

Sustainable Pharmaceuticals

– Public Procurement as a political tool

A study of sustainable public procurement of pharmaceuticals

APOTEK 



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 Stockholms läns landsting

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 CODE OF CONDUCT
FOR SUPPLIERS
SOCIAL RESPONSIBILITY IN PUBLIC PROCUREMENT

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Foreword

This report is the result of a project conducted within the Swedish International Water Institute (SIWI) and its cluster group Water and Pharmaceuticals. The purpose of the project was to survey the current methods for setting sustainability requirements and monitoring compliance with them in the procurement of pharmaceuticals in order to identify areas for improvements. The recommendations highlighted in this report were submitted to the National Agency for Public Procurement prior to their process during 2016 to develop new environmental and social criteria in the procurement of pharmaceuticals. The report also aims to inform relevant stakeholders about the possibilities and challenges with promoting sustainable development through public procurement. The report is based on a pre-study¹ which was conducted during spring 2015, followed by a consultation round between the participating organisations in the cluster group Water and Pharmaceuticals.

The report has been written by the project group 'Procurement as a management tool', but the cluster group as a whole has participated in- and supports the report's content, discussion areas, reflections and conclusions.

¹ Lonaeus, K., 2015, Copenhagen Business School. The study is based on interviews with industry organisations, and on observations from and interviews with buyers and experts within sustainable procurement.

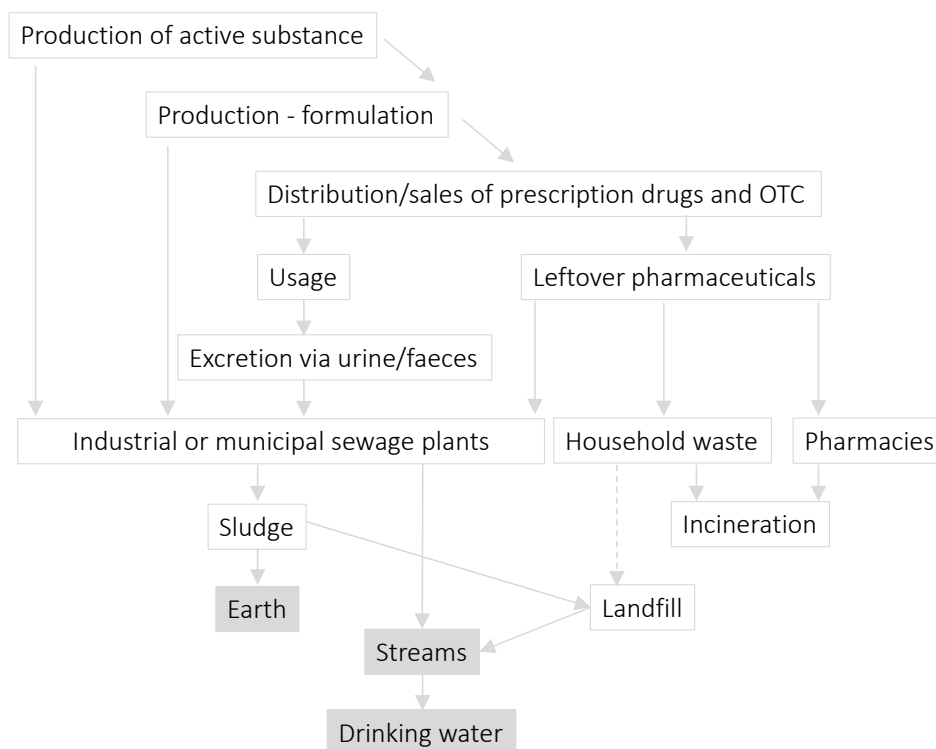
Why sustainable public procurement of pharmaceuticals?

In Sweden, access to health care is a basic civic right. Pharmaceuticals are fundamental to the health and medical care system's ability to cure and treat medical conditions, but they also represent a threat to human health and to the environment.

Pharmaceuticals are manufactured to be chemically stable so that they are not degraded before they reach the target organ (Larsson, 2011). Pharmaceuticals that are not degraded in the body are transported via urine and faeces out into wastewater systems and treatment plants. Due to their chemical stability, pharmaceutical substances are not normally eliminated in wastewater treatment plants and therefore end up in water and soil. A significant problem that has attracted much attention in recent years is the discharge of pharmaceuticals during production. A large proportion of pharmaceuticals are manufactured in low-cost countries such as India and China. Research studies conducted since 2007 in both India and China show very high concentrations of pharmaceuticals in

wastewater². A study from 2007³ for example showed that wastewater treatment plants in Andhra Pradesh in India were discharging therapeutic substances at levels roughly over 1 million times the levels discharged by Swedish wastewater treatment plants. The results also showed that pharmaceutical substances had spread to the groundwater and drinking water, creating severe problems for local populations. What is particularly concerning according to the researchers is the discharge of broad-spectrum antibiotics – that is antibiotics that target many different bacteria – because of the risk for developing resistant bacteria. We know from research that where large quantities of antibiotics are discharged into the environment, the occurrence of resistant bacteria and resistant genes is very high. These environments also facilitate the transmission of resistance between different species of bacteria⁴. Consequently, as we are increasingly facing a global human threat in the development of multi-resistant bacteria, we cannot just look at pharmaceutical consumption and the use of antibiotics in animals

Figure 1. Main flows of active pharmaceutical substances for human use to the environment (Larsson & Löf, 2013, s.1183)



