Procurement of pharmaceuticals in an environmental context and its inclusion into the CSR Compass

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A study within the UN 10YFP SPP Programme on Promoting Supply Chain´s Sustainability

Order
Phone: +46 (0)8-505 933 40
Fax: +46 (0)8-505 933 99
E-mail: natur@cm.se
Address: CM Gruppen AB, Box 110 93, 161 11 Bromma
Internet: www.naturvardsverket.se/publikationer

The Swedish Environmental Protection Agency
Phone: + 46 (0)10-698 10 00 Fax: + 46 (0)10-698 10 99
E-mail: registrator@naturvardsverket.se
Address: Naturvårdsverket, 106 48 Stockholm, Sweden
Internet: www.naturvardsverket.se

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Preface

Sustainable Public Procurement (SPP) is a key area in the work to promote Sustainable Consumption and Production (SCP) in line with UN´s 10-year Framework Programme (10YFP). It is also a key area reaching the Swedish Environmental Goals including a generation goal, 16 environmental quality goals and 24 staged goals.

The public sector is responsible for working with SPP to promote Sustainable Consumption and Production. The Swedish EPA has produced this report with the objective to describe where, from a pharmaceuticals life cycle perspective (research, production, use), it may be appropriate to impose environmental requirements; based on a procurers' perspective.

The pharmaceutical industry was chosen as the sector to review due its complexity. In order to identify different types of obstacles for procurers in their daily work the supply chain and the entire life cycle of a product must be considered.

Another main objective with this project is to suggest amendments to the CSR (Corporate Social Responsibility) Compass based on the experiences gained from the pharmaceutical industry.

The project was carried out by IVL (Swedish Environmental Research Institute) on commission of the Swedish Environmental Protection Agency. The project was coordinated by a steering group and a reference group. We would like to thank all the participants for their contribution with expert knowledge in this area.

Stockholm 2016

Swedish Environmental Protection Agency

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Summary

This project is meant to be a follow-up to the experiences gained in the pre-study on Greening Supply Chains as an attempt to make a "Market Readiness Analysis" regarding potentials for Sustainable Public Procurement (SPP). As the pre-study was carried out mainly as a literature review, this project will focus on experiences from case studies based on practical work. The pharmaceutical industry was chosen as the sector to review due to the complexity of procurement of pharmaceuticals and in order to identify different types of obstacles for procurers in their daily work.

The project includes different sub-studies with the specific objectives to:

- Understand the current knowledge of procurement of pharmaceuticals in the literature
- Review the use of public procurement in Sweden
- Understand the implications of public procurement applied to case studies

Another main objective with this project is to suggest amendments to the CSR (Corporate Social Responsibility) Compass, which now focuses on the social dimension, with relevant information taking also into account the environmental dimension. By adding the environmental dimension into the CSR Compass it will cover a much broader context in line with the definition of sustainability. Hence, the combined approach including both the social and the environmental dimension might very well lead the final achievement of a Sustainability Compass.

Environmental information is sparsely involved in current practices when procuring pharmaceuticals. One important reason is that the primary focus when evaluating risks and benefits with pharmaceuticals are linked to human health aspects and not impacts on the environment. Another equally important reason is the multiple obstacles for going public with environmental information linked to the manufacturing and use of pharmaceuticals following the market-induced secrecy necessary for original pharmaceutical producers to maintain their competitive edge as well as strict rules to adhere to with regard to "green" claims.

However, there exist some future possibilities to broaden the use of environmental information in public procurement. These possibilities include the following areas:

- Developing a more structured overview of what the market can offer and the environmental work at potential suppliers through the Market Analysis
- Make use of Life Cycle Assessments (LCA) and Environmental Product Declarations (EPD) to facilitate the identification of products with superior environmental performance
- Stimulate the provision of more traditional product-related environmental information to be publicly available in www.Fass.se

- Start to routinely request environmental information from manufacturing and packaging as a part of an Environmental Management Systems in contract clauses
- Secure sufficient resources to carry-out follow-up activities to get a better control of deliverables according to contracts and to secure continuous improvements by suppliers and sub-suppliers
- Enhance the cooperation and the dialog between different actors/ target groups along the value chain

Any attempt to make better use of environmental information in public procurement has most likely a better chance to be operational and used in practice if they are related to legislation or to widely recognized management systems on a global scale, e.g. via the new EU directive for public procurement or ISO 14001.

1. Introduction

Sustainable Public Procurement (SPP) is a key area in the work to promote Sustainable Consumption and Production (SCP) in line with UN´s 10-year Framework Programme (10YFP). Within the realization of the 10YFP, the programme on SPP has been separated into different parts in which one of them specifically addresses "Greening Supply Chains", where the activities have started with a pre-study.

This project is meant to be a follow-up to the experiences gained in the pre-study as an attempt to make a "Market Readiness Analysis" regarding potentials for SPP to work with supply chain aspects. As the pre-study was carried out mainly as a literature review, this project will focus on experiences from case studies based on practical work. The pharmaceutical industry was chosen as the sector to review due to the complexity of procurement of pharmaceuticals and in order to identify different types of obstacles for procurers in their daily work.

Manufacturing and selling of pharmaceuticals is strictly regulated. The pharmaceutical sector encompasses a number of inherent problems from a procurement point of view. This includes long supply chains starting in developing countries, specific legislation with regard to procurement and lack of transparency and access of information due to the marketing and proprietary nature of pharmaceuticals.

One of the key prerequisites for sustainable procurement of pharmaceuticals is to understand the way supply chains operates to enable risk assessments to be carried out prior to a specific procurement to allow for tenders to specify relevant requirements. The lack of transparency and the high degree of complexity in the pharmaceutical sector may jeopardize proper risk assessments to be carried out. Elucidation of the requirements, including details about the rationale of the requirements and where in the supply chain specific requirements have to be fulfilled, are usually requested for from bidders. However, this puts demands on the pharmaceutical industry to provide more transparent information about its supply chains and its production processes.

One main objective with this project is to contribute to the understanding of the possibilities and obstacles to set relevant and far-reaching sustainable criteria in public procurement of pharmaceuticals. The project includes different sub-studies with the specific objectives to:

- Understand the current knowledge of procurement of pharmaceuticals in the literature
- Review the use of public procurement in Sweden
- Understand the implications of public procurement applied to case studies

Another main objective with this project is to suggest amendments to the CSR (Corporate Social Responsibility) Compass based on the experiences from the studies of procurement of pharmaceuticals as input to allow for development of the CSR Compass to encompass more Sustainability aspects, i.e. a Sustainability Compass.

As a guide to readers this report consists of the following parts:

- Chapter 1 and 2: An introduction and background to the subject of public procurement of pharmaceuticals and how it is linked to UNEP´s work with the 10-year program for Sustainable Construction and Production (10YFP) and its dedicated work with Sustainable Public Procurement (SPP)
- Chapter 3: The project outline, its coordination and a description what is included in the various Annexes
- Chapter 4: The specific market- and legislative situations for the pharmaceutical sector with regard to public procurement
- Chapter 5: A description on possible criteria's that can be used in public procurement
- Chapter 6: A presentation of the CSR Compass – the initiatives taken by the Nordic Ministry of Councils and the intent of making this tool publicly available
- Chapter 7: The current status on procurement of pharmaceuticals in Sweden
- Chapter 8: The life cycle of pharmaceuticals with special focus on the different actors involved in the activities in connection to public procurement
- Chapter 9: Activities carried out by procurement authorities including future possibilities

2. Background

Globalization in the business sector has resulted in a dramatic growth of the cross border movement of commodities and goods. Consequently, we now see an increase in the complexity of supply chains, with input of commodities, components and products from a variety of countries where different social and economic regulatory frameworks are at hand. This lack of a common playfield regarding important aspects of sustainability creates a need for transparency and new approaches of sustainability work throughout the supply chains.
Sustainable products should promote an efficient management of resources through the whole life cycle and in all stages of the supply chain of goods and services. To assess the sustainability of a product, operations in the entire production system and the stewardship on post-production must be taken into account. Hence, the supply chain and the entire life cycle of a product must be considered.

In recent years, environmentally-adapted (green) public procurement (GPP) has emerged as a potentially powerful tool, not only for gaining environmental and economic benefits, but also to minimize risks and drive research toward new innovative technologies and processes. The political support for green procurement has grown considerably during recent years and has now been manifested at both national, EU and international level.

Sustainable Public Procurement (SPP), which also includes social and economic dimensions, is a key area in the work to promote Sustainable Consumption and Production (SCP). In line with UN´s 10-year Framework Programme for Consumption and Production (10YFP), UNEP and various partners announced at Rio+20 the launch of a Sustainable Public Procurement Initiative SPPI, with the opportunity to form sub-groups targeting specific issues. Within the realization of the 10YFP, SPP has been identified as important area of work (see Figure. 1).

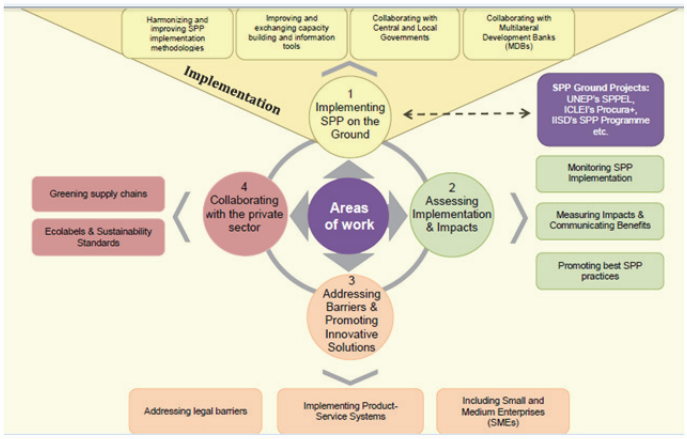

Figure 1. Overview of the program elements included in the UNEP 10YFP on Sustainable Public Procurement.

Due to increasing demand from downstream manufacturers and their purchasing activities, a growing number of organizations are becoming heavily involved in supply chain management (SPM). A common response among many of these organizations is to improve their internal environmental work by addressing their upstream suppliers as part of their own procurement activity.

This is not an easy task, and so far the current state of play on national SPP/GPP efforts show there is a lack of clarity when determining what type of products are the most sustainable ones. In response, many different product claims, eco-labels and standards have been developed to address market interest; which has created a complex market for purchasers to navigate.

To move forward there is a need to handle this complexity, but also to find ways to incorporate a more holistic perspective in procurement practices as such and supply chain management, encompassing the pillars of sustainability; with its environmental, social and economic aspects.

Within the framework of the 10YFP, an attempt has been made to manage some of the problems aforementioned by initiating studies in the work area 4 “Collaborating with the private sector” (see Figure 1). A pre-study has been carried out as a desk-top study (Laurell, 2012) in the sub-group “Greening supply chains” to explore to what extent SPP can be a tool to promote sustainability along the supply chains, and hence show the present potentials and limitations for SPP from this perspective. The objectives of the pre-study are outlined in Figure 2.

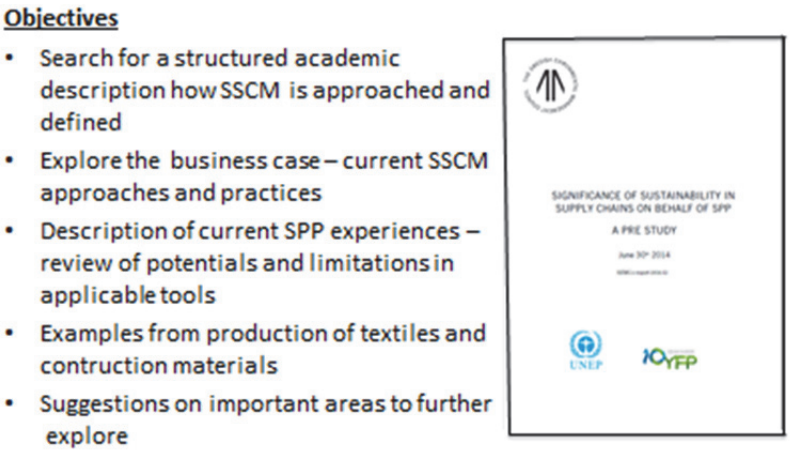

Figure 2. Outline of the objectives in the UNEP pre-study on Significance of Sustainability in Supply Chains on behalf of SPP.

The pre-study explored the market conditions to meet those high ambitions and many national, regional and local policies for public procurement also express high ambitions on sustainability. A variety of incentives and obstacles influencing supply chain management were identified. The major incentives included customer requirements, avoidance of negative publicity, and legal compliance (more often applicable to small and medium-sized companies, SMEs) and the biggest obstacles included contracting supplier conduct, use of a large pool of suppliers, and uncooperative suppliers.

This project provides a follow-up on the experiences gained in the pre-study in order to make a "Market Readiness Analysis" regarding potentials for SPP to work with supply chain aspects. As the pre-study mainly was carried out as a literature review, this study will focus on experiences from case studies based on practical work.

The pharmaceutical sector was chosen as an interesting case study due to the complexity specific for this industry sector with relevance to procurement of pharmaceuticals, e.g. by showing a number of inherent problems such as long supply chains starting in developing countries, specific legislation with regard to procurement and lack of transparency and access of information due to the special industry situation connected to marketing.

