmental benefits are realised.

As the subsidy system involves substantial volumes of medicines – in 2019 it represented 64 percent of the total sales in Sweden (see also Appendix 1) – the inclusion of environmental aspects as selection criteria in the system can have a substantial effect on the work to drive improvements and reduce environmental impacts along the value chain for pharmaceuticals used in Sweden.

National Board of Health and Welfare (Socialstyrelsen)

The National Board of Health and Welfare (SoS)/Socialstyrelsen works to ensure good health, social welfare and high-quality health and social care on equal terms for the whole Swedish population[81]. The activities concern social services, health and medical care, patient safety and epidemiology.

Most of the agency´s activities focus on staff, managers and decision makers, for instance through the development of national guidelines[82]. The national guidelines are a support for those who

[79] TLV, Pharmacy: https://tlv.se/in-english/pharmacy.html
[80] TLV (2019) *Internationell prisjämförelse 2019 - En analys av svenska läkemedelspriser i förhållande till 19 andra europeiska länder.*
[81] Government Offices of Sweden, National Board of Health and Welfare: https://www.government.se/government-agencies/national-board-of-health-and-welfare--socialstyrelsen/
[82] Socialstyrelsen, Nationella riktlinjer: https://www.socialstyrelsen.se/regler-och-riktlinjer/nationella-riktlinjer/

make decisions concerning the allocation of resources within health and medical care and social services. The goal of these guidelines is to contribute towards patients and clients receiving a high standard of medical care and social services. Politicians, senior executives and managers in the regions, as well as the healthcare personnel, can use the guidelines in different decisions on, for example, resource allocation within and between different groups and operations, operational planning, organisation of the different activities, regional and local medical care programmes, as well as individual decisions made by e.g. doctors, case officers within social services or dentists in the consultations with the patients or users.

At present, the National Board of Health and Welfare does not include environmental considerations in development of the national guidelines. The work with the guidelines and support in the field of equal healthcare could, however, provide a model also for implementing environmental aspects into guidance for choice and use of pharmaceuticals for different medical treatments.

Swedish Environmental Protection Agency (EPA)

The Swedish Environmental Protection Agency (EPA)/Naturvårdsverket is responsible for coordinating Sweden´s environmental work – nationally, within EU and internationally. The Agency's remit is threefold[83]:

- Compiling knowledge and documentation, to develop the Agencies' own environmental efforts and those of others
- Developing environmental policy - by providing the Government with a sound basis for decisions and by giving an impetus to EU and international efforts
- Implementing environmental policy - by acting in such a way as to ensure compliance with the Swedish Environmental Code and achievement of the national environmental objectives

In terms of responsibilities concerning pharmaceuticals and the environment, the EPA work together with other Swedish agencies and organizations on international level and within the EU to set emission limits in the manufacture of, among other things, antibiotics and drugs with endocrine disrupting properties[84].

The EPA also ensures that environmental legislation is applied in an appropriate and correct manner, for example that sewage treatment plants use best available techniques (BAT) to remove pharmaceutical residues. The EPA is also responsible for monitoring the state of the environment. Therefore, monitoring and measurements are conducted of presence and levels of various polluting substances. In recent years, the measurements have included several drug substances such as hormones, painkillers, antibiotics, anti-inflammatory drugs, sleeping drugs and antidepressants[85].

[83] Swedish EPA, About the Swedish Environmental Protection Agency: http://www.swedishepa.se/About-us/
[84] Naturvårdsverket, Läkemedel i miljön: http://www.naturvardsverket.se/Sa-mar-miljon/Manniska/Miljogifter/Organiska-miljogifter/Lakemedel/
[85] Naturvårdsverket, Läkemedel i miljön: http://www.naturvardsverket.se/Sa-mar-miljon/Manniska/Miljogifter/Organiska-miljogifter/Lakemedel/

In addition, the EPA is coordinating the Policy Area Hazards within the EU strategy for the Baltic Sea Region (EUSBSR), where pharmaceuticals have been prioritized as a key challenge[86]. As part of this, the EPA coordinates the flagship initiative *Baltic Sea Pharma Platform* that is aimed to bring together projects and stakeholders from the whole region to assist knowledge-sharing, increase effectiveness, streamlining activities and support regional policy development[87]. The flagship started in 2017 and has for example included projects concerning green public procurement (GrePPP[88]) and different emission reduction strategies (CWPharma[89]) as well as several stakeholder conferences.

National Agency for Public Procurement

The National Agency for Public Procurement (UHM)/Upphandlingsmyndigheten has the overall responsibility for developing and supporting the procurement carried out by contracting authorities and entities in Sweden[90]. They shall work for a legally secure, efficient and socially and environmentally sustainable procurement for the benefit of citizens and business development. They shall also promote innovative procurement solutions, as well as provide guidance on state grant issues to municipalities and regions according to regulation (2015:527).[91]

The role of National Agency for Public Procurement is limited to support procuring authorities. The Agency provide the support through for instance[92]:

- Contribute to that procurement is handled strategically through method development or in other ways
- Contribute to that procurement is planned, implemented, followed-up, and evaluated in an appropriate manner
- Promote increased environmental and social considerations and develop and maintain criteria for environmental considerations, including energy requirements, and social considerations in procurement.
- Contribute to that the entire purchasing process can be carried out electronically and participate in the standardization of the same.
- Develop and maintain a criteria database for environmentally sound procurement.

In addition, the Agency should promote that the generational goal and the environmental quality objectives are met within its area of operation, and as needed propose measures for development

[86] Swedish EPA, Policy Area Hazards - Prevent pollution and reduce the use of hazardous substances in the Baltic Sea Region: http://www.swedishepa.se/Environmental-objectives-and-cooperation/Cooperation-internationally-and-in-the-EU/International-cooperation/Multilateral-cooperation/Baltic-Sea-Region-EUSBSR/Policy-Area-Hazards/

[87] Swedish EPA, A regional cooperation platform to reduce pharmaceuticals in the Baltic Sea: http://www.swedishepa.se/Environmental-objectives-and-cooperation/Cooperation-internationally-and-in-the-EU/International-cooperation/Multilateral-cooperation/Baltic-Sea-Region-EUSBSR/Policy-Area-Hazards/A-cooperation-to-reduce-pharmaceuticals-in-the-Baltic-Sea/

[88] Interreg Baltic Sea Region, Green Public Procurement of Pharmaceuticals for the Baltic Sea Region: https://projects.interreg-baltic.eu/projects/greppp-83.html

[89] Interreg Baltic Sea Region, Clear waters from pharmaceuticals: https://projects.interreg-baltic.eu/projects/cwpharma-110.html

[90] The National Agency for Public Procurement, About us: https://www.upphandlingsmyndigheten.se/en/omossmeny/about-us/

[91] Sveriges riksdag (2015) *Förordning (2015:527) med instruktion för Upphandlingsmyndigheten.*

[92] Upphandlingsmyndigheten, Vårt uppdrag: https://www.upphandlingsmyndigheten.se/omossmeny/om-oss/vart-uppdrag/

of the environmental work. The authority should also work for relevant research in the area of procurement and follow and promote international development in the area.[93]

The Agency´s national sustainability criteria library

The sustainability criteria library is a central tool in the agency´s work in supporting contracting authorities in their sustainable procurement[94]. The criteria consist of formulated requirements, together with motives for the requirements and suggestions for how to verify them. They are developed in open and quality assured process in collaboration with different expert groups[95]. As part of the development, the agency makes assessments to what extent it is possible to impose requirements in addition to EU harmonized legislation.

The criteria are formulated as *Special contract terms* or *Award criteria*, and are defined on three levels[96]:

- *Core level* covers basic requirements focused on reducing the majority of the environmental/sustainability impact that is associated with the specific product area, which are more ambitious than the current legislation. They are easy to use and verify.
- *Advanced level* goes beyond basic requirements. They may require more efforts in follow-up and verification.
- *Spearhead level* represents the best available alternatives in the market in terms of environmental and other sustainability aspects. They may require more specialized competence and efforts in work with follow-up and verification

The criteria are, however, voluntary for the contracting authorities to use. The implementation is made by the contracting authorities who decide which criteria to include in the specific procurement situation depending on available information, resources and ambitions. Thus, the National Agency for Public Procurement have limited mandate to influence the actual procurement that is made by contracting authorities, other than by providing guidance and support. Also, the agency does currently not have any role in the follow-up of environmental criteria made by the contracting authorities, for example by information systems and tools to share information.

National criteria for sustainable procurement of pharmaceuticals for inpatient care

The Agency launched the first sustainability criteria for procurement of pharmaceuticals in 2012. The first criteria included special contract terms, and covered availability of aquatic environmental information and procedures for environmental and social responsibility.