² Larsson, 2007; Li et al, 2008

³ Larsson DGJ, de Pedro C and Paxeus N., 2007

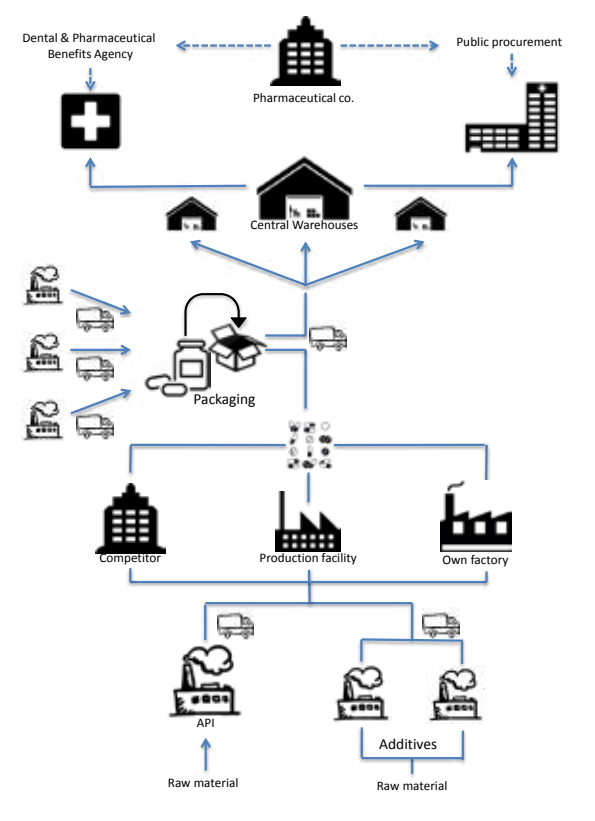
⁴ Larsson & Löf, 2011

and humans. We must also study production patterns in order to understand their spread. Wastewater treatment plants where antibiotics and faeces are mixed, have been identified as a potential breeding ground for the development of antibiotic resistance⁵.

Joakim Larsson (2010), professor in environmental pharmacology at the Sahlgrenska Academy in Gothenburg, Sweden, traced the origins of 242 products on the Swedish market containing any of 9 active substances discovered in outflows in India. Thirty-one per cent of the products and their active substances could be traced back to a wastewater treatment plant in India and the production facilities that sent their wastewater to this plant⁶. This type of research provides a clear indication that pharmaceuticals in the environment and their local and global impacts are of international proportions, where a number of stakeholders need to take active responsibility. For Sweden, this means that involved actors have an obligation to ensure that pharmaceuticals circulating the domestic market are not negatively impacting the environment or people's health and well-being elsewhere.

Sweden's Public Procurement Act (PPA) states that environmental and social requirements should be included in public procurement if the nature of the transaction justifies such action (PPA Section 9a). The Swedish

Figur 2: The pharmaceutical supply chain (Lonaeus, 2015)



⁵ Finley et al, 2013

⁶ Larsson, 2009

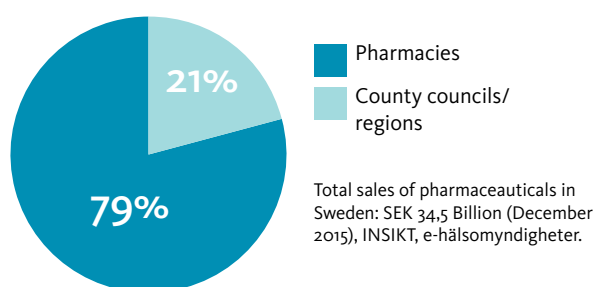
⁷ INSIKT, Swedish eHealth Agency, 2015

Government has developed an action plan for green public procurement (Official Communication 2006/07:54) for the purpose of increasing environmental requirements in public procurement.

Although there is currently limited research linking environmental damage to public procurement, legal obligations as well as the public sector's potential purchasing power indicate that there is an opportunity through public procurement to promote more sustainable production- and consumption patterns when it comes to pharmaceuticals.

As of December 2015, the total value of purchased drugs (prescription and requisition) amounted to SEK 35.9 billion. The pharmacies' purchases pharmaceuticals for SEK 28.4 billion, while county councils and regions purchased drugs for SEK 7.5 billion⁷. In Sweden a number of government agencies and institutions are working actively to introduce sustainability requirements into their

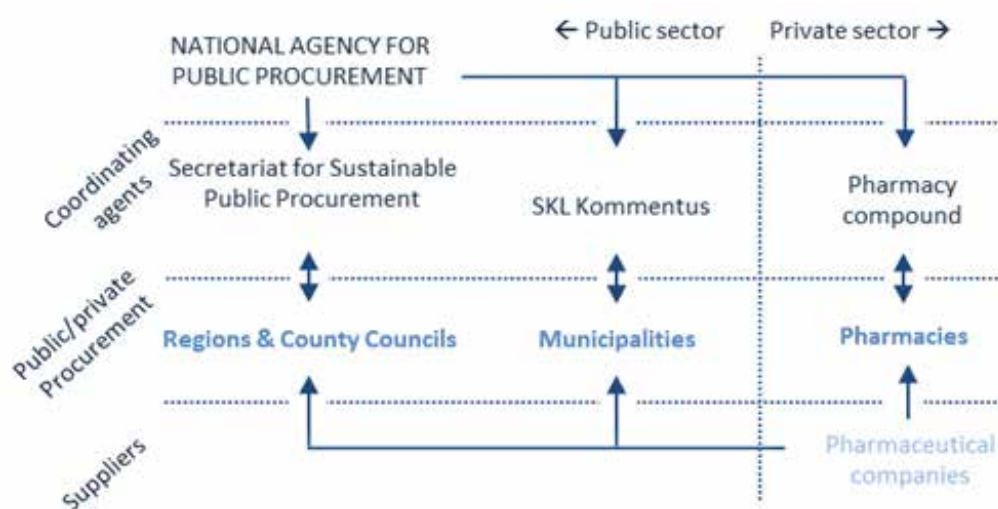
Purchased pharmaceuticals 2015



procurements of pharmaceuticals. The following figure presents the stakeholders that purchase pharmaceuticals in Sweden today, and significant stakeholders in this context, that is, the coordinating and advisory institutions as well as the industry.