As the pre-study specifically pointed out the overall lack of user-friendly and practical tools which would facilitate the daily work of procurers with planning and execution of procurement of goods and services. This study makes an attempt to broaden the so-called CSR Compass (an internet-based tool on supply chain management for Corporate Social Responsibility) with information about the environmental dimension.

3. Project outline

The main objective with this project is to contribute to the understanding of possibilities and obstacles to set relevant and far-reaching sustainable criteria in public procurement of pharmaceuticals. A recent report in Sweden on sustainable pharmaceuticals from a procurement perspective (Lonnaeus, 2016) gives a broad overview of the procurement situation in Sweden, current legislation and challenges for the future and has been a source of some of information in this study. The project has an ambition to build on the experiences from that report by bringing some more details from a life cycle perspective.

It is important to emphasize that this study has its main focus on public procurement and the interrelationship with the CSR Compass and its version directed to public procurement. However, it is well-known that public procurement criteria often are being used also in the private sector. Therefore, some of the conclusions of this study might very well also be relevant for procurement in the private sector.

In Sweden many procurers in the public sector focus on the contribution to the fulfilment of the Swedish Environmental Goals. As a consequence, this study also has an ambition to contribute to the fulfilment of the objectives inherent in the Swedish Environmental Goals including a generation goal, 16 environmental quality goals and 24 staged goals. The generation goal is linked to a commitment to meet the needs of the present without compromising the ability of future generations to meet their own needs where the most significant environmental problems have been solved without creating increased environmental- and health strain in countries outside the Swedish boarders.

The specific parts of this project are to:

- Carry out a literature review on public procurement of pharmaceuticals in general to clarify the exchange of information in supply chains and based on a life cycle perspective as a whole with a specific focus on hindrance to get hold of requested information needed for procurers to make well-informed decisions – See Annex 1.
- Carry out a study on public procurement In Sweden as a general overview – See Annex 2.
- Carry out a study on public procurement on selected cases - a separate chosen pharmaceutical as well as by a separate public authority – See Annex 3.
- Suggest amendment of information with regard to the environmental dimension into the so-called CSR (Corporate Environmental Responsibility) Compass based on the experiences from the studies of procurement of pharmaceuticals as an input to convert the CSR Compass to as Sustainability Compass – See Annex 4.

The project was carried out by IVL (Swedish Environmental Research Institute) on commission of the Swedish Environmental Protection Agency. The project was coordinated by a steering group consisting of

- Kristina von Oelreich, Swedish Environmental Protection Agency
- Annika Kleen, Swedish Environmental Protection Agency
- Pauline Göthberg, Stockholm County Council
- Sven-Olof Ryding, Swedish Environmental Protection Agency
- Jenny Hedman, Swedish Environmental Protection Agency

and a reference group consisting of

- Annika Kleen, Swedish Environmental Protection Agency
- Sven-Olof Ryding, Swedish Environmental Protection Agency
- Jenny Hedman, Swedish Environmental Protection Agency
- Annika Christensson, Blekinge County Council
- Kia Salin, Medical Products Agency
- Margareta Bergh, The National Agency for Public Procurement
- Peter Nohrstedt, SKL Kommentus
- Hedvig Hernevik, Swedish Agency for Marine and Water Management
- Carmela Garcia, Swedish Environmental Protection Agency

During the course of the project three workshops were held – the first one in the form of a discussion with representatives from a branch organization and an international pharmaceutical company and the second two to guide persons carrying out the project on suitable issues to cover in the final report.

Participants in the workshops:

- Sven-Olof Ryding, Swedish Environmental Protection Agency
- Kristina von Oelreich, Swedish Environmental Protection Agency
- Margareta Bergh, The National Agency for Public Procurement
- Peter Nohrstedt, SKL Kommentus
- Karin Lonaeus, Stockholm County Council
- Jenny Hedman, Swedish Environmental Protection Agency
- Mikael Ekhagen, IVL

The report was written by:

- Mikael Ekhagen, IVL
- Michael Martin, IVL
- Sven-Olof Ryding, Swedish Environmental Protection Agency

4. The pharmaceutical sector and its different types of products and competition on the market

Manufacturing and selling pharmaceuticals is strictly regulated in different types of legislation. Pharmaceuticals have to be approved by Swedish and European government agencies. In Sweden, the Medical Products Agency examines and decides whether a pharmaceutical product is in compliance with legislative requirements and carries out comprehensive quality inspections at the manufacturing site.

There are three different types of pharmaceuticals – original pharmaceuticals, generic pharmaceuticals and parallel-imported pharmaceuticals.

Original pharmaceuticals, also known as name brand pharmaceuticals, still being protected by patents, are usually manufactured in-house by pharmaceutical companies and the supply chain is quite linear.

Production of generic pharmaceuticals consists of more complex supply chains including both own- and third-party manufacturers. Getting access to environmental information from the manufacturing of original pharmaceuticals is dependent the willingness of original pharmaceutical producing companies to share information about their processes and supply chains.

The supply chain for parallel-imported pharmaceutical, starts with the purchase of existing pharmaceuticals and consists mainly of repackaging. The parallel trade is driven by price differences on the market, where the business case is to buy pharmaceuticals in a country where the price is lower, repackage and sell them in another country. The parallel trade is mainly focused on original pharmaceuticals with larger margins to make use of these products.

Pharmaceuticals are also subject for direct sales to customers at pharmacies referred to as OTC (Over The Counter) pharmaceuticals.

The pharmaceutical industry is characterized by strict regulation and tough competition. For the original-producing companies it's key to protect the intellectual properties and thereby avoiding insights from other parties into their manufacturing processes. They are playing an important role in the exploration and developing of new original pharmaceuticals but need to keep their specific know-how to themselves to maintain a competitive edge. Both generic producers as well as the parallel-importing companies contribute to the market dynamics by offering products at reduced prices and thereby offering a "level playing field". The strict competition conditions often lead to heightened secrecy in the pharmaceutical

industry. This makes public procurement difficult to carry out in an orderly manner as it could require that company-specific environmental information and insights into manufacturing processes and company routines will become public. The principle of publicity usually results in strict proprietary policies from suppliers whom are not willing to share information in the procurement process as it can lead to that their documentation becomes available to competitors.

One of the key prerequisites for sustainable procurement is to understand and become informed about the way supply chains operate to enable risk assessments to be carried out prior to a specific procurement in order to be able to write a tender with relevant requirements. The lack of transparency and the high degree of complexity jeopardizes proper risk assessments to be carried out. Elucidation of the requirements, including details about the rationale of the requirements and where in the supply chain specific requirements have to be fulfilled, are usually asked for from bidders. However this, in turn, put demands on the pharmaceutical industry to provide more transparent information about supply chains and production processes.

5. Different types of procurement criteria

There are different types of requirements that generally can be used in a procurement context (Sustainable Procurement, 2016):

- Technical requirements: specify physical characteristics of goods or services, e.g. recycled or renewable content, mercury-free, or the way in which the product is manufactured or delivered, e.g. organic or sustainably managed timber and fisheries
- Performance requirements: define the performance standards to be met by the goods or services including definition of the way the goods or services have to be delivered in order to optimize social and environmental impacts related to future performance. For example, standards of care and number of patients for a social care service, delivery time, waste, relocation and carbon emissions reduction
- Functional requirements: define the proposed function to be fulfilled by the goods or services. For example, the strength and durability of concrete to be supplied or energy/fuel efficiency.

Generally, a combination of performance and functional requirements are preferred as they enable suppliers to propose the most efficient technical solution for the required performance or function, leading to potential sustainability benefits such as better energy performance, reduction of waste, advanced safety precautions for users, universal design, disposal and end-of-life management. The organization should be careful when using technical requirements not to specify particular brands, unless it is absolutely unavoidable and accepted by the law.

5.1. Minimum and optional requirements

Minimum requirements can be acceptable when they establish minimum acceptable performance, actively excluding undesirable features, or when they define preferred sustainability solutions. In this case, they should be related to an evaluation criterion that is used to reward performance that exceeds the minimum standards, and possibly to a key performance indicator that should be managed during the contract.

In addition to these two main options, an organization can use additional techniques such as variants in order to encourage better alternative solutions. The previous analysis of the market carried out earlier in the procurement process informs the decision about what should be minimum and optional. For instance, the degree to which suppliers can meet the organization’s sustainable criteria might not always be known when writing the tender, or the market analysis may have revealed that there is a divergence between suppliers' sustainability performance. In that case, the risk of restraining competition and excluding capable suppliers

should be avoided, except if the requirement is an absolute necessity for the organization. If a supplier with lesser sustainability performance is selected, agreements should be made on how the supplier should progress in the future. This should be monitored in the contract phase.

5.2. Procurement criteria as practised in Sweden according to EU Directives

There are four different types of criteria usually practiced in Sweden according to The EU Directives for Public Procurement, which have been introduced in the Swedish legislation on Public Procurement:

- Qualification criteria: Qualification criteria relates to the technical and professional capacity of suppliers. These criteria could reduce the possibility of a supplier to leave a bid as these requirements have to be met from the start. It is therefore important that the qualification criteria such as size, competence and economic status are clearly described to avoid that procurers omit fully capable bidders. As a consequence of this, the use of sustainability criteria is often very basic and can e.g. be limited to only requirements for management systems.
- Technical Specifications: Technical specifications are usually directed towards the products to be procured and shall be described in the procurement advertisement or tender document. Information shall also be given about the assessment procedure, i.e. in case evaluation criteria are used.
- Evaluation criteria: Evaluation criteria should focus on sustainability elements considering technical characteristics about the product performance. In the event that several evaluation criteria are used the tender document shall describe the weighting technique between the criteria, in practice how many points or percentage will be allocated to the different criteria.
- Contract clauses: Contract clauses are mandatory and need to be fulfilled by all bidders, but they do not have to show that the requirements are met in the qualification phase. The requirements should be met during the agreed contract period for the contract, which makes contract clauses a flexible and efficient tool. Furthermore, the contract clauses must be proportional and linked to the subject matter for procurement.

It is recommended to start follow-up activities as early as possible after the contract has been signed and the work begins in order to check that the deliverables meet the defined requirements.

6. Introduction to the CSR Compass

The CSR Compass is a free online tool focusing on the private sector to help companies to implement responsible supply chain management (www.csr-kompasset.dk). Originally it was developed as a Danish initiative in 2005 and the tool underwent extensive revision in 2010.

The tool is mainly targeted at small and medium-sized production, trade and service companies to help them comply with international guidelines for companies' social responsibility in the supply chain. The tool includes useful advice, cases, templates and useful links targeted especially at small and medium-sized enterprises. Larger enterprises and organizations can also find inspiration as it gives an overview of expectations and opportunities for responsible supply chain management and can therefore be a good place to start.

The structure of the CSR Compass and its advice and guidelines are in line with national and international trends and best practice standards, including the UN Global Compact, OECD’s guidelines for multinational companies, Business for Social Responsibility (BSR), Business Social Compliance Initiative (BSCI), the Danish Ethical Trading Initiative (DIEH) and the Danish Council on Corporate Social Responsibility’s guidelines for responsible supply chain management.

The application of the CSR Compass was broadened during 2011 by a Swedish and Norwegian initiative to additionally address aspects related to the public sector and its procurement activities related to CSR issues in the supply chain(www.csr-kompassen.se)

6.1. The different planning stages

Suppliers are expected to exercise due diligence in their sustainability activities. This applies in relation to the companies' own business activities but also in relation to the company's business partners. In a broad sense, the concept of business partners may include a number of relations such as sub-suppliers, investors, customers, buyers, etc.

A thoroughly planned procurement process is very helpful to exercise due diligence in exercising responsible supply chain management. Procurement authorities themselves must also meet the requirements they impose on their suppliers.

In other words, procurement authorities must have policies and processes that can help them to designate the areas in which they are at risk of exerting adverse impacts on CSR principles, thereby failing to comply with international CSR

principles, in order help them to prevent and alleviate any adverse impacts. It is also important that this information can support reporting on their activities.

The CSR compass has the form of a stepwise hierarchic approach on six separate planning levels with the ambition to guide a procurer when taking necessary decisions during the entire procurement process – see Figure 3.

Figure 3. Outline of the different planning stages in the CSR Compass.

A suggested input of the environmental dimension into the CSR Compass is given in Annex 4.

7. Procurement of Pharmaceuticals in Sweden

The total value of purchase of pharmaceuticals in Sweden (prescriptions and requisitions) per December 2015 amounted to SEK 35,9 billion. Purchases by pharmacies amounted to SEK 28,4 billion while purchases by County Councils amounted to SEK 7,5 billion (INSIKT, e-hälsomyndigheten, 2015). The relatively low proportion of pharmaceutical products procured by the public sector results in a fairly limited influence on suppliers for product improvements through its purchasing power. However, Sweden is considered to have a comparatively large influence on suppliers through its leading role in driving sustainability issues. In an international context this could stimulate other countries to make use of the Swedish experiences and practice from public procurement processes.

The procurement of pharmaceuticals lacks environmental impact information. Specific product requirements are evaluated and handled by the Swedish Medical Agency in connection to its approval and registration of pharmaceuticals. The evaluation made by the Swedish Medical Agency is based primarily on a human medical/clinical assessment procedure where risk and benefits are in the focus. Once again, no environmental aspects are reviewed.

Tendering handled by Procurement Authorities is mainly focused on process requirements, such as the organizational environmental work carried out by suppliers, which limits the use of the four types of criteria mentioned above. As a general rule, it seems that the most relevant and effective requirements could be handled by contract clauses rather than by the use of qualification criteria in the tendering process.