In October 2019, the Agency launched updated sustainability criteria for pharmaceuticals.[97] The updated criteria have been developed in a multi-stakeholder working group coordinated by the Agency and consisting of representatives from e.g. regions, pharmaceutical companies and

[93] Sveriges riksdag (2015) *Förordning (2015:527) med instruktion för Upphandlingsmyndigheten.*
[94] Upphandlingsmyndigheten, Ställ hållbarhetskrav: https://www.upphandlingsmyndigheten.se/hallbarhet/stall-hallbarhetskrav/
[95] Upphandlingsmyndigheten, Ställ hållbarhetskrav, Kriterieprocessen: https://www.upphandlingsmyndigheten.se/hallbarhet/stall-hallbarhetskrav/om-kriterierna/kriterieprocessen/
[96] Upphandlingsmyndigheten, Ställ hållbarhetskrav, Krav i olika nivåer: https://www.upphandlingsmyndigheten.se/hallbarhet/stall-hallbarhetskrav/om-kriterierna/kravnivaer/
[97] Upphandlingsmyndigheten, Enklare att upphandla hållbart tillverkade läkemedel: https://www.upphandlingsmyndigheten.se/aktuellt/enklare-att-upphandla-hallbart-tillverkade-lakemedel/

universities. The updated set of criteria includes both criteria that can be used as special contract terms as well as award criteria and are defined on different levels. An overview of the content of the updated criteria is given in Table 2 below.

Table 8. Overview of the updated sustainability criteria for medicinal products, launched in 2019 by the National Agency for Public Procurement[98]

Criteria	Content/Scope	Type	Level	Purpose
Information on location of: - pharmaceutical formulation - API production for medicinal products	Country or countries of manufacturing	Award criteria	Advanced	Increase transparency and traceability to allow identification and prioritisation of environmental and social risks, as well as of follow-up efforts
Information about the production facility in which: - pharmaceutical formulation takes place - APIs are manufactured for medicinal products	Name and address of production facilities	Award criteria	Spearhead	
Available environmental information for medicinal products	Products that is covered by EMA guidelines	Special contract terms	Core	Environmental information obtained and publicly available. Information must at least include details on persistence, bioaccumulation toxicity and environmental risk, compiled in accordance with the latest EMA guideline, FASS guideline or other equivalent publicly available model
Available environmental information for medicinal products	Products that is not covered by EMA guidelines	Award criteria	Spearhead	
Risk management procedures for environmental API emissions during the manufacture of medicinal products	Own operations and subcontractors	Special contract terms	Core	Implemented procedures for identifying and managing risks related to emissions of API
Requirements under the ILO core conventions	Own operations and subcontractors	Special contract terms	Core	Effective risk management regarding worker rights
Sustainable supply chains	Own operations and supply chain	Special contract terms	Advanced	Risk management covering human rights, labour rights, environmental protection and anti-corruption

The updated criteria enable flexibility for contracting authorities in using relevant requirements in the specific procurement situation, where requirements can be differentiated depending on the specific needs and risks for the products to be procured. They also enable for authorities to provide incentives for suppliers through use of award criteria.

As shown in Table 2, the updated criteria include availability of environmental information with focus on environmental risks related to emissions of API from use of the product, compiled in accordance with the latest versions of the EMA guideline[99], FASS guideline[100] or other publicly

[98] Upphandlingsmyndigheten, Produktgrupp Läkemedel: https://www.upphandlingsmyndigheten.se/hallbarhet/stall-hallbarhetskrav/sjukvard-och-omsorg/lakemedel/lakemedel/

[99] EMA (2006) *Guideline on the environmental risk assessment of medicinal products for human use*.

[100] FASS (2012) *Environmental classification of pharmaceuticals at www.fass.se. Guidance for pharmaceutical companies.*

available model for environmental information. The criteria concern both products that are covered by the EMA guideline as special contract terms (core level) and products that are not covered, i.e. products registered before 2006, as award criteria (spearhead level), where the award criteria is intended to encourage companies to make new information publicly available. According to the National Agency for Public Procurement, criteria for API emissions in production and climate impacts was proposed in the update but was left out because of lack of information and consensus on how to set relevant criteria and requirements. The proposed model for environmental assessment of pharmaceuticals (see chapter 2) can enable formulation of such criteria in the future.

Work has started in the regions on how to implement the updated criteria (see Appendix 4 for more details), where the criteria can provide an opportunity to nationally harmonize requirements in the procurement of pharmaceuticals for inpatient care.

Appendix 4. Regions

The description is based on interviews and workshop discussions with representatives from Region Västra Götaland and Region Stockholm, combined with literature review and analysis of results.

The 21 regions in Sweden are self-governing local authorities responsible for providing regional health care. Health care is primarily financed by taxes collected at county level, but the regions are subsidised by the state for the costs of medicines for out-patients.[101]

The responsibilities of regions regarding specifically pharmaceuticals includes:

- *procurement of pharmaceuticals* for inpatient care within hospitals (so called "requisition pharmaceuticals") – managed by procurement units in collaboration with operations
- developing *guidance and recommendations for health care professionals* to promote reliable and rational pharmaceutical use – managed primarily by medicinal products committees
- *prescribe and recommend pharmaceuticals* for medical treatments – managed by healthcare professionals

In terms of environmental responsibility for pharmaceuticals, the regions have a role in promoting environmentally sound pharmaceutical supply chains by using and implementing environmental requirements in *procurement for inpatient care*. The regions also have an important role in promoting sound and sustainable use of pharmaceuticals through *guidance in product choice and use*. This can both include to secure that the "best" drug is used for medical treatment with consideration of overall health, sustainability and environmental performance, and to secure that drugs are used in a way that minimise environmental impacts from use and end-of-life treatment of the product.

Environmental management in the regions are governed by regionally adopted environmental goals, strategies and programs, and consequently the scope and focus for the work vary depending on the political ambitions in the region. In general, there seem to be increased political support and priority in regions for more ambitious sustainability programs, aligned with the national and international political agenda. The importance of clear political priorities and mandate are stressed, to enable and support the strategic and operational work to manage environmental impacts of pharmaceuticals within the regions.

Usually, the regions ambitions and targets for reducing environmental impacts from pharmaceuticals cover the entire value chain - from manufacture, distribution and prescription to waste. However, the complexity of the value chain and the lack of transparency in the pharmaceutical industry makes it difficult for the regions to assess the environmental impacts of pharmaceuticals in a life cycle perspective. The lack of information makes it difficult to prioritise and drive different types of environmental improvement activities, in procurement and in guidance for product choice and use. Thus, the regions see an urgent need to increase availability of environmental information for pharmaceuticals in a life cycle perspective.

In the following subsections we have focused on how environmental information for pharmaceuticals is used or can be used in *public procurement for inpatient care* and to support

[101] TLV (2017) *PPRI Pharma Profile - Sweden 2017.*

guidance in product choice and use. In addition, collaboration between regions are described as well as needs for environmental information and harmonisation of methods, criteria and standards.

Public procurement for inpatient care

The regions can promote environmentally sound pharmaceutical supply chains by using and implementing environmental requirements in procurement for inpatient care. In 2019, public procurement of pharmaceuticals for inpatient care represented 19% of the total pharmaceutical sales in Sweden (see also Appendix 1) and thus inclusion of environmental criteria into procurement decisions could have a considerable effect on the work to reduce environmental impacts of pharmaceutical use in Swedish regions.

The 21 regions in Sweden are independent contracting authorities in procurement of pharmaceuticals for inpatient care. The regions have an established collaboration within the framework of national coordination for sustainable procurement[102]. In this collaboration, pharmaceuticals have been identified as a risk area from both a social and environmental perspective.[103] The network is a good forum for knowledge building and harmonization of requirements in the procurement of pharmaceuticals nationally.

The procurement process within the regions includes a number of steps and activities, as outlined in Figure 8 below. Environmental requirements can be integrated in all steps of the process[104].

Figure 14. Procurement process - from request to monitoring, based on Lonaeus[105],

Below we have specifically focused on the region´s work with defining and using environmental criteria in tenders, supplier evaluation and follow-up of environmental criteria as well as organisation, resources and competence in the work, as well as needs for further harmonization on different levels.

Defining and using environmental criteria in tenders

All regions are using the common Supplier Code of Conduct which are politically endorsed, and which are mandatory to use in all procurement[106]. The code includes basic environmental requirements. Specific environmental criteria are, however, voluntary to use. It is up to the contracting authority to define which requirements to include, and consequently environmental requirements currently differs between the regions.