The National Agency for Public Procurement, the new government agency providing procurement support (was inaugurated on 1 September 2015; formerly the Swedish EMAS Council), provides recommendations on how sustainability requirements can be introduced to procurement processes. In its library of criteria, the Agency suggests requirements at the basic, advanced and spearhead levels that can easily be applied directly in solicitations. For pharmaceuticals, the current recommended criteria concern the availability of aquatic environment data, environmental procedures in the supply chain, and procedures for managing social responsibility in the supply chain.

Figure 3: Stakeholder mapping, pharmaceuticals in Sweden



Stakeholders who currently purchase pharmaceuticals in Sweden are regions, county councils, municipalities and pharmacies. The regions and county councils, who procure pharmaceuticals for Swedish hospitals, are supported by the National Secretariat for Sustainable Public Procurement concerning sustainability requirements. The National Secretariat for Sustainable Public Procurement is a coordinating body that works on a national level to facilitate the integration of sustainable practices in public procurement. Pharmaceuticals is one of the high risk areas identified by the Secretariat, where it is recommended to always include social and environmental requirements. In addition to the secretariat, each county council has their own sustainability department that provides support vis-à-vis environmental issues in public procurement. SKL Kommentus, the municipalities’ central purchasing body, offers framework agreements and procurement support to the public sector and supports municipalities in their sustainability efforts. Municipalities are responsible for providing vaccines to schools.

The pharmacies – which play an important role in this context as they purchase the majority of pharmaceuticals in Sweden – currently have limited opportunities to include sustainability requirements when purchasing prescription drugs. This is due to the fact that sustainability requirements conflict with the pharmacies’ generic substitution obligations.⁸ The obligation demands pharmacies to replace more expensive drugs to equivalent (replaceable) drugs with lower price. The Dental and Pharmaceutical Benefits Agency, TLV, decides which medicines will be subsidized based on prices for the current month, and the pharmacies must offer these products in their range.

The substitution rule hinders pharmacies to set any requirements of their own as they cannot themselves choose which supplier to buy from, as this is decided by TLV. Environmental and social criteria from the pharmacies would thus have little impact on suppliers. However, no such obligation exists for the over-the-counter range. As the public sector operates under another legal framework, it has greater opportunity to integrate sustainability requirements into procurement, and public procurement is therefore increasingly being used as an instrument to promote social policy goals.

Sustainable procurement – definitions and limitations

The goal of **sustainable public procurement** is to ensure that goods and services procured by Swedish government agencies are responsibly manufactured. This responsibility covers both environmental and social considerations. Furthermore, sustainable procurement aims to contribute to sustainable development locally and globally.

Sustainability can in this context be understood in line with the Brundtland Commission's definition of sustainable development: development that meets the needs of the present without compromising the ability for future generations to meet their own needs.⁹

Social responsibility can be understood in accordance with the following definition:

Social responsibility (SR) refers to an organisation's responsibility for the impact of its decisions and activities on the community and environment, and which through transparent and ethical conduct:

- contributes to sustainable development including health and welfare in the community

- takes into account stakeholder expectations
- is compliant with the relevant law and in agreement with international conventions
- is integrated throughout the organisation and practised in its relationships.¹⁰

Procurement can be used as a policy tool to promote sustainable development in more ways than one. For example, procurement can influence consumer behaviour and consumption patterns; in other words, you can impact what happens to the product after it has been procured. However, this report focuses on the product life-cycle up until procurement, that is, the manufacturing phase. Furthermore, the study focuses on the procurement activities of Sweden's regions and county councils, and their sustainability efforts in collaboration with the National Secretariat for Sustainable Public Procurement.

⁸ Lag 2009:366 om handel med läkemedel (Act on trade in medical products)

⁹ Brundtland Commission, 1987

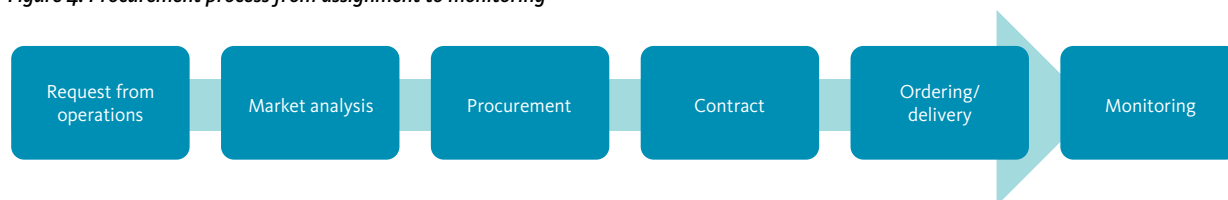
¹⁰ SIS TK 478 Socialt Ansvarstagande, ISO 26000: 2010 Social Responsibility Guidance Standard

Sustainable procurement of pharmaceuticals today

The following section will describe the procurement process as well as when and how sustainability criteria

are included. The current procurement cycle follows the following logic:

Figure 4: Procurement process from assignment to monitoring



Demand from operations | The procurement process is initiated when operations expresses a need for new products or services. Pharmaceuticals are generally procured in cycles of 1 + 2 years or 2 + 1 years.



Market analysis/business environment analysis/spend analysis | When a new request for a product/service is received from operations, the product/service category in question is analysed in order to define its strategic significance. The strategic significance is defined on the basis of a number of parameters including impact on the population, importance to the region's activities, delivery aspects, value of the contract, the length of the contract, the complexity of the goods or services, and social and environmental impact.