Pharmacies, on the other hand, have few possibilities to make use of sustainability criteria when buying prescribed pharmaceuticals. On top of this, pharmacies have to comply with a substitution reform from 2002, stating that when selling “on prescription pharmaceuticals” the least cost equivalent should be chosen, which creates a clear obstacle for pharmaceuticals to drive environmental performance measures.

As mentioned above, a recent report in Sweden on sustainable pharmaceuticals from a procurement perspective (Lonaues, 2016) gives a broad overview of the procurement situation in Sweden and current legislation. The report summarizes the following aspects as important in the future work with making sustainable procurement more efficient in the future. The work recommends the following, to:

- Explore the possibility for pharmacies to require sustainability performance when purchasing pharmaceuticals

- Through dialogue and cooperation between County Councils, regions, industry and other stakeholders, to develop an effective process for sustainable procurement by means of:
    - creating a national platform for future cooperation via the Swedish Agency for Public Procurement;
    - developing clear and common criteria for sustainable procurement of pharmaceuticals;
    - developing a clear and common method for follow-up activities based on goals, risks and non-compliance;
    - developing tools for sustainable procurement including risk assessment and means of follow-up activities;
    - investigate the juridical aspects with regard to transparency and documentation,
    - clearly define and communicate the legal framework for sustainable procurement that needs to be adapted by procurers and practitioners,
    - develop guidelines for handling non-compliance;
    - communicate objectives and goals with sustainable procurement (from visions to setting specific targets with sustainable procurement of pharmaceuticals), and to
    - create an international platform for dialogue and long-term development in collaboration with global actors within sustainable procurement of pharmaceuticals including researchers, National Health Service (NHS), United Nations Development Programme (UNDP) and World Health Organization (WHO) with the overall aim to discuss and make operational common challenges and solutions.

8. The life cycle of Pharmaceuticals

The life cycle of pharmaceuticals viewed from an activity context consists of several phases as illustrated in Figure 4.

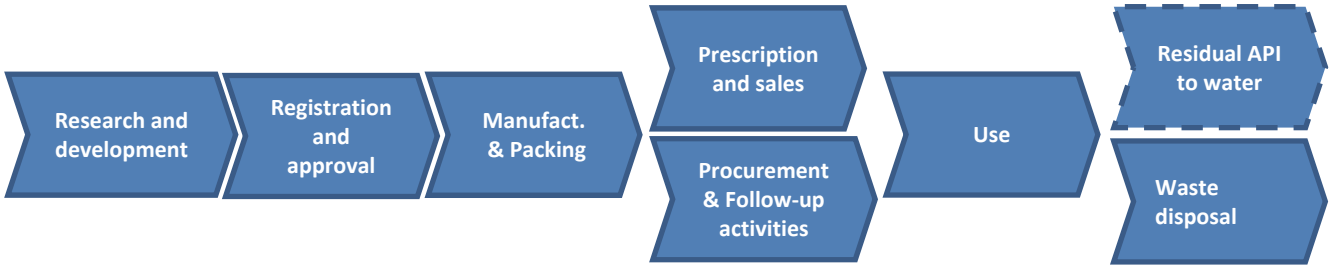

Figure 4. Activities within the product life cycle of pharmaceuticals.

A short description of the different phases in the flow-chart is given below focusing on the work carried out by the different actors involved in the activities in connection to public procurement and how the environmental aspects are included in this phases .

8.1. Research and development (by Original-producing companies)

Some producers of original (name brand) pharmaceuticals consider environmental information in their research and development of new and more effective pharmaceuticals. They are guided by general recommendations on important aspects to focus on from e.g. the Pharmaceutical Roundtable at the American Chemistry Society and the National Health Services Guidelines from which water use, solvent use, reagent use, PMI and Carbon Footprint are specifically highlighted. By conducting their own life cycle assessments (LCA), these companies can gain further and more detailed insights into different types of environmental impacts resulting in significant environmental aspects for their specific substances.

As described in Chapter 6, there are a number of obstacles to procurement of pharmaceuticals as a consequence of protecting intellectual properties and attempts to secure the companies competitive edge on “low price market”.

Additional obstacles exist when attempting to provide transparent environmental information about pharmaceuticals. Current legislation (Läkemedelsverket, 2009) states that pharmaceutical information directed towards the public should be factual, compliant and not misleading; this includes all medical packaging and market information. Currently, there are uncertainties regarding what can and cannot be done regarding the introduction of green claims to pharmaceuticals.

All original pharmaceutical producers follow Good Manufacturing Practices (GMP) in their operations, but in many cases these practices focus primarily on product safety.

Pharmaceutical producers could be contacted by municipalities when planning new design and upgrading the treatment processes in wastewater treatment plants. However, this is merely done on a consultative basis and pharmaceutical companies usually have no direct impact on the decisions to be taken.

8.2. Registration and approval by the Swedish Medical Agency

Manufacturing and selling pharmaceuticals is strictly regulated in different types of legislation. Pharmaceuticals have to be approved by Swedish and European government agencies. In Sweden, the Medical Products Agency examines and decides whether a pharmaceutical product is in compliance with legislative requirements and carries out comprehensive quality inspections at the manufacturing site, as appropriate.

The examination procedure primarily builds on evaluating risks vs. benefits focusing on a medical/clinical human health perspective. Aspects usually considered include substance stability, bio-toxicity and bioaccumulation. The examination, primarily within an ERA, focuses on product properties leaving little opportunity for considering the environmental impact e.g. from pharmaceutical residues entering the aquatic environment and causing environmental damage and other effects to organisms.

8.2.1. Manufacturing and packing (by Original and Generic Pharmaceutical producers, and Parallel-importing Pharmaceutical companies)

As mentioned above, the supply chains for the various types of pharmaceuticals on the market are somewhat different. For original pharmaceutical producers the supply chain includes manufacturing of the active substance, filling materials and packaging materials. For generic pharmaceutical producers, this includes manufacturing of filling materials and packaging materials and for parallel-importing companies manufacturing of packaging materials.

During research and development original pharmaceutical producers usually take into consideration the environmental aspects. It is less apparent to which extent the generic pharmaceutical producers and parallel-importing companies consider environmental aspects in their manufacturing processes. However, any modification of the manufacturing processes for filling and packaging materials

compared to that of the pharmaceutical producers enable companies to go "even greener" in their operations.

8.3. Prescriptions by physicians, and sales (by Pharmacies and retailers)

Environmental aspects are usually not considered in the prescription process carried out by physicians. Some environmental information can be found in Fass (available at www.fass.se), but it does not cover information on environmental impacts and the information is focused on product-related impacts on humans. However, if ERA used by the Swedish Medical Agency will be expanded to also cover more traditional environmental information it will certainly lead to a growing interest by physicians to consider this information as well.

Due to the Law on Pharmaceutical Benefits (2002:160), pharmacies are obliged to replace the prescribed pharmaceutical with the cheapest available equivalent one. The Swedish Medical Agency decides upon which pharmaceutical are replaceable and regularly publishes a list of those product groups. Only products included by the law of pharmaceutical benefits can be subject for being replaced. A pharmaceutical must not be replaced if:

- A medical doctor contradicts a replacement based on medical grounds, e.g. concerning specific allergy circumstances or if a patient has specific needs based on a continuing use.
- A pharmacist contradicts a replacement due to the design of the pharmaceutical or if the replacement may result in disorder of the patient in the form of deteriorated use of pharmaceutical or another risk for health of the patient.

8.4. Procurement and follow-up activities (by Procurement Authorities)

The activities carried out by Procurement Authorities have to follow the rules set out by the legislation on public procurement. Even though some of the elements in the rules for public procurement are fairly strict and leave only small possibilities for changes due to preferences, the legislation is considered quite flexible given that all Procurement Authorities have good opportunities to buy the specific products they have identified in their demand analysis. A detailed description of activities by Procurement Authorities for the entire procurement process is given in Chapter 10.

The new EU Directives offer new opportunities to consider the environmental dimension into the daily work of procurers. This is primarily due to the introduction of a "life cycle perspective" making it possible to claim requirements to be set in all life cycle phases of a product. Another important new element in the new Directives is the recommendation to replace the principle to prioritize bids

with the lowest price with a broader view incorporating a number of sustainability aspects into a combined evaluation based on the most economic advantageous tender (MEAT, also referred to as “Best value for money”). For further information – see Chapter 9.6.

8.5. Use (by Humans)

There are primarily two pathways for pharmaceuticals to enter the environment from use of humans:

- The drug passes through a human body (see below)
- Disposal of unused and expired pharmaceuticals

Any person using pharmaceuticals is an important player to prevent residual pharmaceuticals to pollute the environment. They must be aware that they should bring pharmaceuticals back to a pharmacy if excess quantities still remain after use. It is also important that persons are aware that they should not dispose of surplus liquid pharmaceuticals into a kitchen sink or a toilet.

This type of information should be clearly stated on the packaging materials which also should contain information on how to handle waste separation and disposal.

8.6. Discharge of residual Active Pharmaceutical Ingredients (API) to water

All humans contribute to the discharge of residual pharmaceuticals when they pass the human body and end up in toilet effluents (black water). Most existing sewage treatment plants are designed to reduce pharmaceutical residues in incoming water, as there is a need for specific and targeted treatment procedures. Hence, most of the human contribution of pharmaceuticals passes through a sewage treatment plant almost untreated and reaches the nearest recipient water. Impact on the biota in the water environment is described in Annex 1.

8.7. Waste disposal (by recycling companies)

Waste disposal and recycling companies have specific rules to ensure that the waste fractions are handled appropriately. This could, for example, be to send waste fractions to recycling, incineration or landfill. As such they have their specific permits for the type of services they provide and are subject for surveillance from authorities.

8.8. Waste disposal (by Pharmacies)

Pharmacies have a special duty to be the collecting point for unused pharmaceuticals from hospitals and private persons to fulfil its obligation related to the Producer Responsibility of pharmaceuticals.

9. Activities carried out by procurement authorities

Public procurement is carried out by organization designated to follow the national legislation on public procurement, herein referred to as Public Authorities. Considering the product life cycle of pharmaceuticals, Public Authorities cannot put demands on all actors involved in the activities but can impose demands upon three, those being 1) research and development, 2) manufacturing and packaging and waste disposal as illustrated in Figure 5.

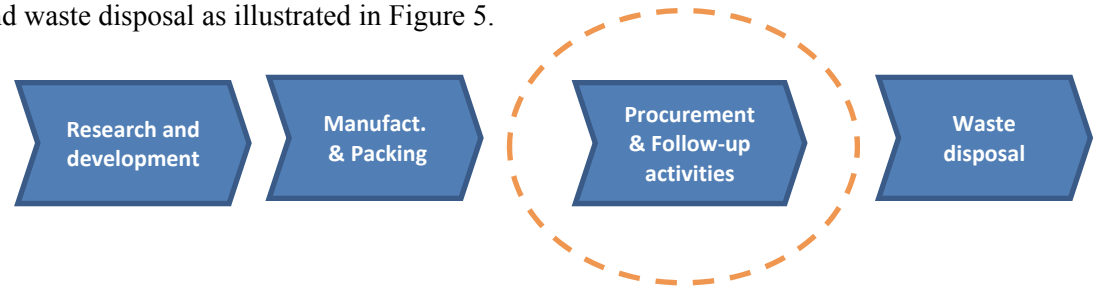

Figure 5. Outline of what activities Public Authorities can put demands on in public procurement

The entire procurement process has the form of a staged approach including a number of interlinked activities. For a Procurement Authority, the activities could be divided into three steps – activities before, under and after the tendering process which entails contracting signing. An attempt to illustrate the entire procurement process is given in Figure 6.

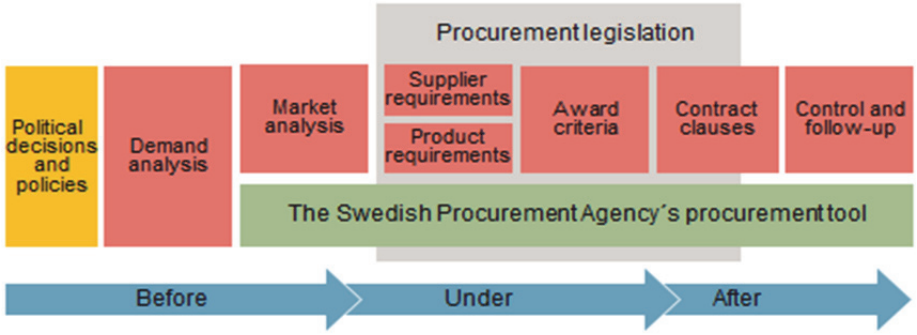

Figure 6. Different elements included in the entire procurement process.

9.1. The demand and market analysis

For the traditional work carried out by Procurement Authorities it is important to start the preparation and planning of an upcoming procurement as early as possible. A thorough preparation based on a demand and market analysis will usually result in a lot of valuable information for the formulation of tenders as well as the follow-up activities.

Information about the environmental work by suppliers can usually be found on their websites or in their environmental or sustainability reports. However, as this

type of information usually differs from one supplier to another, it could be recommended to ask for additional details as specific “Request For Information” (RFI). It is important to utilize this possibility to collect additional information as it is an indication, from the Procurement Agency, that the environmental dimensions are important in the upcoming procurement.