Requirements are largely driven by regional environmental targets and programmes, and therefore the priorities for using environmental requirements also differ between the regions. This contributes to market fragmentation in Sweden and can hamper the potential for regions to

[102] Hållbar Upphandling - Ett samarbete mellan Sveriges regioner: http://www.hållbarupphandling.se/
[103] Hållbar Upphandling - Ett samarbete mellan Sveriges regioner, Läkemedel: http://xn--hllbarupphandling-8qb.se/laekemedel
[104] Lonaeus, K. (2016) *Sustainable pharmaceuticals – Public procurement as a political tool*. SIWI, Stockholm.
[105] Lonaeus, K. (2016) *Sustainable pharmaceuticals – Public procurement as a political tool*. SIWI, Stockholm.
[106] Hållbar Upphandling - Ett samarbete mellan Sveriges regioner, Hållbar upphandling: http://hållbarupphandling.se/hallbar-upphandling

encourage and push suppliers towards more environmentally sustainable supply chains. The possibility to influence suppliers is often linked to purchasing power, and naturally if tenders were coordinated or organised on a national scale the purchasing power would be greater, and consequently also the possibility to implement environmental requirements with the suppliers would be greater. In addition, analyses have showed that the centralized drug procurement in the neighbouring countries Norway and Denmark gives lower prices and higher discounts than in Sweden where the responsibility is regional. [107]

The environmental criteria that are used are, however, to a large extent harmonised between regions through the sustainability criteria developed and maintained by the National Agency for Public Procurement (see Appendix 3). Both Västra Götaland and Stockholm have experiences in applying the former version of the environmental criteria, which included environmental requirements as contract terms i.e. criteria that must be met to fulfil the contract. In these regions, environmental requirements are currently set in all procurement of pharmaceuticals. Other regions are also using environmental requirements to different extents[108]

The regions have also participated in the development of the new updated national criteria for pharmaceuticals launched in 2019. The new criteria are regarded as useful by the regions, but as they are still quite recent, there are not yet any practical experiences in applying them. Both the Västra Götaland region and the Stockholm Region are currently working on how to implement the new criteria. The new updated criteria include requirements on different levels and can be used as basis for both contract terms and award criteria.

Challenges and opportunities in defining and using environmental criteria in tenders

The regions want to be able to work more with environmental award criteria in the tendering process as a way to create incentives and stimulate improvements. Such criteria require clarity both in terms of what is required and how they are evaluated, which of course can be a challenge to achieve. It is also important that the criteria are given sufficient weight in the evaluation and the decision, to truly become an incentive for suppliers.

The regions have experienced challenges in setting feasible environmental requirements since the level of maturity in terms of environmental management varies between different suppliers. If the regions formulate too tough environmental requirements, there is a risk that no one will submit a tender, and then the region may be faced with a situation where they need buy pharmaceuticals outside contracts, without possibility to set any environmental requirements. It is a thus a challenge to make demands that are not perceived as too difficult or expensive to live up to, compared to the benefits that can be gained by having a contract.

Here, a developed and constructive dialogue with the pharmaceutical companies has been identified as an important success factor in defining relevant requirements that give companies incentives to submit tenders and provide information[109]. The Västra Götaland Region emphasizes that they have positive experiences from constructive dialogue on environmental criteria with the pharmaceutical companies in upcoming procurements, where the companies were able to produce the information requested by the contractor.

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[107] Swedish Competition Authority (2016) *Olika pris för samma läkemedel - En kartläggning av landstingens priser vid upphandlingar av rekvisitionsläkemedel*. Rapport 2016:5.
[108] Lonaeus, K. (2016) *Sustainable pharmaceuticals – Public procurement as a political tool*. SIWI, Stockholm.
[109] Ibid

A general challenge in defining and using environmental criteria is of course also to secure that all requirements related to the Public Procurement Act are met, and to handle trade-offs with other business objectives for the procurement. For example, the Act requires equal conditions on the market, where one cannot set requirements that restrict the competition so that certain suppliers benefit or are disadvantaged. Since different suppliers can have different opportunities to meet set requirements, this can be seen as a natural obstacle to competition that affects some suppliers more than others. Here, parallel import companies have been identified as a specific challenge, as such companies generally have limited insight into the supply chains of the imported products and may therefore have difficulties to respond[110]. It can also be difficult to balance and weigh the environmental requirements in relation with other requirements in the tender evaluation, such as price, quality, supply reliability, etc. Here, it is important that environmental priorities and targets are clear, and that the procurement organisation has a clear mandate.

Supplier evaluation and follow-up of environmental criteria

Evaluation and follow-up of suppliers is an important activity to secure that environmental criteria are met and to identify improvements. Follow-up of requirements in procurement contracts is a resource-intensive activity and few regions have the resources and competence to do this in a systematic way. For the requirements set out in the Code of Conduct, there is an established collaboration between regions for follow-up, where resources and information in evaluation and follow-up are shared between the regions. This saves time and money for both the regions and the suppliers. But this is not as formally and well established for environmental criteria, which is still largely done by the individual regions using the criteria, although regions try to share results where this is possible.

One region that has come a long way in establishing systematic evaluation and follow-up is Västra Götaland, where a good dialogue has been established with the suppliers. The region is responsible for pharmaceuticals within the national coordination for sustainable procurement. In 2018, follow-up was made for 55% of the region´s pharmaceutical suppliers[111]. Over the years they feel that a movement has been made by the suppliers, through their work with environmental requirements and follow-up. A few years ago, the purchasing department was asked by suppliers as to why environmental requirements were used. Today, the questions concern how the supplier is complying with, and improving on the requirements. In general, the Västra Götaland region receives positive response to its follow-ups from the suppliers. This demonstrates that setting requirements, follow-up and collaboration with suppliers really makes a difference.

When using environmental requirements in procurement, it is important to also consider and clearly define how they should be evaluated. Ideally, they should be easy to evaluate and not require too much detailed environmental expertise. Otherwise there is a risk that the requirements will not be used to the extent desired, especially in regions that have limited resources for procurement and environmental expertise. It is stressed that common models, methods and standards facilitate both for the suppliers and for those who are responsible for the procurement.

Third-party certifications or verifications, such as environmental labels or Environmental Product Declarations (EPDs), can simplify evaluation and follow-up. Such certification can be used as basis for environmental criteria in public procurement, provided that it is robust and well-established. In this case review and follow-up is made by another independent party, and thus this eases the

[110] Lonaeus, K. (2016) *Sustainable pharmaceuticals – Public procurement as a political tool.* SIWI, Stockholm.
[111] Västra Götalandsregionen (2019) *Uppföljning målområde läkemedel 2018.*

burden for follow-up of the contracting authority. Such certifications are already used in other procurement areas, such as food and IT, and the regions definitely see a potential to use similar systems for pharmaceuticals.

Organisation, resources and competence – sustainability and environmental knowledge and expertise is key

Resources and environmental competence are needed to effectively manage sustainability and environmental requirements and improvements in procurement. Environmental knowledge and expertise are needed in all parts of the procurement process; when prioritizing and defining relevant requirements, in supplier evaluation and follow-up and in driving continuous improvements.

The work with procurement is organized in different ways within the regions. Typically, there is a central procurement unit that is responsible for managing all procurement within the region. Sustainability and environmental expertise in the procurement process are, however, differently organized. In the Västra Götaland region, sustainability and environmental expertise are organized both within the procurement unit and in a central environmental team. The expertise within the procurement unit is dedicated to support procurement of certain product areas, whereas the central team supports other product areas. For pharmaceuticals, the internal competence within the procurement unit supports the procurement process. Whereas in the Stockholm region, environmental strategists and environmental expertise are organized in other organizational units but are closely collaborating with the procurement unit. Some of the members in the sustainability team are specialised and dedicated to support sustainability requirements in procurement.

In general, availability of resources and environmental competence is a major challenge for the regions and especially for smaller regions that do not have dedicated internal expertise similar to that of the larger regions. Many smaller regions do not have sufficient resources and expertise for implementing detailed environmental requirements and supplier follow up. This further highlights the need for national coordination and sharing of experiences and resources, not the least to avoid duplication of work between regions. The national coordination for sustainable procurement is an important network also for this.

Further harmonisation of environmental requirements is wanted – on national, Nordic and EU-level

There is a great desire in regions to further harmonize environmental requirements and their application nationally, but also in the Nordic countries. For pharmaceuticals, the Västra Götaland region is responsible for coordinating this within the national coordination for sustainable procurement. They also think that the work would be greatly facilitated if criteria, follow-up etc. would be harmonised on EU level, but of course this is a bigger undertaking and it is unclear who can and should take the initiative to get this in place.