The medical assessment is always carried out by a pharmaceuticals' committee. There are pharmaceuticals' committees within each county council (1996:1157¹¹). The committees are advisory and support procurement officers in their task to procure pharmaceuticals. The committees advocate for the safe, rational and cost-efficient utilisation of pharmaceuticals. Furthermore, there are expert councils for each of the major therapeutic areas that work together with the pharmaceuticals' committees. The expert panel make independent evaluations that include medical, pharmaceutical and clinical pharmacology assessments. A third council that is involved in the pre-assessment stage of the procurement process is the consumer council, representing patient, pensioner and disability organisations.

Economic and legal assessments are made by the County Councils' purchasing departments while the environmental assessments are made by the local environmental departments. All regions and county councils have identified pharmaceuticals as an area where the risks for environmental and social impacts are great.

Once the strategic evaluations are complete, resources can be allocated for contract management and monitoring, and responsible officers can be allocated to the task.



Procurement | Based on the data retracted from the analysis phase, the tender dossiers can be prepared. This stage involves interaction with an expert reference group. In accordance with the framework laid down by Sweden's Public Procurement Act, procurement is carried out starting with the invitation to bid, followed by tender qualification, evaluation of tenders, negotiation where applicable, and the award of contracts.

It is always mandatory to include the supplier code of conduct in the tender dossier when procuring products and services for the Swedish regions and county councils. Specific environmental criteria are voluntary to include but are usually set in accordance with the recommendations of the former Swedish EMAS Council. 11 of the 21 county councils include these requirements when procuring pharmaceuticals. Seven (7/21) have had additional environmental requirements on packaging and concerning the phasing out of PVC for products where this is relevant.

There are four different occasions where criteria are included in a procurement process:

- Qualification of suppliers,
- Technical specifications,
- Award criteria and
- Special contract terms.

¹¹ Lag (1996:1157) om läkemedelskommittéer

Requirements, regardless of when and how they are imposed, must always be in proportion to- and linked to the object of the contract.

Qualification of suppliers is the process whereby suppliers' technical and professional ability and capacity is assessed. A supplier that does not meet the qualification requirements is to be rejected and does not proceed to the tender evaluation phase. It is therefore important that the qualification requirements such as those related to size, competence, and financial standing are designed in such a way that the procuring agent does not unintentionally exclude suitable suppliers.¹² Sustainability requirements at this stage are often basic and may for example be requirements on environmental management systems. The product/service and its requested characteristics are defined through the technical specifications. The technical specifications should be included in the procurement advertisement or the call for tenders.

Remaining bids, i.e. bids that meet all the requirements of the product/service as set out in the specifications, are evaluated based on the selection criteria. There are two

logics for selecting the winning supplier. Either, the decision is based on the lowest tender price, meaning that the tender with the lowest price is awarded contract as long as all specified requirements and conditions are met. Otherwise, the most economically advantageous tender can be chosen, which means that tenders are evaluated and chosen based on the award criteria and according to the pre-determined evaluation model.

Special contract terms are requirements that will be evaluated during the contractual period. Sustainability requirements are today primarily set as special contract terms. These requirements do not need to be evaluated before contracts have been awarded, but the procuring agency still has an obligation to verify that the supplier complies with these requirements once the contract is active. The challenge with these requirements is usually to ensure that they are monitored systematically to ensure that they are fulfilled within the specified timeframe (usually six months after the start of the contract).

The table below shows which sustainability requirements were incorporated by the county councils in 2015¹³ :

Table 1: environmental and social requirements in public procurement- Swedish County Councils

County council/ region	Environmental criteria	Type of criteria	Social criteria	Type of criteria
Blekinge	Procurement agency's recommended criteria ¹⁴	Contract terms	Code of Conduct	Contract terms
Dalarna	Procurement agency's recommended criteria	Contract terms	Code of Conduct	Contract terms
Gotland	Calls off Stockholm's agreements. Requirements on environmental management systems, packaging, monitoring in supply chain	Qualification Criteria: management systems. Contract terms: packaging	Code of Conduct	Contract terms
Gävleborg	Procurement agency's recommended criteria	Contract terms	Code of Conduct	Contract terms
Halland	Procurement agency's recommended criteria	Qualification criteria	Code of Conduct	Contract terms
Jämtland/Härjedalen	Procurement agency's recommended criteria	Contract terms	Code of Conduct	Contract terms
Jönköpings län	Environmental management systems	Qualification criteria	Code of Conduct	Contract terms
Kalmar	Environmental management systems, packaging	Qualification criteria: Management systems. Contract terms: Environmental information	Code of Conduct	Contract terms
Krono-berg	Procurement agency's recommended criteria	Qualification criteria	Code of Conduct	Contract terms
Norrbottnen	Show sustainability report before or during contract period	Contract terms	Code of Conduct	Contract terms
Skåne	Procurement agency's recommended criteria and phasing out of PVC where applicable	Contract terms, award criteria	Code of Conduct	Contract terms

¹² The (Swedish) National Agency for Public Procurement, 2015

¹³ Lonaus, 2015

¹⁴ Previously Environmental Management Council

Continued: Table 1: environmental and social requirements in public procurement- Swedish County Councils

County council/ region	Environmental criteria	Type of criteria	Social criteria	Type of criteria
Stockholm	Procurement agency's recommended criteria as well as requirements on management systems and packaging.	Qualification criteria: management systems. Contract terms: packaging	Code of Conduct	Contract terms
Sörmland	No environmental criteria	--	Code of Conduct	Contract terms
Uppsala	Procurement agency's recommended criteria	Contract terms	Code of Conduct	Contract terms
Värmland	No environmental criteria	--	Code of Conduct	Contract terms
Västerbotten	Procurement agency's recommended criteria	Contract terms	Code of Conduct	Contract terms
Västernorrland	Procurement agency's recommended criteria	Contract terms	Code of Conduct	Contract terms
Västmanland	Procurement agency's recommended criteria	Contract terms	Code of Conduct	Contract terms
Västra Götaland	Procurement agency's recommended criteria	Contract terms	Code of Conduct	Contract terms
Örebro	Procurement agency's recommended criteria	--	Code of Conduct	Contract terms
Öster-götland	Procurement agency's recommended criteria	Contract terms	Code of Conduct	Contract terms



Contracts | Once the tenders have been evaluated, the procuring agency decides which tenderer(s) will be awarded contract(s). The contract is valid once authorised representatives of both parties have signed the contract in duplicates.