Several types of questions could be used, such as:

- Do you have a certified environmental management system or a system according to best practice?
- How do you incorporate a life cycle perspective in your environmental work?
- How is your environmental work connected to the UN Sustainable Development Goals?
- How do you identify your significant environmental aspects?
- Which are your significant environmental aspects and short and long-term environmental targets?
- Describe the routines in your environmental work with regard to distributing responsibility and track the environmental performance of your sub-suppliers?
- How do you follow-up your environmental work and secure continuous improvement?
- Can you present the documentation sent in to the Medical Agency in relation to the registration and approval process?
- Can you present a Carbon Footprint for your products?

It is always an advantage to have an early and continuous dialogue with potential suppliers.

This usually raises the interest by potential suppliers to participate in the upcoming tendering process. Additionally, this may facilitate relevant criteria to be included when formulating the tender document.

9.2. Qualification criteria

Due to the lack of product-related environmental information in the pharmaceutical industry the qualification criteria will have to focus on the organization work of suppliers in terms of their technical and professional capacity expressed as e.g. size, competence and economic status.

As qualification criteria must be fulfilled for a supplier to stay in the further evaluation of bidders, mandatory requirements with regard to environmental work set by Procurement Agencies must be practiced with caution as to not omit serious and competent suppliers which fulfil many of the other requirements. One possibility could be to ask for an environmental management system based on some of the information gained in the market analyses. In case an environmental

management system is judged to be an essential element in the tendering process, but not existent for most suppliers, it possible to include such a requirement as a part of the contract clauses – see also Chapter 9.4.

9.3. Award criteria

Award criteria are usually linked to technical characteristics about product performance. As mentioned above, product-related environmental performance of pharmaceuticals is seldom publicly available from manufacturers and therefore not used in current procurement of pharmaceuticals. However, some possibilities following the new procurement legislation might lead to making better use of qualification criteria when procuring pharmaceuticals in the future, such as asking for an estimate of a Carbon Footprint. As international standardized procedures for Carbon Footprint calculations are developed for a number of product categories and widely recognized it may be possible to give higher points to products with a low Carbon Footprint.

9.4. Contract clauses

Contract clauses are widely used in daily procurement of pharmaceuticals in almost all County Councils. They can be used for comparatively far-reaching requirements, as a supplier is committed to comply with the requirements during the contract period. Contract clauses are, as indicated above, a good instrument to establish environmental management systems in small- and medium sized companies as they can “phase-in” an environmental management system according to their own prerequisites.

Usually, contract clauses focus on aquatic environmental information and environmental routines carried out in the supply chain. Examples of how such contract clauses can be formulated are given in the fact box below.

Aquatic environmental information

”The supplier commits itself from the day of signing the contract, for the products subject for the procurement, provide own environmental information or refer to other environmental information which corresponds to the transparent model for environmental classification practiced in FASS. This entails, that the environmental information shall be verified and approved by a competent third-party before its publication. Additionally, the supplier shall post this information on www.fass.se or another publicly available website”.

“The supplier commits itself from the day of signing the contract, to provide a description where the environmental information is available for the pharmaceuticals subject for the procurement. The supplier shall inform which competent third-party has verified and approved the environmental information. Furthermore, it should be justified if there is a lack of environmental information available for specific substances”.

Environmental routines carried out in the supply chain

“The supplier shall, no later than 6 months after the start of the contract work, have implemented routines securing a minimal environmental impact from the proper use and handling of active substances and other raw materials/chemicals made use of in the manufacturing process of the offered product. Theses routines should at least include the following:
- national legislation for environment, health and safety,
- information about sampling frequency and reporting from control of pollutant emissions to soil, water and air from the manufacturing process of the active substance and other chemical substances, and
- a continuous dialogue with sub-suppliers with regard to their control of emissions of chemicals to soil, water and air encompassing a description of how the dialogue is carried out, risk assessments and how non-compliances are handled”.

Contract clauses can also be used for a number of other purposes, such as:

- Commitments to comply with *Code of Conducts*
- Continuously improve their environmental performance
- Passing on procurement requirements along the value chain from suppliers to their sub-suppliers and a mandate to follow-up achievements reached by sub-suppliers
- Regular reporting from suppliers about the result of their environmental work as a result of the procurement criteria
- Information about compliance with other duties related to suppliers environmental work such as *Producer Responsibility*

9.5. Follow-up activities

To follow-up the fulfilment of environmental criteria is important and necessary for several reasons. Primarily it creates credibility for the Procurement Agency by

showing that the conditions and requirements included in the tender document will be subject for control and evaluation. It is also necessary to avoid any contradiction with the principle of equal treatment which, in case no follow-up activities take place, can jeopardize fair competition and may favor suppliers that do not fulfil all preset requirements.

It is recommended to start follow-up activities as early as possible to ensure that the deliverables meet the preset requirements and requested improvements. Follow-up activities can take different forms, such as making use of questionnaires which a supplier is required to respond to within a given time period. Based on input from the questionnaire, a Procurement Agency can set up a plan for improvements, if found necessary, where the supplier must comply within a preset period. It is important to give a supplier sufficient time to meet the requirements. In case suppliers do not meet the expectations set by the Procurement it is possible to conduct "revision-on-site." If no improvements are made by a supplier, this could give reasons for a cancellation of the contract. However, in such a case, it is to be recommended to "freeze" the cancellation if the supplier starts to pay more attention to fulfil the preset requirements for improvements in the contract.

9.6. Future possibilities

Environmental information is currently sparsely involved in current practices when procuring pharmaceuticals. This is due to a number of reasons. One important reason is the fact that a primary focus when evaluating risks and benefits with pharmaceuticals making use of an Environmental Risk Assessment (ERA) are mostly linked to human health aspects and not its direct effects in the environment. Therefore, one of the main conclusions of this study is to put a much stronger focus on environmental information in the work of the Swedish Medical Agency.

Another equally important reason is the multiple obstacles for going public with environmental information linked to the manufacturing and use of pharmaceuticals following the market-induced secrecy necessary for original pharmaceutical producers to maintain their competitive edge as well as strict rules to adhere to with regard to "green claims. Still another reason is the legislative obstacles to sell pharmaceuticals other than those with the lowest price.

However, there exist some future possibilities to broaden the use of environmental information in public procurement. These possibilities include the following areas:

- Developing a more structured overview of what the market can offer and the environmental work at potential suppliers through the Market Analysis
- Make use of Life Cycle Assessments (LCA) and Environmental Product Declarations (EPD) to facilitate the identification of products with superior environmental performance
- Stimulate the provision of more traditional product-related environmental information to be publicly available in www.Fass.se

- Start to routinely request environmental information from manufacturing and packaging as a part of an Environmental Management Systems in contract clauses
- Secure sufficient resources to carry-out follow-up activities to get a better control of deliverables according to contracts and to secure continuous improvements by suppliers and sub-suppliers
- Enhance the cooperation and the dialog between different actors/ target groups along the value chain

Any attempt to make better use of environmental information in public procurement has most likely a better chance to be operational and used in practice if they are related to legislation or to widely recognized management systems on a global scale, where both options are exemplified below.

9.6.1. New EU Directive for Public Procurement

To create a level playing field for all businesses across Europe, EU law sets minimum harmonized public procurement requirements. These requirements organize the way public authorities and certain public utility operators purchase goods, works and services. They are transposed into national legislation and apply to tenders whose monetary value exceeds a certain amount. For tenders of lower value, national rules apply. Nevertheless, these national rules also have to respect the general principles of EU law.

In 2014 the European Parliament and the Council decided to repeal the previous Public Procurement Directive with a new one (Directive 2014/24/EU). In Sweden, the new rules will be introduced into national legislation by early 2017.

Some of the more important changes are requirements for:

- background data covering the entire life cycle of a product, for instance on the use of chemicals during manufacturing or the use of energy-efficient appliances,
- technical specifications to be open for competition with the overall aim to meet sustainability goals,
- environmental management systems to proof that a supplier has the necessary technical capacity to fulfil a contract, where references shall be given to standardized methods or equivalent and that suppliers shall verify the compliance with standardized methods in case they refer to an equivalent system,
- the use of Eco-labels provided that the requirements are linked to the subject matter for the procurement, being objective, verifiable and developed in an open participatory process, and if not all requirements are referred to in a label, the specific requirements have to be spelled out in the tender document,
- evaluation and assignment of the winning bid to be based on the most economic advantageous tender (MEAT, also referred to as “Best value for

money") to replace the principle of "lowest price" to the extent possible and where Member States can ban the use of lowest price, and for
- the inclusion of Life Cycle Costing (LCC) in the tendering process, provided that the principle of "lowest price" is not applied and where internal costs and the costs of externalities can be included in the calculations.

9.6.2. New version of Environmental Management Systems according to ISO 14001

The ISO 14001 standard for environmental management has been around for 20 years and is one of the most widely used ISO standards, with more than 300 000 certificates around the world. In 2015 a new version of the standard was released (ISO, 2015) which put's additional focus on:

- Increased prominence of environmental management within the organization's strategic planning processes
- Leadership
- Addition of proactive initiatives to protect the environment from harm and degradation, such as sustainable resource use and climate change mitigation
- Improved environmental performance
- A life cycle perspective when identifying significant environmental aspects, environmental goals and establish routines for purchasing
- External reporting taking due consideration to stakeholders.
- Communication strategy

One of the most significant changes from a procurement perspective is the changes connected to the mandatory use (a shall requirement) of a life cycle perspective. This means to consider the entire product life cycle in a number of activities, especially highlighting the importance of determining the environmental requirement(s) for the purchase of products and services.

In order to set the right requirements it is essential to first increase awareness among procurers about the environmental performance of the products or services being procured. If the procurer lacks sufficient knowledge about the significant environmental impacts from a life cycle perspective it is impossible to set relevant requirements and the process might only cause additional administrative burden which may not result in reducing the environmental impact.

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www.csr-kompasset.dk

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11. Annex 1. Review of pharmaceutical materials flows in a life cycle perspective

Pharmaceutical material flows in a life cycle perspective ought to be separated in two different parts:

- One part illustrating "upstream process" giving an overview of the supply chain (Figure 7)
- One part illustrating the "downstream processes" giving an overview of the different pathways of pharmaceuticals reaching the environment (Figure 8)

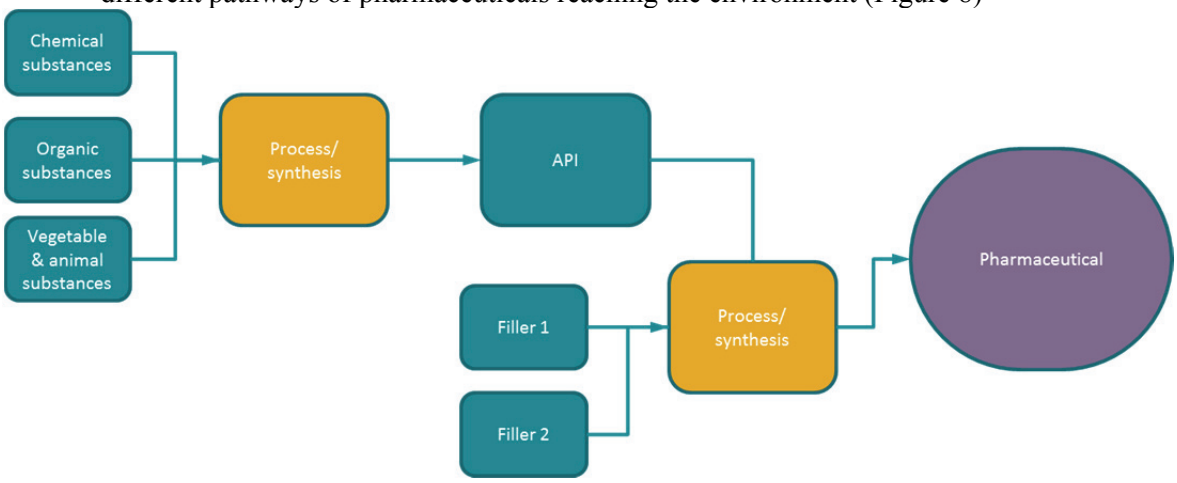

Figure 7. Outline of the pharmaceutical material flows with regard to "upstream process" for the supply chain.

There is a large body of literature related to pharmaceutical flows to the environment and the effects of different substances in the environment. These are primarily related to pharmaceutical residues released and transported via waste water; see e.g. (Brandmayr et al., 2015; Halling-Sørensen et al., 1998) In a review by Jones et al. (2001), the pathways of human pharmaceuticals reaching the environment are assessed. From the review, and as outlined in Figure 8, a number of pathways for pharmaceuticals in the environment can be seen and the evidence for their relative dominance also categorized.

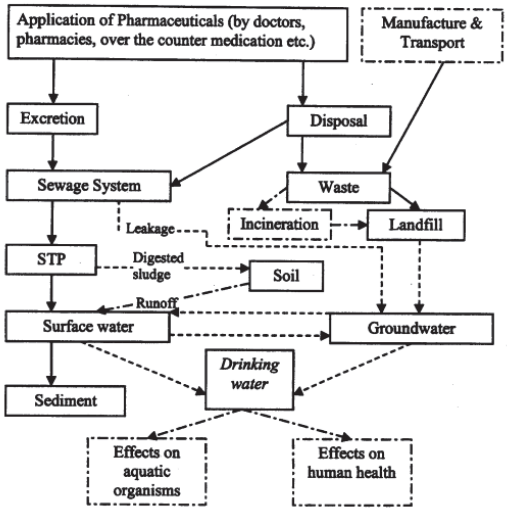

Figure 8: Possible pathways of human pharmaceuticals in the environment

As Jones et al. (2001) and Bound et al. (2006) suggest, there are primarily two pathways for pharmaceuticals to enter the environment including:

- the drug is passed through a human body and thereafter, or
- through disposal of pharmaceuticals (both unused and expired).