There is also an established Nordic network for joint development and sharing of experiences related to sustainable procurement with contracting organizations in Norway, Denmark and Iceland, where the Västra Götaland region is responsible for representing Sweden in the network. These countries are all working on developing and implementing environmental criteria in procurement, and there is a lot to gain if criteria, follow-up etc. is harmonised and aligned on Nordic level, e.g. to share costs for development and facilitate implementation and follow-up.

In Norway, the contract authority Norwegian Hospital Procurement Trust (Norsk Sykehusinnkjøp HF), has for example recently performed a successful pilot in implementing environmental criteria

in procurement[112]. The criteria were developed in dialogue with the industry, represented by the environmental committee of the Norwegian pharmaceutical trade association LMI, where both content and follow-up were discussed to define a realistic level that also meet the legal framework for procurement. The criteria were pilot tested in a tender for antibiotics in 2019. As part of the development and pilot test the criteria were given a clear weight in the evaluation, where environmentally sound production was weighted by 30 percent as allocation criteria, thereby giving an incentive for companies responding to the tender. The authority is currently evaluating the results and planning next steps.

Guidance in product choice and use

The regions have an important role in promoting sound and sustainable use of pharmaceuticals through *guidance in product choice and use*. This can both include to secure that the "best" drug is used for medical treatment in terms of overall health, sustainability and environmental performance, and to secure that drugs are used in a way that minimise environmental impacts from use and end-of-life treatment of the product.

The work with *guidance in product choice and use* includes

- *integrating environmental considerations in the work of the medicinal products committees* when developing guidance and recommendations for healthcare professionals. The recommendation lists prepared by the committees are important tools for healthcare professionals in their work with prescribing and recommending pharmaceuticals for different medical treatments.
- *training and raising awareness among healthcare personnel* about the environmental impacts of pharmaceuticals, highlighting how they can and should contribute to reduce the impacts.

In addition, it can include specific actions for substances that have been identified as hazardous to the environment and monitoring of pharmaceutical residues in the environment.

Below, Region Stockholm has primarily been used as case to describe activities and way of working in this area, based on interviews and workshop discussions with personnel in the region.

Integrating environmental considerations in the work of the medicinal products committees

The medicinal products committees have a central role in the work with harmonizing the prescription of drugs within the regions. According to the Medicinal Products Committees Act (SFS no 1996: 1157) there should be one or more medicinal products committee in each region, consisting of representatives of pharmaceutical and medical expertise[113]. The Committee shall, through recommendations to health care personnel or in any other appropriate way, promote reliable and rational use of drugs within the region. The recommendations should be based on science and proven experience. In issues of strategic importance, the regional medicinal products

[112] Norsk Sykehusinnkjøp, New environmental criteria for the procurement of pharmaceuticals: https://sykehusinnkjop.no/nyheter/new-environmental-criteria-for-the-procurement-of-pharmaceuticals
[113] Sveriges riksdag (1996) *Lag (1996:1157) om läkemedelskommittéer.*

committees collaborate through the network for Swedish medicinal products committees (LOK - nätverket Sveriges läkemedelskommittéer)[114]

An important task for each Committee is to produce a list of recommended pharmaceuticals to be used by health care professionals in prescription of pharmaceuticals. The extent to which environmental considerations are included in the preparation of the lists in each region, vary across regions. In the same way as discussed for procurement, integrating environmental aspects into the work of the regional medicinal products committees can be a challenge due to lack of resources and dedicated environmental expertise, especially in smaller regions. Here, the national networks are important to enable sharing of knowledge and experiences between the regions.

Region Stockholm has come far in integrating environmental aspects into the preparation of their list of recommended pharmaceuticals, named "Kloka listan"[115]. In addition to medical and health-economic aspects, also the risk of negative environmental impacts is considered when choosing and recommending products. For comparable medical efficacy and safety, cost and environmental assessment should be weighed together and the most advantageous alternative recommended. This means that in the event of a slight price difference, the environmental assessment should be decisive for the recommendation. The focus of the environmental evaluation and recommendations is on what they themselves can influence, i.e. the use of pharmaceuticals. Impacts in other parts of the pharmaceutical life cycle is typically not included, primarily due to lack of information.

Basis for the environmental evaluation: the environmental database at Janusinfo

The assessment of environmental aspects in the recommendations in "Kloka listan" is based on the environmental database at Janusinfo, which has been built up as part of the environmental work, and which is also part of the collaboration with other regions[116]. Other regions use environmental information from the database insofar as environmental aspects are considered in the recommendations.

The environmental aspects that are considered and included in the environmental database at Janusinfo are environmental hazard i.e., data on persistence, bioaccumulation, and ecotoxicity include and environmental risks when the drug is used, with focus on the active pharmaceutical ingredient (API). The information in the database is based on available information which is collected and compiled from different sources, such as the environmental information presented in the EPARs at EMA's website and the environmental classification at Fass.se[117], scientific reports and articles regarding occurrences of substances in the environment including Stockholm Region´s own monitoring of pharmaceutical residues in the environment[118], as well as specific studies commissioned by the region aimed at comparing environmental impacts of medically equivalent alternatives that can be used for specific treatments.

A major challenge in the work is the lack of environmental risk information for many APIs, especially for substances that were approved before year 2006, i.e. when the EMA guidelines on ERA was published and ERA became mandatory in the product approval process (see also

[114] Janusinfo (Region Stockholm), LOK – nätverket för Sveriges läkemedelskommittéer: https://janusinfo.se/lakemedelskommitten/lok.4.6b32b8ec162bd970d6bc8.html
[115] Janusinfo (Region Stockholm), Kloka listan: http://klokalistan2.janusinfo.se/20201/
[116] Janusinfo (Region Stockholm), Läkemedel och miljö: https://www.janusinfo.se/miljo
[117] FASS, Miljöinformation i Fass: https://www.fass.se/LIF/menydokument?userType=0&menyrubrikId=11123
[118] Janusinfo (Region Stockholm), Provtagningar av läkemedelsrester i vatten, sediment och fisk för Region Stockholm: https://www.janusinfo.se/beslutsstod/lakemedelochmiljo/miljo/provtagningaravlakemedelsresterivattensedimentochfiskforregionstockholm.5.7e654e8f16641fa242e4f31.html

Appendix 2). There is an urgent need for more information to improve the environmental evaluation of substances.

It can also be difficult to compare environmental assessments for different products. For example, the environmental risk classification of substances at Fass.se is based on the total sales for a specific year, where the reported classification may pertain to different years, thereby making it difficult to compare.

List of environmentally hazardous drugs

Within the framework of Region Stockholm's environmental program 2017-2021, a list of environmentally hazardous drugs has been prepared, together with proposed concrete actions for each drug. The concrete actions were developed in collaboration with the medicinal products committee to contribute to the target in the environmental program to reduce emissions of hazardous substances. Several of the drugs on the list is included in "Kloka listan", but for those there are also concrete advice on how to work in order to reduce impacts. For several of the hazardous substances on the list, specific environmental review has been performed to identify equivalent alternatives on the "Kloka listan".[119]

Environmental training and information for healthcare personnel

The healthcare professionals are key personnel in the regions for implementing environmental considerations in product choice and use, since they in the meeting with patient prescribe and recommend pharmaceuticals for different medical treatments. In this, knowledge and awareness are of course needed about the environmental impacts of pharmaceuticals, as well as their role in contributing to reduce impacts. In general, the awareness and interest in environmental issues are increasing among healthcare professionals.