Ordering/delivery | During the contract period, deliveries of pharmaceuticals are handled by supply operators. These are logistics services (transportation and warehousing) that are usually supplied by pharmacies. The person appointed responsible for following up on the contract terms regularly monitors and checks any price adjustments, changes in the product range, the flow of deliveries and follows up on delivery delays.



Contract management and compliance monitoring

| The purpose of contract management is to monitor the fulfilment of the contract to ensure that the supplier complies with set requirements. Compliance monitoring and evaluation is often a challenge that requires time and resources. Therefore, it is important to foresee this phase of the process at the early stages of procurement, in order to ensure that that tenders only include requirements that can realistically be followed up upon during the contract period. The Secretariat for Sustainable Public Procurement recommends procuring agencies to limit their sustainability demands to reasonable requirements that can be followed up upon during the given timeframe.

Monitoring process for environmental requirements for suppliers | As environmental requirements are not coordinated nationally, monitoring of these requirements is handled individually by each county council. So far, two county councils have conducted follow-ups on their environmental requirements. Stockholm County Council developed a compliance monitoring form containing questions based on the requirements in the special contract terms in the County Council's framework agreement for pharmaceuticals on requisition. If responses from suppliers were incomplete, the county council met with suppliers to seek clarifications and if responses were not provided at all, a corrective action plan was developed. Sörmland county council has done desktop audits to verify that suppliers' have environmental management systems in place. Incomplete responses were questioned and the results of this compliance monitoring have been compiled in a report.

Compliance monitoring process for social responsibility requirements for suppliers | The Secretariat for Sustainable Public Procurement has developed a process for monitoring suppliers' compliance with the code of conduct. The national steering group suggests which county councils or regions are to be responsible for compliance monitoring. The responsible county council then selects a suitable contract, product and supplier to monitor. Currently, Västra Götaland, Blekinge County Council and Sörmland County Council have begun such a compliance monitoring process.

Selected county councils and regions contact suppliers and ask them to fill out a self-assessment questionnaire consisting of 15 questions. These questions are intended to check whether the supplier has conducted risk assessments throughout the entire supply chain, and to see how dialogue with subcontractors is conducted in relation to the requirements in the contract. The selected County Council can receive help from groups of experts in assessing and evaluating the responses. This assessment is the basis for determining whether an on-site audit will be conducted¹⁵.

As the code of conduct also includes an environmental clause, questions have been developed in order to address specific environmental concerns within the scope of the code of conduct. The questionnaire addresses emissions and questions are asked about where and in what stages of the production discharges occur and what type of treatment technologies are being used. Discharges of active substances into the environment have been identified as a prioritized risk area by the Secretariat and its Steering Committee.

The following section will present the different challenges and opportunities for sustainable public procurement as experience from the procuring perspective as well as from the industry's perspective.

¹⁵ For more information, go to www.hallbarupphandling.se

Public sector – opportunities and challenges with sustainable public procurement

When sustainability requirements are introduced to the public procurement process, complexity is added to the supply chain as it creates new levels of sustainability requirements and compliance monitoring processes in the chain. The accumulated purchasing power allows the public sector, as a mega consumer, to become more active in the management of the supply chain. This however has implications. First of all, it creates multiple layers of requirements that must function in harmony in order for sustainability efforts to be effective, although different stakeholders may have different levels of ambition when it comes to goals and impact of sustainability initiatives. For example, the county councils want to ensure that goods and services procured are manufactured under responsible conditions, while the industry to a greater extent manages sustainability issues on commercial grounds in order to protect a brand or to gain advantages in public tendering processes.

The power dynamics, meaning which chain actor has the greater influence over other actors in the chain, also impacts the chain governance structures. It determines whose sustainability agenda gains greater attention in the chain. It is often assumed that the public sector as a mega-consumer has purchasing power and can thus steer markets in certain given directions. Chain governance and the concept of power is however often understood in absolute terms, while it should be juxtaposed to other chain actors' influence. For global pharmaceutical companies, the Swedish public sector constitutes a small part of total sales volumes. It is therefore important in this context to understand that Sweden is a small market and consequently its purchasing power is limited in the pharmaceuticals product category.

Despite Sweden's limited purchasing power, the industry admits to seeing the market as a pilot for future international trends within public procurement, which gives the industry great incentive to follow the developments on this market.¹⁶ This means that public procurement has a role to drive and encourage sustainable develop-

ment, rather than having the power to force change. In acknowledging their role as a pilot-agent for sustainable public procurement, it becomes vital to include and involve important stakeholders to gain attention and to ensure that good practices are spread and dispersed within the international procurement community. Important stakeholders in this context for example include the United Nations, the European Commission, the British National Health Service and other European procurement organisations. By building on its momentum, the Swedish public sector can increase its influence and generate a significant market for sustainable pharmaceuticals.

Reduce auditing fatigue and establish systematic compliance monitoring | As the public sector – the consumer – is addressing sustainability in supply chains, more actors are interfering with the sustainability management of the supply chain. Several actors in the same supply chain, as well as competitors within the industry are required to conduct audits at supplying factories. The risk for auditing fatigue can thereby increase, which can have the effect that subcontractors' focus is taken away from environmental and social performance improvements to manage repeated audits requested by numerous different companies and organisations. Furthermore, if the requirements differ, suppliers have to work with short-term improvements to comply with specific requirements in order to pass audits, instead of focusing on long-term improvements.¹⁷ The harmonisation of requirements and coordination of audits therefore is fundamental to avoid misperception and auditing fatigue, and to ensure that efforts are focused on common goals for sustainable development.