While, again, there is a relative abundance of studies on the flows of pharmaceuticals to the environment from the end-of-life (or waste), there are very few studies reviewing the life cycle (and impacts) of pharmaceuticals; due primarily to a lack of data related to raw materials, processes, etc. see a discussion by (Mata et al., 2012). Nonetheless, Jones et al. (2001) suggest that upstream processes may not lead to large waste streams as disposal of waste in the pharmaceutical industry is under strict control for manufacturers, retailers and hospitals (Jones et al., 2001). The primary source of pharmaceutical waste and exposure in the environment is again from consumers.

In order to reduce wastes to the environment, the US EPA (EPA, 2008) reviews some actions to reduce and prevent waste of pharmaceuticals. They even provide recommendations to avoid waste in hospitals but also increase labelling to ensure consumers are aware of the consequences of handling pharmaceuticals.

Nonetheless, efforts to reduce these emissions of pharmaceuticals to the environment may not be effective as the public has no obligation, only advised, to return unused and expired medications to the pharmacies (Daughton and Ternes, 1999). As in Brandmayr et al. (2015) a wealth of literature reviews exist on end-of-pipe solutions to prevent potential waste and flows of pharmaceuticals in the environment; though recent developments have begun to review the importance of upstream measures to reduce the prevalence of pharmaceuticals which may reach waste water treatment.

11.1. Enviromental problems arising from pharmaceutical residues to water

Besides effects on human health and the aquatic environment, environmental impacts occur along the pharmaceutical supply chain and there are a very limited number of studies reviewing these impacts occurring along the supply chain. Recommendations have been given reviewing active pharmaceutical ingredients (API) production and optimization to reduce environmental impacts in upstream processes for pharmaceutical production (Ott et al. (2014). Furthermore, studies are often related only to API in the pharmaceuticals and associated with the residues reaching the environment subsequent to human ingestion and excrement. Modelling the life cycle impacts of pharmaceuticals has proven to be difficult. This is due to the lack of transparent data and strict intellectual property rights from the pharmaceutical industry (Curzons et al., 2007; Mata et al., 2012)

The effects and toxicity of pharmaceuticals in the environment are highly debated in the scientific literature. While designed for mammalian physiology, the effects for other organisms are not entirely understood (Jones et al., 2001). Many studies found wastewater effluent to be genotoxic. There is also concern that antibiotics in wastewater streams may increase the resistance amongst different bacterial strains, giving rise to a medium for antibiotic-resistant organisms (Boon and Cattanach, 1999). This is of concern for fish farms and other aquiculture (Bound et al., 2006). Pharmaceuticals have also been shown to increase the risk of feminization of fish, through endocrine disrupting compounds (Bound et al., 2006; Kidd et al., 2007; Lange et al., 2001; Ternes et al., 1999)

Although many studies of the effects, and measurements, of pharmaceuticals show low levels of toxicity, the “cocktail” effect is not known. While in isolation the different compounds may be innocuous, though together they may create harm (Bound et al., 2006).

In the LCA community, life cycle impact assessment (LCIA) methods to show e.g. toxicity in the life cycle are relatively immature and databases and methods are continually being developed.

A serious problem that has been observed during recent years is emissions of pharmaceutical residues to recipient waters from manufacturing sites mainly in low-income countries such as India and China. A comparable large part of manufacturing of pharmaceutic manufacturing takes place in in low-income countries such as India and China. Research studies have also shown very high concentrations in effluent water at manufacturing sites in India and China (Li et.al. (2008). A study carried out 2007 showed concentrations of pharmaceutical residues in wastewater in the area of Andhra Pradesh exceeding concentrations in Swedish wastewater plants in by a million times (Larsson, DGJ., de Pedro C. and Paxeus

N., 2007) The results also showed that pharmaceutical residues had been spread to ground- and drinking waters, which is becoming an apparent problem for the local population. This is a specific and worrying problem according to scientists as discharges of broad spectrum antibiotics can influence many different types of bacteria due to the risk of development of resistant bacteria. Other research studies have indicated that substantial water discharges of antibiotics often lead to high presence of resistant bacteria and resistant genes and create a favorable environment for transfer of resistance between types of bacteria (Larsson and Lööf, 2011). The specific recipient water conditions close wastewater treatment plants where excrement and antibiotics are mixed together have been noted to create potential risks for the development of antibiotic resistance (Finley et. al., 2013).

11.2. Uncertainties related to environmental impact data in the supply chain

There are large uncertainties in the flows and impacts associated with pharmaceuticals in the environment. There is also conflicting information on the effects of pharmaceuticals in the environment (Bound et al., 2006). Reviews can be found for some of the uncertainties related to the interactions with pharmaceuticals in the environment (Boxall, 2004). Among these are factors on the physio-chemical properties of the pharmaceuticals, characteristics of receptors, distribution. The study also goes in depth and reviews the sorption behavior of substances in the environment, which may have large variability. Suggestions have been raised that the biodegradability and transformations that may occur in the compounds during different treatment processes, and once they are in the environment, may also increase the uncertainty of how they may affect the environment (Jones et al., 2001)

There is also uncertainty of where pharmaceuticals originate. Hospitals, a source of high concentrations of pharmaceutical residues, may be connected to waste water systems directly and hard to monitor (Kummerer, 2001). A large body of literature exists for pharmaceuticals in water. Nonetheless, pharmaceuticals in landfills have received relatively little attention in the literature (Bound et al., 2006; Slack et al., 2005). The literature also contains discussions about the importance of the pharmaceuticals for animals (Halling-Sørensen et al., 1998).

12. Annex 2. Public procurement of pharmaceuticals in Sweden – a general overview

The way procurement criteria for pharmaceuticals is usually set in Sweden can preferably be done based on a traditional life cycle perspective, separated into different phases as illustrated below in Figure 9.

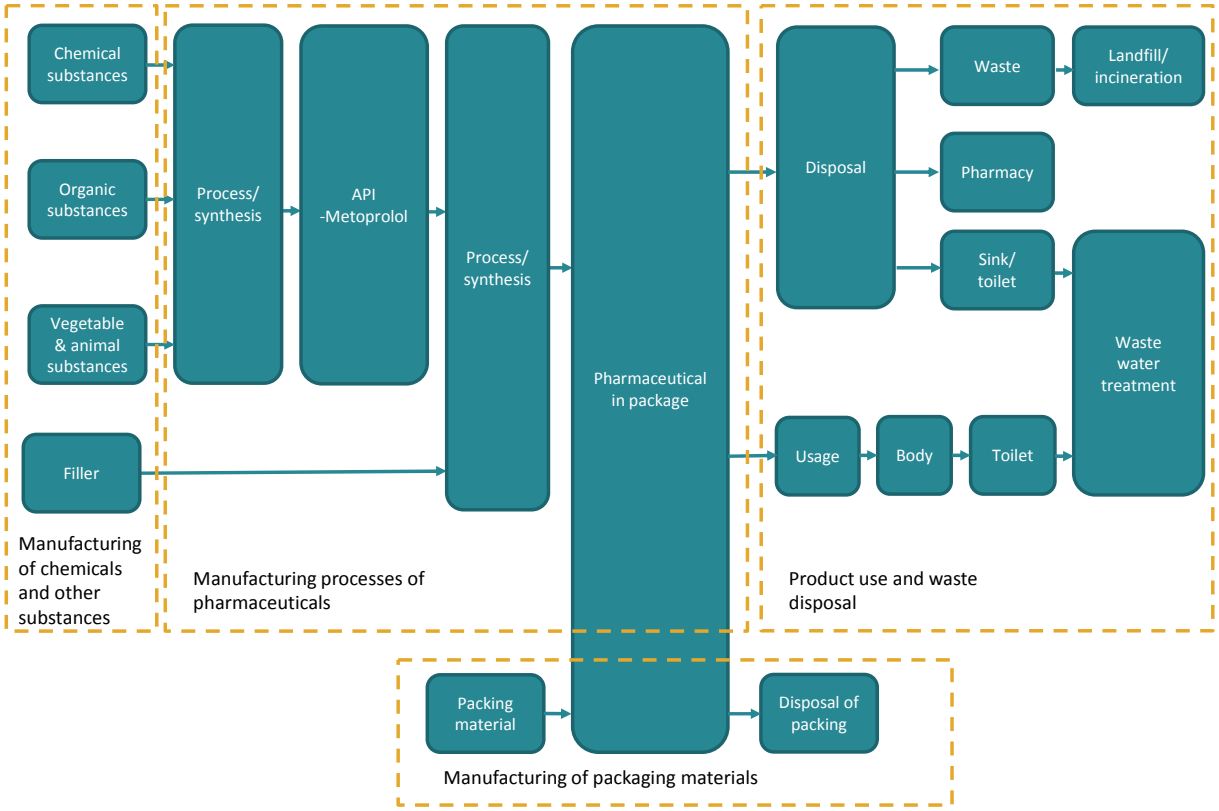

Figure 9. Outline of separation of the product life cycle of pharmaceuticals into different life cycle phases.

12.1. Criteria setting for the different life cycle phases

There are different possibilities to formulate procurement criteria for pharmaceuticals. Some of the more frequently used criteria are generally referred to below.

<u>Manufacturing of chemicals and other substances</u>

- Legislation
- Good environmental governance
- Continuous environmental improvements
- Substitution of hazardous chemicals/substances

- Waste handling

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Manufacturing processes of pharmaceuticals

- Legislation
- Good environmental governance
- Continuous environmental improvements
- Substitution of hazardous chemicals/substances
- Energy efficiency
- Emissions to air (SOx, NOx)
- Emissions to water (toxicity, BOD, COD)
- Waste handling

Manufacturing of packaging materials

- (Emissions to air and water - SO_X, NO_x and toxicity, BOD, COD)
- Information about packaging materials:
    - Paper bleaching
    - Use of PVC
- Waste handling

Product use and waste disposal

- Environmental information on active substances in Fass.se
- Information on how to dispose packaging materials

12.2. Criteria setting in Swedish County Councils

Table 1 summarizes the setting of criteria used in public procurement in all County Councils in Sweden during 2015[1].

Table 1. Overview of procurement criteria used in Swedish County Councils during 2015.

Landsting	**Miljökrav**	***Typ av krav***	**Sociala krav**	***Typ av krav***
Blekinge läns landsting	Upphandlingsmyndighetens rek. Krav	*Kontraktsvillkor*	Uppförandekod	*Kontraktsvillkor*
Dalarnas läns landsting	Upphandlingsmyndighetens rek. Krav	*Kontraktsvillkor*	Uppförandekod	*Kontraktsvillkor*
Region Gotland	Avropar från SLLs avtal. Systematiskt miljöarbete, obligatoriska krav på förpackning, miljörutiner i leverantörskedjan.	*Kvalificeringskrav på miljöarbete. Kontraktsvillkor på förpackning*	Uppförandekod	*Kontraktsvillkor*

[1] Lonaeus, K. (2016) Hållbara Läkemedel. Upphandling som styrmedel – En studie om möjligheter och utmaningar med hållbar upphandling av läkemedel. SIWI Draft Report, March 2016.

Region Gävleborg	Upphandlingsmyndighetens rek. Krav	*Kontraktsvillkor*	Uppförandekod	*Kontraktsvillkor*
Region Halland	Systematiskt miljöarbete, krav miljöinformation.	*Kvalificeringskrav*	Uppförandekod	*Kontraktsvillkor*
Region Jämtland/Härjedalen	Upphandlingsmyndighetens rek. Krav	*Kontraktsvillkor*	Uppförandekod	*Kontraktsvillkor*
Region Jönköpings län	Bedriva systematiskt miljöarbete.	*Kvalificeringskrav*	Uppförandekod	*Kontraktsvillkor*
Kalmar läns landsting	Systematiskt miljöarbete, förpackning	*Kvalificeringskrav på systematiskt miljöarbete. Kontraktsvillkor för miljöinformation*	Uppförandekod	*Kontraktsvillkor*
Region Kronoberg	Upphandlingsmyndighetens rek. Krav	*Kvalificeringskrav*	Uppförandekod	*Kontraktsvillkor*
Norrbottens läns landsting	Ta fram miljöredovisning inför upphandling eller under avtalstid	*Kontraktsvillkor*	Uppförandekod	*Kontraktsvillkor*
Region Skåne	Upphandlingsmyndighetens rek. krav samt fråga om PVC. Krav anpassade till det som upphandlas t.ex. vätsketerapi.	*Kontraktsvillkor, tilldelningskriterier*	Uppförandekod	*Kontraktsvillkor*
SLL	Systematiskt miljöarbete, förpackning och miljörutiner i leverantörskedjan.	*Kvalificeringskrav på miljöarbete. Kontraktsvillkor på förpackning*	Uppförandekod	*Kontraktsvillkor*
Sörmlands läns landsting	Inga krav utöver uppförandekod	*Ställer inge krav utöver kod*	Uppförandekod	*Kontraktsvillkor*
Uppsala läns landsting	Upphandlingsmyndighetens rek. Krav	*Kontraktsvillkor*	Uppförandekod	*Kontraktsvillkor*
Värmlands läns landsting	Inga krav utöver uppförandekod	*Ställer inge krav utöver kod*	Uppförandekod	*Kontraktsvillkor*
Västerbottens läns landsting	Upphandlingsmyndighetens rek. Krav	*Kontraktsvillkor*	Uppförandekod	*Kontraktsvillkor*
Västernorrlands läns landsting	Upphandlingsmyndighetens rek. Krav	*Kontraktsvillkor*	Uppförandekod	*Kontraktsvillkor*
Västmanlands läns landsting	Upphandlingsmyndighetens rek. Krav	*Kontraktsvillkor*	Uppförandekod	*Kontraktsvillkor*

Code of conducts for suppliers is requested in all procurement activities. Environmental criteria according to recommendations from the former Swedish Environmental Management Council were used in 11 cases out of 21, and in 7 of these there were additional environmental requirements, for instance on systematic

environmental work, requirements for phasing-out PVC and specific requirements for packaging.