Region Stockholm perform different types of environmental training for healthcare personnel to raise awareness and knowledge about the environmental impacts of healthcare, including environmental impacts of pharmaceuticals. The sustainability department have developed a web-based training focused on pharmaceuticals and the environment. [120]

One of the unions for healthcare professionals, the Swedish Medical Association (Läkarförbundet), launched a digital brochure in 2020 to guide their members about the environmental consequences of pharmaceuticals, with practical advice on what they can do to reduce impacts. Among the advice in the brochure are; to avoid prescription where possible (and instead use other forms of treatment), make a pharmaceutical review (to identify if some drugs can be removed), start with a smaller packaging size in prescription of a new pharmaceuticals where possible (to not prescribe more drugs than will be needed), choose drugs with the lowest environmental impact when there are alternatives (based on environmental information at FASS.se, "Kloka listan" or Janusinfo), and encourage the patient to return unused drugs to the pharmacy.[121]

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[119] Janusinfo (Region Stockholm), Förteckning över miljöbelastande läkemedel med åtgärdsförslag framtagen inom ramen för Region Stockholms miljöprogram 2017–2021: https://www.janusinfo.se/download/18.5f0ead9216532d0a6a113e1f/1582279327814/Forteckning-over-miljobelastande-lakemedel.pdf

[120] Janusinfo (Region Stockholm), Lär dig mer om läkemedlens miljöpåverkan: https://www.janusinfo.se/beslutsstod/lakemedelochmiljo/miljo/lardigmeromlakemedlensmiljopaverkan.5.691fcf616219e10e93478ad.html

[121] Sveriges läkarförbund, Läkemedel och miljön: https://slf.se/publikationer/lakemedel-och-miljon/

Collaboration between regions

The regions have several national forums within the area of pharmaceuticals, for harmonisation and joint development and for sharing of knowledge and experiences. Two examples have already been mentioned above - the national coordination of sustainable procurement, and the network for Swedish medicinal products committees (LOK - nätverket Sveriges läkemedelskommittéer). The different forums are of course important also in the work to harmonise environmental management of pharmaceuticals between the regions. Since 2009, there is a network for pharmaceuticals and the environment in which all regions in Sweden participate. The network aims to increase knowledge and share information regarding all aspects related to environmental impacts of pharmaceuticals. From most regions sustainability strategists as well as pharmacists and doctors participate in this network.

Since 2018, the regions have a common system to steer knowledge (system för kunskapsstyrning) for health and medical care, with the overall aim of knowledge based, equal and resource efficient care of high quality. The system works to develop, disseminate and use the best available knowledge within health and medical care. Within the system, a national collaboration team (nationell samverkansgrupp (NSG)) has been established for pharmaceuticals and medical devices[122].

Need for environmental information and harmonisation of methods, criteria and standards

The discussions with the regions clearly confirm that there is a great need in the regions for increased availability of environmental information for pharmaceuticals to enable increased environmental considerations in both procurement and in guidance of product choice and use. The regions also acknowledge that in order to achieve increased availability of information, incentives will be needed to encourage pharmaceutical companies to share the information, for example through incentives in procurement and in the benefit subsidy system. In addition, it is perceived as a challenge that the formal regulatory framework regarding drugs and the environment is not particularly strong. Legislation can ensure a minimum level and can support requirements.

In regard to procurement, the regions emphasise that there are still significant gaps to fill regarding criteria for environmental requirements and that further knowledge build-up, development and harmonisation is needed, in dialogue and collaboration with the pharmaceutical industry. The criteria used today primarily include requirements concerning systematic way of working with environmental issues and risk management. They have experienced challenges in formulating requirements concerning environmental performance, in terms of climate impacts, emissions and risks in production. In regard to guidance in product choice and use, the regions are very much restricted to information that is publicly available.

The proposed model for environmental assessment of pharmaceuticals (see chapter 2) is perceived as a step in the right direction and a promising initiative, although they recognise that further development is needed. They see a clear need for industry standards for how to assess and report

[122] Kunskapsstyrning hälso- och sjukvård, Läkemedel och medicinteknik: http://kunskapsstyrningvard.se/programomradenochsamverkansgrupper/nationellasamverkansgruppernsg/nsglakemedelochmedicinteknik.701.html

environmental performance for pharmaceutical products, which harmonises how data collection and calculations are performed for API emissions and environmental risks and carbon footprint. This would greatly facilitate both environmental requirements in procurement and environmental evaluations in preparation of recommendations for product choice and use.

Challenges and opportunities in using product-specific environmental information

The regions see both opportunities and challenges in using product-specific environmental information delivered by the proposed model in both procurement and in the work in the medicinal products committees.

First of all, parts of the information delivered by the model is new and has not been available so far. This especially concerns the local environmental risk assessment for production and carbon footprint in a life cycle perspective. As the information is new, knowledge and experience on how to apply it needs to be developed. Possibly also the way of working may need to be changed or developed, to further integrate this into procurement and to support guidance in product choice and use. For example, how should environmental risk relating to API be evaluated in comparison with climate impacts? Here, supporting tools and guidance will be needed.

In terms of content, they emphasise that the new element in the environmental risk part of the model – evaluation of local environmental risks in production - is important. Also, they highlight that the risk assessment must include risks related to antimicrobial resistance to secure relevance, as this is a key challenge and focus for society. The carbon footprint part is also important as several regions have climate targets or are working on developing new targets, and where more knowledge is needed about the climate impacts of pharmaceuticals.

They do see some challenges in achieving comparability in results, both between different suppliers of the same API, and between different APIs that can be used for a specific treatment. They also see challenges in keeping the information up to date. This as supply chains are long and complex, and it is difficult to have detailed insights in every step of the chain. Here, also access to the underlying data for the assessment may potentially be an issue, for example in the evaluation in procurement. It has been proposed that the assessment and underlying data should be verified by an independent third party, and that not all background information will be available for the end-user. In this case, it will be important to agree what background information should be made available together with the assessment result, to enable correct interpretation and use.

In terms of applying the model in procurement they, for example, think that it might be difficult for all companies to report this type of information, and therefore a first step could be to start demanding it, and award the suppliers that report. This would help build up knowledge and practical experience both within the regions and the industry. The acquired knowledge can then be used in the next step e.g. to start making more detailed requirements on environmental performance levels. With the current lack of knowledge, it is virtually impossible for a contracting authority to make such requirements. What is a good or reasonable level of climate footprint for a pharmaceutical product? What is an acceptable emission level and risk for API?

Also, they see an opportunity to use a more "risk-based approach" to setting environmental criteria and use more specific requirements and measures for different types of pharmaceuticals, that focuses on the main challenges for the specific substance or category to be procured or evaluated. That is, prioritise requirements and guidance based on environmental significance, and focus efforts where it matters the most. But again, to be able to make such assessments and prioritisation, more detailed knowledge and information is needed about the environmental impacts.

Appendix 5. Pharmacies

The description is partly based on discussions at workshops and meetings with representatives from pharmacies and the Swedish Pharmacy Association, combined with literature review and analysis.

The Swedish pharmacy market consists of five major chains, three purely e-commerce players and around forty individually operated pharmacies. In total, there are more than 1,400 outpatient pharmacies, ten distance or internet pharmacies and 36 hospital pharmacies that provide medical care to inpatients[123]. The basic responsibility for pharmacies is to promote good and safe pharmaceutical use by:

- ensuring that the consumer has access to prescribed drugs and goods
- providing specialist and individually adapted information and advice on medicines
- implementing and informing about the generic substitution of drugs when there are cheaper alternatives

The majority of pharmaceuticals are distributed at pharmacies, and thus the personnel at pharmacies have an important role in the dialogue with the consumers to guide and inform about all aspects of pharmaceutical use.

In terms of environmental responsibility for pharmaceuticals, the pharmacies have a role in promoting sound and sustainable use of pharmaceuticals by informing and guiding consumers in *product choice and use*. This can both include advice on choosing the environmentally preferable option among alternatives, as well as advice on how to use and handle the drug to minimise environmental impacts from use and end-of-life treatment of the product. As part of this, the pharmacies have a general role in *raising consumer awareness* about environmental aspects. Also, the pharmacies can promote environmentally sound pharmaceutical supply chains by using and implementing environmental requirements in *procurement*. In addition, the pharmacies have a role in *reducing pharmaceutical waste*, e.g. by advice on packaging size, selling doses instead of packages, as well as receive and handle unused drugs from consumers.

Depending on the type of pharmaceutical; prescription drugs within the benefit system or OTC (over the counter) drugs; the pharmacies do, however, have different possibilities to influence the environmental impacts along the value chain.

Environmental management in pharmacies are in general governed by company specific sustainability strategies, targets and programs, usually decided by the company management team and/or board. The scope and ambition level consequently vary between different pharmacies. Most pharmacy chains have developed and implemented sustainability programs, with targets and strategies related to environmental aspects of pharmaceuticals.

The pharmacies are experiencing increasing interest and demands from consumers regarding sustainability and environmental aspects. The consumers also have confidence in the sustainability work of pharmacies. For example, two pharmacy chains (Apoteket AB and Apotek Hjärtat) are among the top 20 companies in the yearly Sustainability Brand Index that ranks brands on

[123] Sveriges Apoteksförening, Om apoteksbranschen: http://www.sverigesapoteksforening.se/om-apoteksbranschen/

sustainability [124]. The index is based on research among Swedish consumers and shows how brands are perceived within environmental and social responsibility.