What is also important is to understand that different actors have different roles and responsibilities towards each other. Take a look at figure 5: Company Y needs to have systems in place to handle sustainability in their supply chain. As part of those processes, they need to do on-site check-ups to ensure that their suppliers live up to expectations. The county councils however, who have Company Y as their only contracting party, do not have direct access to the lower tiers of the supply chain where risk usually is higher. Audits carried out at a subcon-

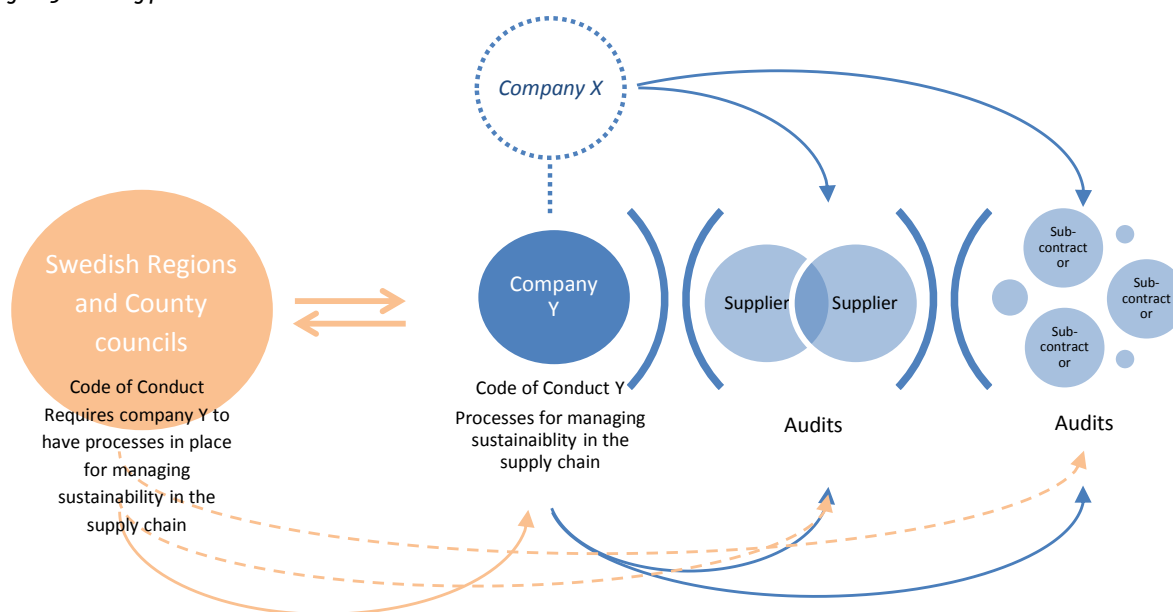
¹⁶ Lonaeus, 2015

¹⁷ Lund-Thomsen & Lindgreen, 2013

tractor's facility in areas prone to risk must therefore be managed and understood in relation to the contracting party's management system for environmental and social responsibility. It is therefore vital to highlight the purpose of the audit and bring the issue 'home' to your organisation and business relationships, and ensure that the audit results are understood within the context of internal processes and routines. A one-off audit at a supplier's further down the chain is in fact only a snapshot indicating the situation in the facility at the time that the auditor is on-site. If this audit is not anchored in the contracting party's management systems for sustainability, the audit will have little to no long-term effect.

For the County Councils, compliance monitoring should therefore primarily always be an assessment of the contracting party's systems for monitoring sustainability in their supply chain, their risk assessment procedures and their compliance monitoring processes. In addition, and with this purpose in mind, random audits ought to be conducted further down in the supply chain in order to assess the effectiveness of these systems.

Figure 5: Auditing patterns



Some additional aspects that are important to bear in mind when monitoring compliance with sustainability requirements, and which were highlighted during the interviews in the study, are:

- Sustainability requirements are rarely followed-up upon today. Without compliance monitoring, these requirements are not seen as credible or effective.
- Suppliers are given little time to prepare for audits at their subcontractors'. It takes time to gain access to subcontractors' production facilities, and for this reason the industry is asking for better forward planning
- Designating a facility for an audit should be done in dialogue with the contracting party in question and can be done based on a joint risk assessment.¹⁸

Coordination | Coordination and cooperation are cornerstones of any sustainability initiatives. Both public-public partnerships as well as public-private partnerships are vital for the success of sustainable public procurement.

For this purpose, three forms of collaboration are especially relevant:

- Public-private partnerships between procuring agencies and supply chain actors, in order to share knowledge and benefit from different skillsets:
 - There is a need to establish a permanent platform where buyers and supply chain actors can meet to dialogue and share knowledge. It is important that the public sector listens to the challenges and opportunities that the industry faces with regards to matters of sustainability in the supply chain. By involving the industry early on in the development process, the requirements have a greater chance to become relevant, attainable and adapted to the industry's level of maturity with regards to sustainability.
- Public-public/private partnership between public procurement agencies and private buyers (pharmacies) for harmonization of requirements:
 - In order to reduce auditing fatigue and increase influence, the public sector should ensure to harmonize sustainability requirements internally as well as externally with other purchasing actors such as the pharmacies (where possible). The industry is reques-