Follow-up activities were carried out in only two County Councils based on a questionnaire which reviewed the requirements formulated in the contract clauses. In case the answers were not considered sufficient, specific meetings were held with the suppliers and improvement plans were established as appropriate. Activities are currently ongoing in cooperation with all County Councils to develop an online follow-up procedure to reduce costs and to share experiences.

13. Annex 3. Public procurement of pharmaceuticals in Sweden – selected cases

This project included a sub-study looking at public procurement of pharmaceuticals as selected cases to obtain further insights into life cycle flows both from a more scaled-up supply chain and from a mass-balance perspective for a specific pharmaceutical (Metoprolol) as well for a selected Public Authority (Stockholm County Council).

13.1. Life cycles for Metoprolol

A detailed illustration of ”upstream processes” for Metoprolol[2] is given in Figure 10. It gives much more detailed information about the manufacturing of API including processing of chemical and organic raw materials as well as syntheses and fermentation. It also gives better insights into all the steps involved in manufacturing of the final pharmaceutical product.

[2] www.ncbi.nlm.nih.gov/pubmed/26115339

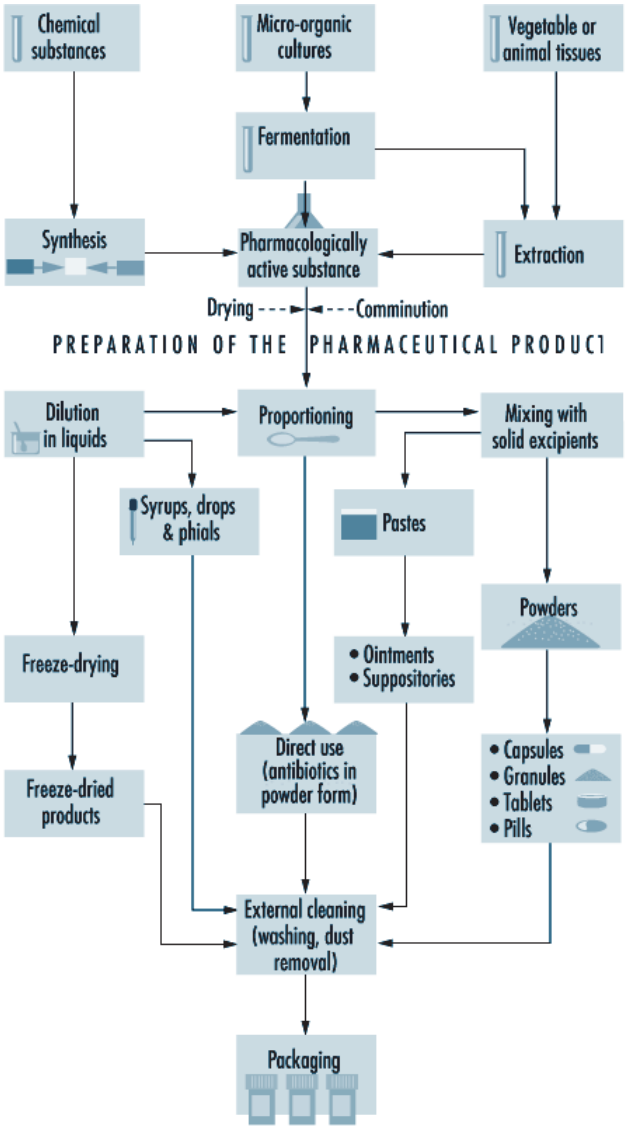
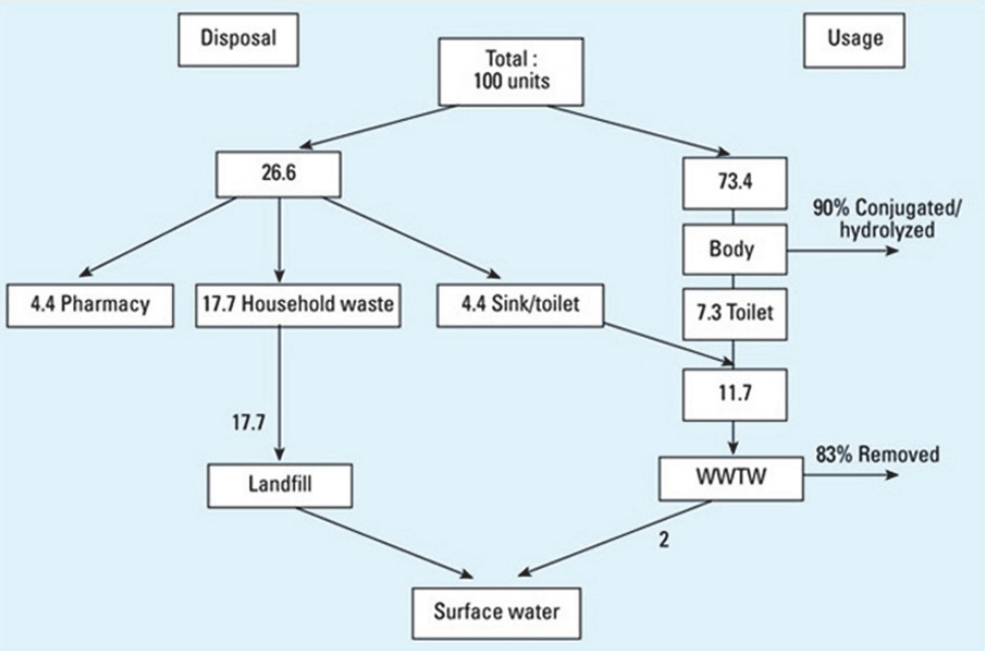


Figure 10. An illustration of the ”upstream product life cycle” for Metoprolol.

The life cycle for “the downstream processes” (use phase) based on a mass perspective is described in Figure 11. It shows the proportion of one unit of the pharmaceutical and how it is dispersed for disposal and usage in their various pathways to the recipient water. Almost three times the amount of pharmaceuticals are transferred via the human body compared to disposal, where most of it goes to landfill.



Source: http://www.medscape.com/viewarticle/518748_3

Figure 11. Mass-balance for Metoprolol in the downstream processes.

13.2. Procurement criteria as practised by the Stockholm County (SLL)

The procurement criteria used by the Stockholm County focusing on environmental aspects could be seen as separated into three parts:

- Requirements specified in "Environmental Annex for pharmaceuticals"
- Requirements specified in "Code of Conducts for suppliers"

13.2.1. Requirements specified in "ENVIRONMENTAL ANNEX FOR PHARMACEUTICALS

Information about the environmental work is linked to a certified environmental management system such as EMAS or ISO 14001 or an equivalent environmental management system. The supplier shall, no later than six months after signing the contract, have established a structured and documented environmental work plan, including an environmental policy, measurable and time-related goals, subject for examination by the procurer. The environmental work shall be active during the entire contract period. The supplier shall also appoint a person responsible for the environmental work and ensure that the goals will undergo follow-up activities at least once a year.

Additional to information about environment management systems there are requests linked to PVC plastics in the packaging materials where SLL has the

ambition to phase out all PVC plastics in goods and services. Only in exceptional cases will SLL accept PVC plastics in packaging materials.

There are also other requirements linked to the packaging materials of cellulose where the outer packaging shall be produced by recycled pulp, unbleached pulp or by pulp bleached without chlorine gas.

Suppliers shall additionally present environmental information and follow the model approach in "Environmental classification of pharmaceuticals" which includes information about risks, degradation and bioaccumulation.
The supplier shall also have implemented routines for evaluation of its sub-suppliers at the latest 6 months after signing the contract. The routines shall ensure that the handling of active substances and other raw materials/chemicals used in the manufacturing processes shall be done in a safe manner reducing the environmental impact to the extent possible, including as a minimum:

- A commitment to follow national legislation for environmental, health and safety in the country where the manufacturing takes place
- Control of pollutant emissions from the manufacturing site to soil, water and air
- An ongoing dialogue with sub-suppliers with regard to their control of environmental impact as referred to above
- A commitment to follow SLL´s environmental political program
- Provide information about separation of materials in the package

13.2.2. Requirements specified in "CODE OF CONDUCTS FOR SUPPLIERS"

The manufacturing company shall strive to minimize its resource and energy consumption, pollutant emissions to soil, land and water as well as waste. Chemicals shall be handled in a secure way, both from a human and ecological perspective.

Suppliers shall carry out their activities taking due consideration to the environment and follow local and national legislation. By strict routines to identify, measure and follow-up its environmental impact, suppliers can facilitate work towards continuous environmental improvement and minimize resource consumption and pollutant emissions. Suppliers shall strive towards making use of a life cycle perspective with regard to environmental impact from their goods and services and shall enforce environmental requirements on their sub-suppliers.

<u>Manufacturing of chemicals and other substances</u>

- Suppliers shall have implemented routines to ensure that the use and handling of active substances and other raw materials/chemicals in the manufacturing of these substances will create as low environmental impact as possible. This shall, as a minimum, include:
    - National legislation covering environment, health and safety

    - Control of pollutant emissions to soil, water and air
    - Suppliers to have an ongoing dialogue with its sub-suppliers with regard to their emission of chemicals to soil, water and air

Manufacturing processes of pharmaceuticals and sales

- Environmental work
    - The supplier shall, at the latest six months after contract signing, have implemented a structured and documented environmental work open for examination
- Environmental information
    - The supplier shall present of environmental information following "Environmental classification of pharmaceuticals" which includes information about risks, degradation and bioaccumulation
- Compliance with "Code of conducts"
    - The supplier shall show compliance with prescribed "Code of Conducts" including commitments to follow national legislation and the ambition to make use of a life cycle perspective when working with reduction of environmental impact from good and services

Manufacturing and waste disposal of packaging materials

- PVC compounds in the packaging materials
    - PVC compounds should not be used in the packaging materials
- Packaging materials of cellulose
    - Outer packaging shall be produced of recycled pulp or unbleached pulp or of pulp bleached without chlorine gas
- Separation of packaging materials
    - The suppliers should, upon request, give information about have to separate the different types of material in the package

Product use and waste disposal

- No requirements or recommendations are being used

14. Annex 4. The CSR compass – suggested input of the environmental dimension into a sustainability compass

Note! This Annex is meant to provide an overall input for how to include environmental information into the CSR Compass for public procurement. It is based on the same staged approach as for the existing CSR Compass and are in may contexts the same, but has been somewhat modified with regard to the various planning steps to better suit the type of information relevant for environmental aspects.

Future work on this concept needs to amend recommended links and references to other sources for different types of more detailed guidelines.

14.1. Ambition and organization

A top-level management commitment is of vital importance to enable the procurement organization to work in a systematic and structural way with green public procurement including all phases of the entire procurement process.

It is beneficial to organize the procurement work based existing management procedures and routines to secure that the overall environmental ambitions will be dealt with in close connection to the procurement activities.

There is a need for political support for buying goods and services having a high impact on the environment to increase the possibility and acceptance of setting environmental criteria in public procurement. On an organizational level, a well-defined policy could be very helpful in a procurement organization as an internal platform for identifying the necessary prerequisites for being successful in the procurement process and to meet pre-set goals. Initially, it is important to decide how to carry out the work and on what level of ambition.

It could also be worthwhile to, as early in the process as possible, have a dialogue with suppliers to get their expectations and present some of the details in the procurement policy. The following issues are usually important to identify:

- To what extent has internal resources been allocated to the procurement process?
- What types of procurement criteria are currently being used?
- Are there new specific procurement routines that must be considered?
- Can the work be more effectively coordinated if other parties are included, either internal or external?
- What are the expected deliverables viewed both from a short-term and long-term perspective for both the procurement authority and the supplier?

It is good to initially focus on some selected product groups; for which specific requirements are set and where follow-up activities will be carried out. Based on the results and experiences of procuring such product groups, other product groups can be further added.

Even if the available resources (financial or personal) are limited there are always possibilities at hand to work with green procurement with good results. Some examples of such possibilities are to make use of different tools for making priorities and identify risks with procuring selected goods and services or to carry out follow-up activities in a systematic way making use of recommended matrices.

14.1.1. Setting the organisational framework

There is a need for strong and dedicated top management commitment to effectively make use of environmental (green) procurement as a contribution to sustainable development. A strong engagement for green public procurement from the top management will give the procurement unit the possibility to prioritize buying goods and services that are environmentally beneficial. Such a mandate should enable access to personnel resources as well as ensure a sufficient budget for the entire procurement process.