Pharmaceuticals within the benefit subsidy system

Pharmacies are obliged to provide all prescribed medicines and all products covered by the benefit subsidy system. For all pharmaceuticals within the generic substitution part of the benefit subsidy system, the pharmacies are obligated to make changes when there are equivalent medicines at lower prices, so-called generic medicines, to keep the costs down for the citizens (see also Appendix 2 and Appendix 3).[125]

Due to the regulations of the benefit system, the pharmacies have very limited possibilities to influence the environmental impacts in the production and supply chain of prescription drugs, or to influence which prescription products should be included in the assortment. Instead, the focus is on advice to as far as possible ensure use and handling of the drug that benefits both the individual and the environment.

The Swedish Pharmacy Association and several pharmacy chains are actively promoting that environmental considerations should be included as one of the criteria for TLV in choosing pharmaceuticals within the benefit system. The pharmacies could have a central role in this as they, in the meeting with the consumers, can inform and guide consumers in selecting the environmentally preferable option among the alternatives in, for example, the generic substitution.

OTC (Over the counter) pharmaceuticals

The pharmacies do, however, have possibility to influence environmental aspects for the OTC (over the counter) part of their assortments. To guide the customers in choosing environmentally sound products, Apotek Hjärtat was the first pharmacy chain to develop a product label "Choose with the heart".[126] The label is based on their own set of criteria and includes a supplier evaluation, rather than a product specific evaluation. The pharmaceutical suppliers have the possibility to label their products when they fulfil all of the following requirements: a third party verified sustainability report equivalent to the GRI (Global Reporting Initiative) standard, a membership in PSCI (Pharmaceutical Supply Chain Initiative), and the products does not include specific pollutants according to Swedish regulation for water quality (Swedish Agency for Marine and Water Management, HVMFS 2013:19).

The label has now been transferred to the Swedish Pharmacy Association, as a basis for a common product label to be used by all pharmacies, thereby harmonizing such labelling within Sweden[127]. A task force consisting of the pharmacy chains Apotek Hjärtat, Apoteket AB, Kronans Apotek are collaborating with the Swedish Pharmacy Association in the development of this common label. The aim was to launch the label named "Choose sustainable" in mid-2020, but due to the Covid-19 pandemic, it has been postponed to later in 2020.

[124] Sustainable Brand Index, Result 2020: https://www.sb-index.com/sweden
[125] Sveriges Apoteksförening (2019) *Branschrapport 2019.*
[126] Apotek Hjärtat, Välj med Hjärtat: https://www.apotekhjartat.se/om-oss/valj-med-hjartat/
[127] Aktuell Hållbarhet 2019, Apotek Hjärtat överlämnar miljömärkning till hela branschen: https://www.aktuellhallbarhet.se/miljo/klimat/apotek-hjartat-overlamnar-miljomarkning-till-hela-branschen/

Sustainable procurement and promoting improved environmental legislation for manufacturing

Several pharmacies are working with sustainable procurement to contribute to environmental protection and improved labour conditions in their supply chains, where they have established their own code of conducts, follow-up, etc. They have, however, experienced difficulties in implementing this in the prescription category. As discussed above, the pharmacies have limited possibility to influence this category due to the regulations in the benefit subsidy system.

The Swedish Pharmacy Association also calls for improved environmental legislation for manufacturing of pharmaceuticals. They have proposed that environmental aspects should be included in the international regulation for good manufacturing practice for pharmaceutical production (GMP), as a way to regulate environmental impacts from production[128].

Managing and reducing pharmaceutical waste

To avoid that pharmaceutical residues are spread due to improper waste management, all Swedish out-patient pharmacies receive leftover drugs from the public. The waste is sent for incineration in special approved facilities. The amount of leftover drugs is considerable. In 2018, all Swedish pharmacies collected over 1,400 tonnes of drug residues in total.[129]

To reduce this waste, the Swedish Pharmacy Association are promoting that the pharmaceutical industry should provide smaller packaging sizes, and that the prescribers adapt the packaging size in the prescription to the actual intended use. Large quantities of drugs are discarded because of the fact that too large packaging sizes are prescribed, that is never used[130].

Raising consumer awareness and opinion

The pharmacy chains are also actively working with different campaigns to raise consumer awareness, for example about the importance of returning leftover drugs to the pharmacy instead of flushing it down the toilet or throw it in the municipal waste.

To raise awareness and form opinion about manufacturing and procurement of pharmaceuticals, Apotek Hjärtat launched the campaign "A Hard Pill to Swallow" in 2019[131]. The campaign is based on analysis of pharmaceutical residues in water performed by RISE (Research Institutes of Sweden), where the campaign states the following about the result: "In Hyderabad, India, a place where many of Sweden's medical drugs are manufactured, the water contains enough drug residues that we could actually extract it. The result was Sordidum Pharmacum - a medicine few would take voluntarily." The campaign has received a lot of media attention and has also received several awards[132].

Need for product-specific environmental information

In order to fulfil the responsibility to guide and inform consumers about medicines, relevant and accessible knowledge and information is naturally required. The pharmacies possibility to fulfil this responsibility is, however, hampered by the lack of transparency in the pharmaceutical supply chain and the lack of information about environmental consequences of pharmaceuticals. They notice that that consumers are asking more and more questions about the environmental impacts

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[128] Sveriges Apoteksförening, Läkemedel och miljö: http://www.sverigesapoteksforening.se/lakemedel-och-miljo/
[129] Sveriges Apoteksförening (2019) *Branschrapport 2019.*
[130] Sveriges Apoteksförening (2019) *Branschrapport 2019.*
[131] Apotek Hjärtat, A Hard Pill to Swallow: https://hardpilltoswallow.se/en/
[132] Resume, Ytterligare guldägg till "A hard pill to swallow" – vinner i PR: https://www.resume.se/kommunikation/tavling/ytterligare-guldagg-till-a-hard-pill-to-swallow-vinner-i-pr/

of products and that consumer environmental awareness, knowledge and expectations is increasing.

The pharmacies have taken steps to require environmental information from pharmaceutical companies but have had difficulties in accessing information. Also, there is a knowledge gap in what kind of information can and should be requested.

Thus, the pharmacies see a great need for methods and standards for reporting product-specific environmental information and think that there is a lot to gain if they can be shared between different actors, as this can contribute to increased availability of information. Such standards can support and strengthen their initiative for product labelling for OTC products by enabling more detailed requirements as well as lead the way for integrating environmental considerations in the benefit subsidy system.

Appendix 6. Pharmaceutical companies and supply chains

The description is based on interviews and workshop discussions with representatives from pharmaceutical companies (AstraZeneca, Bayer and Pfizer) and the industry association LIF, combined with literature review and analysis.

The pharmaceutical companies and their supply chains have a central role in the pharmaceutical value chain, as they are responsible for development, manufacturing, marketing and sales of pharmaceuticals. The supply chains for pharmaceutical products are often long and complex, located in different parts of the world.

Pharmaceutical companies can be divided into three main types:

- *Research-based pharmaceutical companies* are companies that develop, produce and market original patented drugs under a brand name.
- *Generic pharmaceutical companies* produce and market copies of drugs for which the patent has expired.
- *Parallel importers* are companies that buy drugs in countries where the price is low, in order to repackage and resell them where the price is higher.

In practice the distinction into these types is not as clear-cut. For example, research-based companies can also produce and sell generic substitutions and some generic companies develop and produce original drugs.

The supply chains of pharmaceutical companies consist of:

- *API subcontractors* i.e. companies producing active pharmaceutical ingredients (API)
- *Other raw material and packaging suppliers* i.e. companies producing raw materials (other than API) which is needed in the production of API and the formulation of products, as well as companies producing packaging materials.

Environmental responsibilities of the pharmaceutical industry cover the entire value chain, from selection and sourcing of raw materials, development of substances, manufacturing, distribution, to the use and end-of-life of the products. This includes overall *product and process improvements*, by promoting environmentally sustainable production and use of products in a life cycle perspective. The responsibility also includes stakeholder engagement, where *environmental reporting and communication to different stakeholders* is an important part to report and communicate environmental performance, activities and progress. The information can be used by the stakeholders as basis for taking informed decisions within their frame of their responsibility, e.g. in procurement, product choice, or financial investments.

Environmental management in pharmaceutical companies and supply chains are in general governed by company specific sustainability strategies, targets and programs, usually decided by the company management team and/or board, as well as by efforts to secure legal compliance in countries of operations. Many pharmaceutical companies have well established sustainability programs that includes the whole chain, with ambitions and targets relating to, for example, API emissions and risk and climate impacts covering products, manufacturing and supply chain. However, the level of maturity and ambitions for the sustainability and environmental work varies

between different pharmaceutical companies. This is partly due to differences in driving forces for working with sustainability, and probably also partly due to differences in resources for the work depending on the market situation in which the company operates. For example, generic drug suppliers operate on a very cost-conscious market, which implies that their operations also need to be very cost-conscious and streamlined in order to be competitive, which in turn can be difficult to combine with an ambitious sustainability agenda.