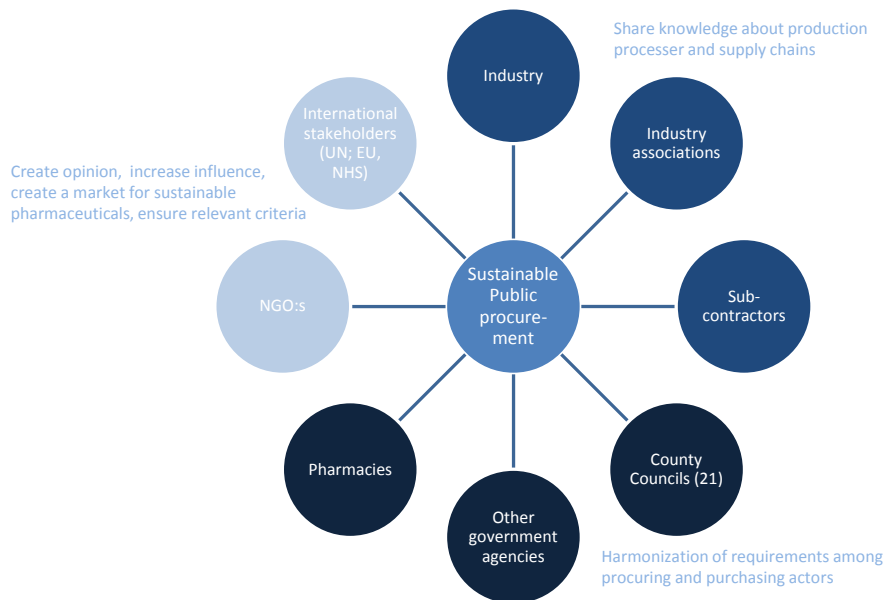
¹⁸ Lonaeus, 2015

ting a greater degree of coherency among sustainability requirements in procurement.

- Collaboration with international organisations and other stakeholders
 - In order to increase its influence further and to stimulate public opinion, procuring agencies should stri-

ve to cooperate with major international stakeholders to public procurement, such as the United Nations, the European Union and the NHS. Furthermore, it is important to have a dialogue with leading sustainability experts in order to ensure that appropriate and urgent sustainability issues are addressed.

Figure 6: Stakeholders, sustainable public procurement



Handling stakeholder dialogues will thus be an essential part of developing sustainability requirements and implementing them. Creating, managing and maintaining platforms for dialogues in order to develop new and innovative solutions for sustainable public procurement is therefore encouraged.

Several initiatives for sustainable procurement of pharmaceuticals already exist and can be harmonised moving forward:

Informal Interagency Task Team on Sustainable Procurement in the Health Sector (iIATT-SPHS):

United Nations informal Interagency Task Team on Sustainable Procurement in the Health Sector (SPHS) brings together United Nations agencies and global health financing institutions, committed to introduce sustainable procurement in the global health aid market and beyond. By leveraging its normative and market power, the SPHS Task Team is dedicated to lowering the environmental impact of its procurement, with the aim of improving human health and well-being. The SPHS has established partnerships with UN Member States, philanthropic organizations, businesses, academia and various other stakeholders.¹⁹

EU GPP: The EU’s Green Public Procurement Initiative aims to assist EU member states to stimulate demand for more sustainable (green) products and services. The GPP initiative develops green criteria for procurement but to date has had relatively little focus on pharmaceuticals as a product area.²⁰

National Health Service (NHS): The British National Health Service has worked to include sustainability aspects in procurements for many years. Reducing CO₂ emissions and improving working conditions through procurement are two priority areas for the NHS.²¹

Swedish Environmental Protection Agency: Within the UN’s 10YFP global framework for action and its focus areas of sustainable consumption and production, the Swedish environmental protection agency has been tasked with studying pharmaceuticals and their environmental impact from a life-cycle perspective. Information from different production stages is to be transferred to a web-based tool for purchasers to use in procurement. The task of conducting the study has been assigned to IVL.²²

¹⁹ www.savinglivesustainably.org

²⁰ European Commission, 2015

²¹ NHS, 2016

²² Swedish Environmental Protection Agency, 2015

Sweden's Public Procurement Act (PPA) – does it limit or facilitate sustainable procurement?

Public procurement in Sweden is regulated by Sweden's Public Procurement Act (PPA) which aims to promote cost-effective utilisation of tax revenue and safeguard competition. The PPA was adopted in 1993 as a consequence of the EEA agreement on the implementation of EC law. The PPA is based on a number of EU directives which in turn have their origins in agreements signed within the World Trade Organisation (WTO). On 1 January 2008, PPA was amended and now consists of two Acts:

- Procurements within the classic sector,
- Procurements within the areas water, energy, transport and postal services for the utilities sector.

Pharmaceuticals fall under the classic Act. The fundamental principles for public procurement are specified in Chapter 1, Article 9 of the PPA and apply to all procurement of products and services.

- **The principle of non-discrimination:** The 'principle of non-discrimination' means that it is prohibited to discriminate suppliers, directly or indirectly, on grounds of nationality. Even if the contracting authority does not expect any foreign tenders, it may not include requirements that only Swedish companies are aware of or can perform in the contract documents. The contracting authority may not, for example, give preference to a local company.
- **The principle of equal treatment:** The 'principle of equal treatment' means that all suppliers should be treated equally and be placed on an equal footing. All suppliers must, for instance, have access to the same information at the same time.
- **The principle of transparency:** The 'principle of transparency' means an obligation for the contracting authority to create transparency by providing information about the procurement procedure and how it will be conducted. In order for tenderers to be afforded the same opportunities for the submission of tenders, contract documents must be plain and clear and contain all of the requirements regarding the subject matter of the contract. Consequently, suppliers will be able to see what is of greatest importance when choosing a supplier. A 'contract relating to a public works concession' means a contract of the same kind as a works contract but which involves compensation

comprising wholly or in part the right to exploit the work. A 'service concession' means a contract of the same kind as a service contract, but which involves compensation for the services comprising wholly or in part the right to exploit the service.