It is equally important to set a long-term strategy for the organization. The strategy should include ambitions and plans on how to achieve far-reaching sustainability goals. Some useful advises could be to:

- define a clear and understandable vision as well as a procurement policy,
- establish work with a management system,
- make use of existing processes,
- distribute and appoint roles and responsibility,
- educate the personnel, and to
- take into account relevant legal prerequisites.
-

When environmental aspects are to be integrated in the procurement process some key aspects need to be considered. First, it is necessary to define roles and responsibility for those involved in the work. In order to facilitate such an approach it could be beneficial to develop:

- A decision matrix giving an overview to what the organization has committed itself to
- A work plan following the procurement policy showing the different work elements within the procurement process that should include environmental aspects
- An implementation plan focusing on how to carry out the work in practice.

14.1.2. Well-defined and concrete objectives linked to a fixed time schedule will give clear motives and activities linked to these aspects. Make use of existing processes and resources

A good way to integrate the environmental dimension into the procurement work in an efficient manner is to initiate new procurement activities as early as possible. If it is possible to make use of guidance documents, existing checklists, internal reporting systems or external communication activities it will make it easier to ensure the environmental dimension will become a natural part the procurement activities.

Defining different roles and responsibilities among the personnel, as mentioned above, should be done in the initial phase. It is often an advantage if it is identified and recognized among the entire staff who:

- is responsible for different activities
- has the mandate to take decisions at different levels and
- will carry out the follow-up activities

Some essential questions to settle in this context are listed below.

- *Who decides whether the organization has the necessary skills and experiences*? Capacity and competence are key to secure an efficient procurement procedure. If an organization do not have the possibility to secure such a function in- house, it is always possible to engage and contract external experts.
- *Who will decide when to ultimately formulate the environmental criteria?*
- This can either be dealt with as a part of the procurement policy or become an operational decision for the procurement unit to decide upon. It is important to emphasize that every procurement activity must have a certain degree of flexibility to ensure an efficient procurement process (from an environmental point of view).
- *Who has the responsibility to carry out the follow-up activities?*
- Follow-up activities are typically the element in the entire procurement process that fails with regard to appointing necessary resources. In larger organizations, it might be good to have a central function for all types of follow-up activities, not only the ones for green procurement. For smaller organizations, it might be more efficient to initially let a qualified external consultant be responsible for the follow-up activities but later on, when the organization has learned about suitable procedures for follow-up activities, manage these procedures themselves.

With regard to education and awareness-raising among the personnel it is important to clearly motivate why and in what way the environmental dimension shall be a part of the procurement process. In many situations there is a need, not only for a general understanding of the importance to consider environmental aspects, but also to gain full acceptance of the type of work every individual is expected to carry out. The education, apart from information about environmental issues as such, should highlight most of the elements listed below.

- What is expected out of everyone being a part of the procurement procedure?
- Who carries the responsibility for distributing the necessary tasks among the personnel?
- What type of guidelines and tools are available to help and support the procurement work?
- Who will be the contact person in case different types of questions arise?
- Who is responsible for internal reporting and external communication?

There are several advantages if the education can be held as a staged approach enabling questions and eventual uncertainties to be settled as they appear. Such a procedure will most likely contribute to secure the awareness and maintain the importance of green public procurement.

14.2. Planning

It is important to integrate environmental considerations already in the planning phase of procurement.

Be sure to devote sufficient time in the planning phase to be able to properly define the actual demands for new products in your organization and what the market has to offer.

Set the highest priority to products with a minimum risk for environmental degradation.

Environmental considerations ought to be included already in the planning phase of any procurement activity. In the planning phase there are usually many possibilities at hand to consider the degree of demand to incorporate environmental considerations. Later in the process such decisions tend to become much more time-consuming and costly. From an environmental point of view it is beneficial to make an overall assessment if the goods and services, intended to be bought, cause a significant environmental impact. If this is the case, there are good arguments for making use of environmental criteria in the procurement process that contribute and stimulate future environmental improvements for those goods and services.

The need for addressing environmental aspects in the procurement process should be based on a risk assessment. Priorities should be set based on the risk assessment, including all relevant issues to consider from the total volume of goods and services, available resources (both with regard to competence and economy) and the commitment to carry out follow-up activities.

14.2.1. Demand and market analysis

Defining the purchasing demands is a vital component in all procurement processes. When the demands are identified the next step is to describe how the market can meet these demands. Relevant issues to clarify are:

- Who is going to make use of the purchased good or service?
- When will the demand actually arise and for how long?
- Are there specific environmental requirements that have to be met?
- Are there reasons for the demands to be revisited in the future?

- Are there reasons for the demands to consider other activities in the organization (having the same demands)?
- Is it possible to find other alternatives to meet the identified demands, e.g. by leasing a product?
- Are there suppliers on the market that can offer products fulfilling the identified demands?

A thorough preparation based on a demand and market analysis will usually result in a lot of valuable information for the formulation of tenders as well as the follow-up activities. Information about the environmental work by suppliers can usually be found on their websites or in their environmental or sustainability reports. However, as this type of information usually differs from one supplier to another, it is recommended to ask for additional details as specific "Request For Information" (RFI). It is important to utilize this possibility to collect additional information as it is an indication, from the Procurement Agency, that the environmental dimensions are important in the upcoming procurement.

Several types of questions could be used, such as:

- Do you have a certified environmental management system?
- How do you incorporate a life cycle perspective in your environmental work?
- How is your environmental work connected to the UN Sustainable Development Goals?
- How do you identify your significant environmental aspects?
- Which are your significant environmental aspects and short and long-term environmental targets?
- Describe the routines in your environmental work with regard to distributing responsibility and track the environmental performance of your sub-suppliers?
- How do you follow-up your environmental work and secure continuous improvement?
- Can you present the documentation sent in to the Medical Agency in relation to the registration and approval process?
- Can you present a Carbon Footprint for your products?

It is always an advantage to have an early and continuous dialogue with potential suppliers.

This usually raises the interest by potential suppliers to participate in the upcoming tendering process. Additionally, this may facilitate relevant criteria to be included when formulating the tender document.

14.2.2. Risk assessment

One further step in the planning procedure could be to carry out a preliminary risk assessment of all goods and services that are subject for being bought in the future. This is to select those goods and services where environmental criteria are relevant

to be used. A risk assessment is valuable in order to identify and set priorities for those products that are most important to focus on. Such an approach will make it possible to focus on products with comparable high environmental impact offered by reliable and responsible suppliers.

It is usually wise to start in a small scale by selecting a few product groups to study and learn from before introducing environmental aspects on a broader scale. Internal aspects to consider are e.g. the level of ambition, prevailing competences and available resources. External aspects to consider are e.g. if there are specific environmental or health risks connected to potential suppliers, their manufacturing processes viewed from a life cycle context or if some suppliers have failed in meeting contract requirements in earlier procurements.

It is often a fairly time-consuming process for a procurement organization to get hold of all vital background information about the environmental performance of the goods and services up for procurement, as well as on the status of potential suppliers. However, this is often crucial for larger organizations to obtain and they usually have sufficient resources available.

In smaller organizations with limited resources it could be good to consider some overall strategic decisions to be taken, for instance:

- Extent and importance of the procurement.
- Buying large volumes of goods and services will most likely give the procurement organization more influence to actually get what they want. If organizations have limited resources to follow-up contract deliverables they should prioritize the ones with the largest volumes and the higher risks.
- Type of procurement.
- A framework agreement will increase the possibility to a systematic dialogue and cooperation with suppliers. Separate contracts will often lead to limited possibilities of carrying out sufficient follow-up activities.

It is important to keep in mind that is not allowed to discriminate suppliers or boycott separate companies, i.e. companies with production in countries where environmental problems are reported to take place. In public procurement all suppliers have to be treated on equal terms.

14.3. Setting criteria and evaluation of bids

Advise and information on how to select and set environmental criteria and how to properly identify and formulate this in the tendering process.

A dialogue with suppliers and potential bidders is valuable to describe and communicate planned requirements.

A third-party verification will facilitate the work of the procurer as it is a reliable proof-of-evidence that a good or service meet the requirements set in the tender document.

Setting environmental criteria is usually a multi-facetted task involving many types of considerations. In principal it consists of two major phases:

- Identify relevant environmental criteria
- Consider how to formulate the criteria

There are different types of requirements that generally can be used in a procurement context:

- Technical requirements: specify a physical characteristic of goods or services, e.g. recycled or renewable content, mercury-free, or the way in which the product is manufactured or delivered, e.g. organic or sustainably managed timber and fisheries
- Performance requirements: define the performance standards to be met by the goods or services including definition of the way the good or service have to be delivered in order to optimize social and environmental performance. For example, standards of care and number of patients for a social care service, delivery time, waste, relocation and carbon emissions reduction
- Functional requirements: define the proposed function to be fulfilled by the goods or services required. For example, the strength and durability of concrete to be supplied or energy/fuel efficiency.

Generally, a combination of performance and functional requirements are preferred as they enable suppliers to propose the most efficient technical solution for the required performance or function, leading to potential sustainability benefits such as better energy performance, reduction of waste, advanced safety precautions for users, universal design, disposal and end of life management. The organization

should be careful when using technical requirements not to specify particular brands unless it is absolutely unavoidable and acceptable by law.

There are four different types of criteria usually practiced in according to the EU Directives for Public Procurement:

- Qualification criteria: Qualification criteria relates to the technical and professional capacity of suppliers. These criteria could reduce the possibility of a supplier to leave a bid as these requirements have to be met from the start. It is therefore important that the qualification criteria such as size, competence and economic status are clearly described to avoid that procurers omit fully capable bidders. As a consequence of this, the use of sustainability criteria is often very basic and can e.g. be limited to only requirements for management systems.
- Technical Specifications: Technical specifications are usually directed towards the products to be procured and shall be described in the procurement advertisement or tender document. Information shall also be given about the assessment procedure, i.e. in case evaluation criteria are used.
- Evaluation criteria: Evaluation criteria should focus on sustainability elements considering technical characteristics about the product performance. In the event that several evaluation criteria are used the tender document shall describe the weighting technique between the criteria, in practice how many points or percentage will be allocated to the different criteria.
- Contract clauses: Contract clauses are mandatory and need to be fulfilled by all bidders, but they do not have to show that the requirements are met in the qualification phase. The requirements should be met during the agreed contract period for the contract, which makes contract clauses a flexible and efficient tool. Furthermore, the contract clauses must be proportional and linked to the subject matter for procurement.

Contract clauses are a very useful tool in a procurement context especially for follow-up activities. They can include a number of purposes, such as:

- Commitments to comply with *Code of Conducts* (which usually is more relevant for social aspects but can be used for environmental aspects, especially for more complex procurements with extensive supply chains)
- Continuously improve their environmental performance
- Passing on procurement requirements along the value chain from suppliers to their sub-suppliers and a mandate to follow-up achievements reached by sub-suppliers
- Regular reporting from suppliers about the result of their environmental work as a result of the procurement criteria
- Information about compliance with other duties related to suppliers environmental work such as *Producer Responsibility*

In many cases, suppliers are reluctant to leave information that could be regarded as a part of intellectual properties needed to be protected for a company to maintain its competitive edge as such information may have to become public in the evaluation of bids. However, it seems that tender documents often require much more information than actually needed for the evaluation. Here, public authorities must be cautious and not ask for more information than actually being understood and used by themselves in their evaluation. In doing so, it is most likely that the information required will not be detailed enough for other parties to reveal company secrets.

It is possible to omit a supplier in case the leave a bid with an unreasonable low price, which could be an indication of that it do not fulfil all requirements set. In such a case the supplier shall always be given the possibility to explain the reason for its low offered price.

14.3.1. Dialogue with suppliers and potential bidders

It is to recommend to inform about the requirements planned to be used in the upcoming procurement process in due time. One way could be to arrange a workshop/seminar where suppliers and representatives from branch organizations are invited to attend. The objective with such an arrangement is to inform about the time schedule for the procurement to come and to present the environmental criteria planned to be used. As a result suppliers attending the workshop/seminar can prepare activities to meet the requirements in case they need additional activities to do so. It could also be good to invite other interested parties to attend the meeting. The meeting could include both external stakeholders as well as the organization´s own procurement staff.

14.3.2. Verification

There are different types of verification/proof-of-evidence that could be required from potential suppliers. As a common practice in procurement a supplier can either show the fulfilment of requirements by making use of self-declaration scheme or through a third-party certificate.

Self-declarations

A supplier can prove that they fulfil the requirements by a self-declaration showing established routines on good management practices (GMP) and work with continuous environmental improvements including supply chain management. It is important that the tender document clearly inform about when a supplier could choose to deliver such a statement, and the content of such a statement.

Third-party certification

A third-party certification means that a third-party verifies that an offered good or service meets the preset requirements, which considerably simplifies the work for a procurer as they do not have to check the information themselves. There are several types of third-party certifications available on the market. It is important to be

aware of that a certification system usually is limited to cover certain parts of the production in a life cycle context. In complicated supply chains many upstream production units may not be covered at all.

14.4. Follow-up activities

Follow-up activities should always be carried out to check the compliance as stipulated in the contract. Primarily it creates credibility for the procurement organization but also to secure equal treatment among the suppliers.