Among the driving forces and reasons as to why pharmaceutical companies are working strategically and operationally with sustainability are; to protect and strengthen brand and competitiveness, requirements and demands from investors and other stakeholders, to attract and keep employees, manage and reduce risks, and to take responsibility for the company´s sustainability impacts based on corporate visions and policies.

According to the companies, sustainability is increasingly becoming a requirement to attract both investors and talent. Requirements from customers are, however, not on the same level, even though they can see a slight increase, especially in the Nordic countries. In general, clear customer expectations and requirements is an important driving force for companies in advancing their sustainability efforts, as has been demonstrated in other sectors such as in the retail and fashion industry. The pharmaceutical companies highlight that their customers (regions, pharmacies and benefit subsidy system) have an important role to play in creating a demand and a willingness to pay for environmentally sound products and processes.

In the following subsections we have focused on the pharmaceutical companies work with *product and process improvements, both internal and in collaboration with partners* including with suppliers, as well as work with *environmental reporting and communication to different stakeholders* including for product approval and procurement tenders.

Product and process improvements – internal and in collaboration with partners

As mentioned, the pharmaceutical industry´s efforts to manage, control and reduce environmental impacts of products and processes usually covers the entire value chain. Based on this, the companies work with *product and process improvements* can in general be divided into three main parts:

- *Product development and innovation;* focusing on improving the overall environmental performance of products – from resource extraction to end-of-life, including performance in use and end-of-life treatment of the product. This can, for example, include integrating environmental assessments in different stages of the product development work to early identify and mitigate environmental risks in different parts of the life cycle.
- *Process and production development;* focusing on improving the environmental performance of own operations and manufacturing. This can, for example include technology development, improving emission control, as well as considerations of where to localize production sites. Improvements for products and manufacturing processes are, however, often very much dependent on each other, as the process used to produce the product often also influence the design of the product or substance.

- *Procurement and supply chain management;* focusing on improving the environmental performance in supply chain, in production of raw materials by suppliers and sub-suppliers. This can, for example, include integrating environmental requirements and follow-up in different parts of the procurement process, such as in evaluation and choice of supplier, in contracts, and in continuous supplier improvements.

Work with environmental improvements of products and processes is driven both by efforts to secure legal compliance in countries of operations, and by own proactive environmental ambitions and targets that goes beyond legal compliance. For example, some multi-national companies have set their own minimum environmental standards that apply to all locations, that are in line with or go beyond local environmental legislation in locations of manufacturing.

Some companies highlight that the environmental legislation for pharmaceuticals is weak and should be improved. The industry associations in Sweden for both research-based pharmaceutical companies (LIF) and generic pharmaceuticals and biosimilars (FGL) support tougher environmental legislation for pharmaceutical manufacturing, but their opinions on how this may be implemented differ. LIF propose to utilize existing environmental legislation in the Industrial Emissions Directive within EU, and similar regulations in other jurisdictions across the globe, combined with improved environmental requirements and follow-up in public procurement and other financial instruments[133], whereas FGL propose to integrate environmental aspects into Good Manufacturing Practice (GMP)[134].

Company environmental targets and programs are usually set on corporate or group level and are then broken down on different levels within the company, in business units and functions such as research & development, sourcing, operations and marketing & sales. Thus, the work requires internal collaboration between different functions and business units within the company. Many pharmaceutical companies have intensified their environmental work and are setting increasingly ambitious environmental targets. For example, AstraZeneca, Bayer and Pfizer have all committed to the Science Based Targets initiative[135], Bayer aims to achieve carbon-neutral production by 2030[136] and AstraZeneca has recently launched their "Ambition Zero Carbon" strategy to eliminate emissions by 2025 and be carbon negative across the entire value chain by 2030[137].

Voluntary industry collaboration with partners

A value chain perspective in sustainability and environmental work requires collaboration with different partners along the chain, such as suppliers and sub-suppliers, customers and industry peers. The work and collaboration with partners are very much facilitated by common methods and standards for e.g. collecting and sharing environmental information. The industry association EFPIA (European Federation of Pharmaceutical Industries and Associations) are promoting increased collaboration and partnerships with society across industry to build a healthier and more environmentally sustainable future[138].

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[133] LIF, Läkemedel och miljö: https://www.lif.se/fragor-vi-arbetar-med/ovriga/lakemedel-och-miljo/
[134] FGL - ställningstaganden, Miljökonsekvenser vid läkemedelstillverkning: https://www.generikaforeningen.se/wp-content/uploads/2014/02/Miljokonsekvenser-vid-lakemedelstillverkning.pdf
[135] Science Based Targets initiative: https://sciencebasedtargets.org/
[136] Bayer, Climate Protection: https://www.bayer.com/en/sustainability/climate-protection
[137] AstraZeneca, Ambition Zero Carbon: https://www.astrazeneca.com/media-centre/press-releases/2020/astrazenecas-ambition-zero-carbon-strategy-to-eliminate-emissions-by-2025-and-be-carbon-negative-across-the-entire-value-chain-by-2030-22012020.html
[138] EFPIA, Environment, Health, Safety and Sustainability: https://www.efpia.eu/about-medicines/development-of-medicines/regulations-safety-supply/environment-health-safety-and-sustainability/

The pharmaceutical industry has started several voluntary initiatives to address specific joint challenges and drive collective change and sustainability improvements. Such initiatives are key for both knowledge building and for development of industry standards. Two important examples are the Pharmaceutical Supply Chain Initiative (PSCI) focused on "building responsible supply chains together" and the AMR Industry Alliance focused on "uniting to act on antimicrobial resistance". These two initiatives are briefly described below. In addition, there are several voluntary initiatives focused on capacity building. For example, as part of IMI (Innovative Medicines Initiative), the CHEM21 online learning platform has been created to promote the uptake of green and sustainable methodologies in the synthesis of pharmaceuticals[139].

The *Pharmaceutical Supply Chain Initiative* (PSCI) is aimed to develop and harmonise sustainability practices and standards in the supply chain. It was formed in 2006 and is a non-profit business membership organization whose vision is to "establish and promote responsible practices that will continuously improve social, health, safety and environmentally sustainable outcomes for our supply chains"[140]. The initiative is open to open to all companies operating in the pharmaceutical or healthcare industries and has currently 44 members. As part of the initiative, *Pharmaceutical Industry Principles for Responsible Supply Chain Management* have been defined that "articulate what the industry expects from the supply chain"[141]. The PSCI Principles addresses ethics, human rights and labour, health and safety, environment and management systems. In addition, PSCI provides guidance for implementation of the principles for both members and suppliers, which includes programs for collaboration on supplier auditing and supplier capacity building. A key priority area in the initiative is "environmental sustainability and efficiency of resources" with focus on water use and management, waste management, pharmaceuticals in the environment, anti-microbial resistance and energy use and carbon footprint.[142]

The *AMR Industry Alliance* was launched in 2017 and is aimed to provide sustainable solutions to curb antimicrobial resistance, where over 100 biotech, diagnostics, generics and research-based pharmaceutical companies and associations are joining forces. The signatories agree to collectively deliver on the specific commitments made in the AMR Industry Declaration and the Industry Roadmap for Progress on Combating Antimicrobial Resistance, and to measure progress made in the fight against AMR[143]. The Roadmap includes a broad set of actions, including stakeholder collaboration, research & development, manufacturing and environmental consideration, appropriate use and access to treatment. Information and knowledge sharing are central elements in the initiative, where it is stated that *"We break down the traditional silos across the life-science industry and share information to increase accountability and facilitate progress."*[144]

[139] CHEM21: http://learning.chem21.eu/
[140] Pharmaceutical Supply Chain Initiative, About us: https://pscinitiative.org/about
[141] Pharmaceutical Supply Chain Initiative, Principles: https://pscinitiative.org/principles
[142] Pharmaceutical Supply Chain Initiative, About us: https://pscinitiative.org/about
[143] AMR Industry Alliance, The AMR Alliance´s commitments: https://www.amrindustryalliance.org/shared-goals/
[144] AMR Industry Alliance, How we work: https://www.amrindustryalliance.org/how-we-work/

Environmental reporting and communication to different stakeholders

Pharmaceutical companies compile, report and communicate different types of environmental information to several different stakeholders, such as customers (including Swedish regions and pharmacies), authorities (on EU level, national or local), investors and owners, employees, etc. Basically, the following main types of reporting and communication can be identified:

- *Regulatory reporting*, including environmental risk assessment (ERA) in the product approval process as part of the market authorisation, and other environmental reporting to authorities as part of, for example, local environmental permits
- *Corporate sustainability reporting*, for example in accordance with Global Reporting Initiative (GRI)[145], and in different reporting systems such as CDP[146], Dow Jones Sustainability Index[147], etc.
- *Communication with customers*, for example information in public procurement tenders, information to pharmacies, etc.
- *Communication with other business partners*, for example with suppliers
- *Other voluntary communication*, for example providing information for the environmental classification at FASS.se, commitments and progress in joint initiatives such as the AMR Industry Alliance, etc.