It is usual quite difficult for a procurer to gain a good insight about the environmental performance and deliverables from suppliers. In contract clauses a procurer can set requirements on their suppliers, being the principal contract partner, but also for suppliers to have clear instructions for control of sub-suppliers.

Follow-up the fulfilment of environmental criteria is very important and necessary of several reasons. Primarily it creates credibility for the procurement organization by showing that the conditions and requirements included in the tender document will be subject for control and evaluation. If not there is a risk that the criteria will have no practical environmental effect. It is also necessary to avoid any contradiction with the principle of equal treatment which, in case no follow-up activities take place, can jeopardize fair competition and may favor suppliers that may not fulfil all pre-set requirements.

Many procurement authorities face limited resources to carry out follow-up activities. It is therefore to recommend to secure necessary resources for follow-up activities prior to drafting the tender documents. As a general rule it is not good to set stringent environmental criteria if they face not to be followed-up.

Some useful advises when planning follow-up activities are listed below.

- Prioritize your follow-up activities when allocating resources for the entire procurement process
- Decide when the follow-up activities shall be carried out
- Send out an enquiry to the suppliers and evaluate the responses when found necessary (if not included in contract clauses)
- Make use of regular meetings with suppliers as appropriate
- Carry out site-specific supplier visits in case problems arise in the regular communication with suppliers

When working with social criteria these types of activities is often common practice. However, when including environmental aspects in procurement,

suppliers usually have to report annually on their environmental work to surveillance authorities, in annual corporate reports, in sustainability reports etc. it is therefore fairly easy for a procurer to keep track on supplier´s environmental work without requiring additional environmental information. Hence, the need for enquiries, meetings or site visit is not required in the same way.

14.4.1. Systematic follow-up activities

It is usually difficult for a procurer to have sufficient overview and control of environmental information in the supply chain. This should perhaps be feasible for a main supplier who has signed the contract but in more complex supply chains with several sub-suppliers it becomes much more difficult. It is therefore natural to discuss what a reasonable responsibility for a procurer is in this context and what is the responsibility of a supplier and their sub-suppliers?

The aim of setting environmental criteria is that they should be relevant for the entire supply chain. As a procurer it is important to initially focus the follow-up activities on the contract partner. The procurement legislation will not allow a procurer to set specific requirements on sub-suppliers. However, it is possible for any supplier to set requirements on their suppliers (i.e. the procurer´s sub-suppliers). It is therefore recommend that procurers shall demand suppliers to have clear instructions and routines for them to manage and control their own suppliers. Procurers should therefore specify routines for suppliers to provide the required environmental information along the supply chain. This will also include sub-suppliers that should report on the outcome of their environmental work. Clear commitments and engagement by suppliers and sub-suppliers in this context will most likely lead to a higher probability that the environmental work by all parties will be sustained over time both during and after the duration of the contract. It is most likely that suppliers' which gets asked for good environmental performance will gain market advantages in future procurements.

Requirements set as contract clauses must be controlled during the contract period, which should be clearly indicated in the tender document. It is wise not to wait too long before initiating the follow-up activities to show that a procurer is serious with the requirements set. This will also ensure that the correcting measures can be implemented before the end of the contract period.

Procurers should be aware of that industrial branches may differ with regard of having experiences in supply chain management. If a contract is signed with a supplier that can handle their own suppliers in an efficient way it is most likely that they can respond to questions and enquiries from procurers within a fairly limited time (maybe already within 3 months). However, if that is not the case the response time for questions and enquiries might have to be prolonged to some 6 months or even longer. Information about the status of potential suppliers with regard to experiences of supply chain management including environmental aspects should

therefore be a part of market and risk analysis carried out at the start of the procurement (in the planning phase).

A detailed plan for follow-up activities should be established, especially for those suppliers where low compliance can be expected, to ensure that the requirements in the contract are fulfilled. In such cases a recommendation could be to ask for a third-party certificate or an equivalent proof-of-evidence to safeguard reliable environmental information.

14.4.2. Possibilities for sanctions

It is quite common that non-compliances are identified even though suppliers have programs running for continuous environmental improvements. In cases of significant breaches of the contract sanctions may have to be considered. They could either have the form of corrections, fines or cancellation of the contract.

Corrections are to prefer in cases of minor non-compliances or shortcomings at the supplier organization which could be fairly easy to cope with. The use of fines should be limited and, in the first place, activated as a means of pressure and get the supplier aware of the need for making corrections and improvements. Cancellation of contracts should be seen as the very last way to act in case the supplier show no interest and are unwilling to carry out necessary corrections or provide the procurement organization with misleading information.

14.5. Continuous improvement

Procurement work could very well include organizational work at the supplier level for continuous environmental improvements. Therefore suggested measures for improvement ought to be subject for discussions between procurers and suppliers before setting the framework for the follow-up activities.

A plan for improvement of the environmental work should be settles between the procurement organization and the supplier if found necessary. The responsibility to handle the execution of the plan rests with the supplier.

In public procurement there are some limitations as to establish long-term cooperation with contractors to find ways for future environmental improvements. In terms of procurement, public procurement organizations do not have the same legal flexibility as private companies in cooperation with suppliers through education and competence-raising to improve the environmental performance, as this might be in conflict with the proportionality principle. However, there are other ways to accomplish measures to combat deviations; some of these are listed below.

- Inform both the staff in the procurement organization and the supplier about the results of the follow-up activities
- Adopt a plan of actions for improvements
- Check the measures for improvements
- Consider the use of sanctions

14.5.1. Inform about the results of follow-up activities

It is important to early on inform the supplier about the results of the follow-up activities especially if non-compliances have been identified with regard to meeting the requirements and, if not, what fails and to what extent. In case there are non-compliances these have to be included in an action plan for improvements.

It is a usually good to inform the internal staff in the procurement organization, which directly or indirectly are involved in the procurement process, about the results of the follow-up activities. Taking environmental considerations in the procurement process could be a fairly new concept for some people in the staff. In such a situation it is especially important to describe the reasons why environmental criteria have been introduced. This could be used as basis for understanding the outcome of the follow-up activities which will lead to awareness- and competence-raising among the staff. The personnel shall also be informed about suggested measures to be taken.

Finally, it should be noted that if the follow-up activities identifies a significant breach of the procurement agreement, it could lead to sanctions and ultimately cancellations of contracts – see above Chapter 14.2.

14.5.2. Measures for improvement

Environmental management usually includes organizational work for continuous environmental improvements. Therefore measures for improvement ought to be subject for discussions between procurers and suppliers before setting the framework for the follow-up activities. This is especially important where non-compliances have been identified. Non-compliance could have different forms either being systematic i.e. linked to processes and routines in the organization of the supplier. In such a case the processes and routines may have to be somewhat modified. Modifications should be requested by the procurer. Other forms of non-compliance could be more of a practical character e.g. linked to the handling and delivery of the goods and services. These forms of non-compliance are much easier to correct.

The plan should be as concrete as possible to avoid misunderstanding and facilitate future control of the suggested measures. Such a plan should, as a minimum, include:

- a description of the non-compliance identified,
- agreed-upon measures for improvement,
- responsible contact person at the supplier, and a
- time schedule for correcting activities

It is important to emphasize that the suggested measures for improvement must be proportional to the magnitude of the non-compliance. For urgent measures needed, improvements may have to be taken care of and follow-up as an immediate course of action.

It is also worth mentioning that it might be time-consuming for a procurement organization to engage in following-up the plan for improvement. However, it is important that the expectations what to be achieved by the procurement are realistic and fully understood by the supplier. The responsibility to handle the execution of the plan for improvements rests with the supplier. It is more rational for the procurement organization to check the execution and fulfilment of the plan for improvements. In some more complex situations it could be necessary to involve an external auditor to check and verify that the measures are carried out according to plan.

14.6. Communication and reporting

Communication and reporting are vital components in the procurement process. Communication and outreach activities can be carried out in several ways and directed towards different audiences.

Internal communication will ensure that all personnel in an organization will be aware of commitments and policies with regard to procurement, which will result in better knowledge about and increased engagement in procurement activities. External communication is needed to reach out to outside audiences including, stakeholders, interested parties, branch organizations, authorities and suppliers.

An annual report on the procurement work is preferred both for internal and external audiences. An annual procurement report should be seen as a voluntary ambition to distribute information to a wide audience having a special interest on a more detailed scale and for assessing and evaluation the procurement work.

Communication and reporting can have several objectives, e.g. to inform:

- top management about the results of the procurement activities and how they have met policies and targets,
- internal staff working with procurement,
- public authorities working with procurement of similar products,
- potential suppliers on future environmental criteria to meet, and
- the public at large focusing on citizens in the local community.

14.6.1. Internal communication

A comprehensive and reliable internal communication will have several advantages, some of which are listed below.

- Involvement of more in-house experts in other areas through better knowledge in the organization of why environmental aspects are to be seen as natural parts of the procurement activities. It may also raise the interest in general of the procurement activities, which might help to avoid situations where only a few very motivated persons will carry the full responsibility for the procurement
- Securing that policies and strategies are well-known and met

- Awareness-raising and increased attention on the procurement work, as guidance to all personnel, about how the work is carried out and what it means for the entire organization and specific units

There are several ways of internal communication i.e. via intranet, homepages, physical meetings or webinars. Making use of as many different means of communication as possible will increase the possibility to reach out to a majority of employees.

14.6.2. External communication

External communication can meet several requirements, some of which are listed below.

- Making the procurement visible
- Describing an organization´s strategies and ambition to reduce the environmental impact by effective public procurement will strengthen the organization´s competitive edge in many aspects. Information about procurement work at a public authority has quite a large public interest as well as from various stakeholders where they can learn about how to identify the environmental issues and the possibility to mitigate them through a systematic procurement process and follow-up activities
- Openness and transparency
- Showing how the procurement process is carried out and what results are obtained throughout the process. This should be presented in an open and transparent manner to gain credibility
- Good environmental behaviour
- Showing the systematic procurement work will increase the awareness and understanding of the organizational work and the complexity of including the environmental dimension into the procurement work and how to cope with and reduce product-related impact on the environment
- Influencing the market and potential suppliers
- Open information about significant environmental aspects to consider and the current selection of relevant environmental criteria in the tendering process of goods and services is usually of vital importance to indicate views on possible future use of environmental criteria in upcoming procurement – key information to the market and potential suppliers to meet to become successful in future procurement

External communication should, in the first place, make full use of existing in-house communication channels e.g. via homepages, annual reports and advertising. There are also ways of external communication making use of local, regional and national media. External communication about the procurement processes and the results gained should always be included in connection to sustainability reporting. Making use of as many communication channels as possible will increase the possibility reach out to a wide external audience.

14.6.3. Reporting

Many organizations are increasingly making use of existing and recognized reporting tools such as Global Reporting Initiative (GRI) or the UN Global Compact – tools that make it possible to include information about the procurement activities.

For organizations not having specific requirements for reporting or will adjust to common structures in publicly available tools, an advice is to follow a structured outline starting with the established commitments according to a procurement policy and thereafter describe its procurement activities in accordance with all elements in the entire procurement process.
Such an approach could give the following advantages:

- communicating commitments in the way an organization work,
- possibilities of alignment to performance tracking and continuous improvements,
- report on how the work has progressed related to the procurement policy and objectives set, and
- providing a quantitative baseline for evaluation and benchmarking of the results gained.

To be able to evaluate and benchmark the results of procurement activities, either internally or externally with other organizations, it could be useful to include some key aspects e.g. the extent of:

- open dialogues with potential suppliers,
- contracts including environmental information,
- contracts where importance of environmental information for the winning bidder was dominating, and
- contracts where the environmental information have been subject to followed-up activities.

The reporting activities should be revisited at regular intervals to allow improvements and future refinement of the procedures used.

Procurement of pharmaceuticals in an environmental context and its inclusion into the CSR Compass

REPORT 6735

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This report focuses on procurement of pharmaceuticals in an environmental context. The report presents where, from a pharmaceuticals life cycle perspective (research, production, use), it may be appropriate to impose environmental requirements based on a procurers' perspective. The report also suggests amendments to the CSR (Corporate Social Responsibility) Compass based on the experiences gained from the pharmaceutical industry.

Sustainable Public Procurement is a key area for reaching the Swedish Environmental goals as well as in the work to promote Sustainable Consumption and Production in line with UN's 10-year Framework Programme (10YFP).

The pharmaceutical industry was chosen as the sector to review due to the complexity of procurement of pharmaceuticals and in order to identify different types of obstacles for procurers in their daily work. It is a complex industry that lack transparency and environmental information is rarely a part of the process when procuring pharmaceuticals.

- The project includes different sub-studies with the specific objectives to:
- Understand the current knowledge of procurement of pharmaceuticals in the literature
- Review the use of public procurement in Sweden
- Understand the implications of public procurement applied to case studies.

Global Action for Sustainable Consumption and Production

Swedish EPA SE-106 48 Stockholm. Visiting address: Stockholm - Valhallavägen 195, Östersund - Forskarens väg 5 hus Ub, Tel: +46 10 698 10 00, fax: +46 10 698 10 99, e-mail: registrator@swedishepa.se Internet: www.swedishepa.se **Orders** Ordertel: +46 8 505 933 40, orderfax: +46 8 505 933 99, e-mail: natur@cm.se Address: Arkitektkopia AB, Box 110 93, SE-161 11 Bromma. Internet: www.swedishepa.se/publications