The information is used by stakeholders in e.g. assessment in conjunction with product approval, procurement, to guide product choice and use, as well as in investment decisions. Thus, companies need to collect, manage and compile environmental data and information in different ways and formats, based on different stakeholder requirements.

Below we have focused the description on *communication with customers, including responding to procurement tenders* as well as efforts to *collect and compile product-specific environmental information.* Also, needs for *further development and harmonization* is highlighted.

Communication with customers, including responding to procurement tenders

As mentioned above, customer requirements regarding sustainability and environmental issues are still fairly limited, and there is no competition in regard to sustainability. The pharmaceutical companies in general think that business incentives are lacking to share specific environmental information. If the companies are required to provide more information, then there should also be a business value to disclose it. For example, in public procurement there should be a clear added value that reward companies that disclose information. Here also the benefit subsidy system (see Appendix 2 and Appendix 3) as well as the pharmacies´ initiative to develop a product label "choose sustainable" for OTC products (see Appendix 5) are highlighted as key applications that have a clear potential to provide business incentives. It is now important to take this discussion to the next level.

The companies are noticing an increased demand for environmental information and data in public procurement tenders. Several regions want to use this type of requirements. However, the

[145] Global Reporting Initiative: https://www.globalreporting.org/Pages/default.aspx
[146] CDP: https://www.cdp.net/en
[147] S&P Dow Jones Indices: https://www.spglobal.com/spdji/en/indices/equity/dow-jones-sustainability-world-index/#overview

general picture in the Swedish market is that it is still the lowest price that apply. So far, the environmental requirements have exclusively been about contract terms, which does not provide specific incentives or premium in the tender evaluation. The companies highlight the recent pilot test performed by the Norwegian procurement authority the Norwegian Hospital Procurement Trust (Norsk Sykehusinnkjøp HF) as an interesting case, where the environmental criteria were given a clear weight in the evaluation, thereby providing an incentive (see also Appendix 4). The pilot has received attention within the companies, as it is perceived that this is the first time that environmental performance has been an integral factor in the award decision. They hope that the new sustainability criteria developed by the National Procurement Agency, which enables use of award criteria (see also Appendix 3), will be used in a similar way to create incentives also in Sweden.

To have real environmental effects, however, the companies stress the importance of using criteria that are relevant and significant from an environmental perspective for the specific product to be procured. In some procurement tenders, the environmental relevance of some requirements has not always been clearly specified. Here of course dialogue and knowledge sharing between the procurement authorities and the industry play an important part.

A general question when responding to procurement tenders is also what information can be disclosed and what cannot be disclosed to business partners. For example, detailed information about the supply chain is normally confidential information. Today, it is perceived that it could be a business risk to share information, especially if you are the only one sharing - ”There is little to gain, but potentially a lot to lose”.

It can also be a challenge for Swedish and Nordic marketing and sales companies to collect and report environmental information in tenders, even if it available within the group. Many pharmaceutical companies are global, where operations, product development and marketing and sales are located in different parts of the world. Usually several different functions and business units within the company is involved in collecting and producing environmental information for products and processes. Due to this, it may be difficult for the market and sales companies in the Swedish and Nordic markets to obtain detailed environmental information, as they often do not have direct access to the information but must go to the right unit or person within the group. Thus, it requires personal relationships and networks with key individuals within the group that can support in collecting and compiling information.

The Nordic countries are generally considered to be ahead of the rest of Europe and internationally concerning environmental requirements, and the companies are keeping watch on what happens on these markets. However, this also to some extent means that some market and sales companies in Sweden and Nordic countries sometimes need to “fight” with their own head office to meet the requirements. It can be a resource-consuming task to compile the documentation required to submit a procurement tender. It is then important to be able to present a strong business case to get the support of the global company. As Sweden is a small market, there generally need to be some added business value in order to motivate the additional work of producing information, when this is not easily available.

Thus, market incentives are strongly needed. For global companies operating on many markets, it is also difficult to handle specific requirements from individual regions or markets. The work would be greatly facilitated if requirements are harmonised, between the regions on the Swedish market and between Nordic or Baltic countries. Ideally, they should be harmonised on EU or international level.

Collecting and compiling product-specific environmental information – a resource demanding and complex task

Pharmaceutical companies collect and compile detailed environmental information for both their processes and products. The information is used both for internal follow-up and improvements and in external environmental reporting and communication, such as reporting to authorities, business partners, sustainability reports, etc.

However, detailed environmental data on product level is often a challenge both in terms of availability of data and methods. This is therefore done to varying degrees by different companies, where also ambitions can vary between different products e.g. depending on the strategic importance of the product. Some of the challenges and opportunities in collecting and compiling data for environmental risks relating to emissions of API from production and carbon footprint in a life cycle perspective is further elaborated in the report describing the proposed model[148]. Most companies collect quantitative environmental data from their production sites, and some also collect such information from their suppliers. Thus, data can be available on production site level. But it is often a challenge to allocate data on production site level to the individual products produced within the same site to assess the environmental risk related to emissions of API or climate impact for a specific product.

It should be recognised that collecting, compiling and reporting environmental information on product level for an entire product portfolio is a resource demanding and complex undertaking, especially in global companies with complex supply chains. It is also a challenge to keep the data up to date, due to e.g. changes in production, suppliers, etc. For most companies this will require investments. This can include development and changes in information systems and ways of working, in terms of organisation, roles and responsibilities, methods and routines.

It will also require new or changed ways of working with the supply chain, since product-specific environmental information requires data from suppliers of APIs or other relevant raw materials. Data collection in the supply chain is a specific challenge as data may be required not only from the 1st tier supplier, but also further upstream in the chain. Here, for example confidentiality and verification of data are key difficulties that must be addressed. Data collection in the supply chain would, however, greatly benefit from shared requirements and standards, as this will ease the burden of reporting also for suppliers to the pharmaceutical companies, in the same was as shared requirements in procurement tenders facilitate for pharmaceutical companies.

Thus, for individual companies, investments will be needed to deliver product-specific environmental information. For companies that already have such systems and routines in place, they still may need to be adapted or changed in order to achieve comparability in results with other suppliers. Again, it is stressed that there need to be clear business incentives to make such investments.

Need for further development and harmonization of requirements, standards and methods

The companies stress that common standards and requirements facilitate the ability to produce and report information to various stakeholders. Such standards would in general facilitate collaboration along the value chain, both upstream with suppliers and sub-suppliers, and

[148] Pålsson AC., Belleza E., Ryding SO., Örtlund L., Westberg E. (2019) *Environmental assessment model for pharmaceutical products – Environmental risks related to Active Pharmaceutical Ingredients (API) and carbon footprint in a life cycle perspective*. Report B2352, IVL Swedish Environmental Research Institute.

downstream with customers. Such standards would also make it easier for companies to motivate investments, as they can be focused on one way of compiling and reporting information, rather than several which is the case when different stakeholders are requiring the information to be compiled and reported in different ways. As many companies are global, the standards should ideally be international, and for example be developed and maintained within ISO.

There is also a need for further method development. Regarding environmental risk assessment, limitations in existing methods are highlighted. A substantial number of methods and models for risk assessment are available, but important risks are not satisfactory captured. For example, existing models do not take mixture effects, or hormonal effects into account. The deficiencies in standardized and reliable methods are highlighted as an important reason why legislation and regulations regarding drugs and the environment are relatively weak. Regarding climate impact, there are no harmonized standards for how this should be calculated on product level (i.e. product category rules). As several of the companies are currently taking their climate ambitions to the next level, this is an important area for development.

The development of standards and methods must also include how the information should be communicated and used. To be useful in e.g. procurement, the information should be clear and easy to understand, and here of course the level of environmental expertise of the intended users need to be considered.

A key question is which player(s) should invest in the development of such standards and methods. So far, the pharmaceutical industry has driven much of the development, but it is important that also intended users of the information are engaged and contribute in development. This as development should start from actual information needs, to secure that it meets their needs and requirements. Shared development can also secure buy-in and commitment by different stakeholders to also apply the standards and methods, once they are finalised.

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