- **The principle of proportionality:** The 'principle of proportionality' means that requirements for the supplier and requirements in the specification must have an obvious link with and be proportionate in relation to the subject matter of the contract. The requirements imposed must be both appropriate and necessary to achieve the aim of the public procurement. If there are several alternatives, the alternative chosen should be the one which is the least intrusive or onerous for the suppliers.
- **The principle of mutual recognition:** The 'principle of mutual recognition' means that diplomas and certificates issued by authorities authorised by a Member State shall also apply in other EU/EEA countries.²³

The PPA is often experienced by public procurers and other practitioners as an obstacle for including sustainability requirements in public procurements²⁴. The extent to which the PPA actually does limit the possibilities for setting requirements in public procurements is debated in the public procurement context. While the legal considerations fall outside of the scope of this study, it is important to highlight that clarification regarding the legal leeway is needed, as uncertainties regarding what is permitted or not hinders practitioners to include sustainability in procurements. Despite the fact that both EU directives and Sweden's PPA encourage sustainability requirements in procurement to a high degree, there is still much uncertainty about how this can be implemented correctly without legal consequences. There is particular perplexity around how to handle parallel distributors that are not themselves accountable in terms of the information required. Consequently, a clarification of the legal scope linked to the actual implementation of sustainability requirements is needed moving forward²⁵.

²³ <http://www.upphandlingsmyndigheten.se/en/publicprocurement/about-the-public-procurement-rules/>

²⁴ Lonaeus,2015

²⁵ Lonaeus,2015

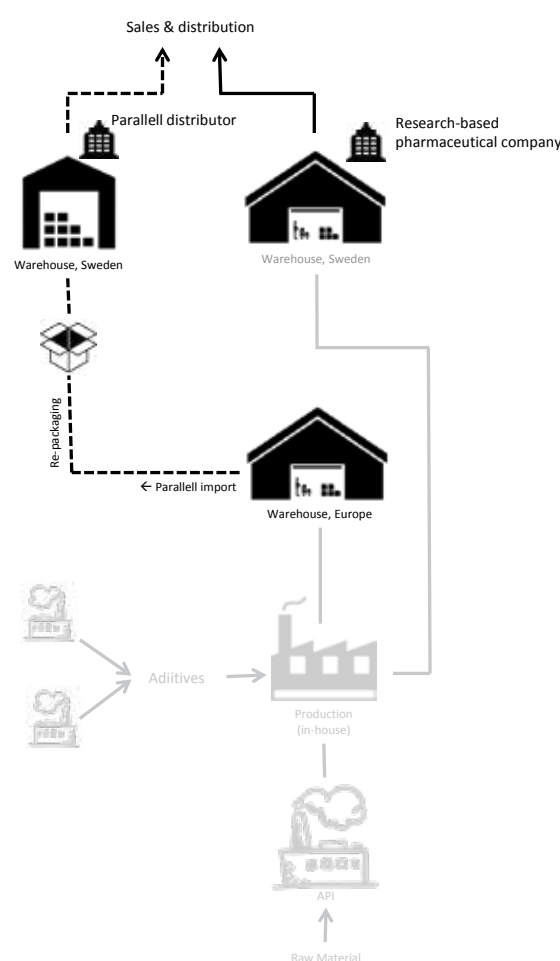
The pharmaceuticals industry – particular challenges for sustainable public procurement

The market for pharmaceuticals in Sweden | The manufacturing and sale of pharmaceuticals are subject of strict legislation. To be sold in Sweden, pharmaceuticals must be approved by the Swedish and European medical products agencies. The Swedish Medical Products Agency examines and determines if the product fulfils the legislative requirements and conducts comprehensive quality inspections at the manufacturer's site. In Sweden there are today around 11,500 medical products for humans that are approved for sale²⁶. Original pharmaceutical products, generic pharmaceutical products²⁷ and parallel imported pharmaceutical products²⁸ are sold on the Swedish market. In 2013, generic pharmaceutical products accounted for 16 per cent of the Swedish pharmaceuticals market in terms of value, and 53 per cent in terms of volume (MAT, 2013)²⁹.

There are three principal types of supply chains within the pharmaceuticals industry. New pharmaceuticals, still protected by patents, are mostly manufactured in-house by the research-based pharmaceutical industry, and the supply chain is relatively linear (see Figure 2).

The supply chain for parallel imported pharmaceuticals begins with the purchase of the finished product and consists primarily of repackaging (Figure 7). The business model for parallel distribution is based on price differences for pharmaceuticals in Europe, where there is a commercial upside in purchasing pharmaceuticals in a country where the price is lower, repackaging them, and selling them in another country where price levels are higher. Parallel distributors mostly trade with original pharmaceuticals (not generic) as there are greater margins to take advantage of for these products.

Figure 7: Supply chain(s), parallel distribution (Lonaeus, 2015)



²⁶ Medical Products Agency (Sweden), 2014

²⁷ When the patent on an originator pharmaceutical product expires, other pharmaceutical companies may manufacture it. A generic pharmaceutical product contains the same active substances and in the same quantity as an originator pharmaceutical product, but is sold under a different name. Generally, a generic pharmaceutical product has a lower price than the originator pharmaceutical product. Generic pharmaceutical products are neither better nor worse than the originator pharmaceutical product; they are medically equivalent.

²⁸ Parallel distribution of pharmaceuticals is based on the free movement of goods within the European Economic Area (EEA*) and means the sales of a centrally approved pharmaceutical product in an EEA country other than the country in which the pharmaceutical product was originally manufactured and for which it was released. The pharmaceutical product is packaged and relabelled with Swedish labelling and provided with a Swedish patient information leaflet by an approved repackager. Parallel distribution is supervised by the European Medicines Agency (EMA) and questions relating to parallel distribution of pharmaceuticals are therefore referred to the EMA (Swedish Medical Products Agency, 2016)

²⁹ Generikaföreningen, 2013

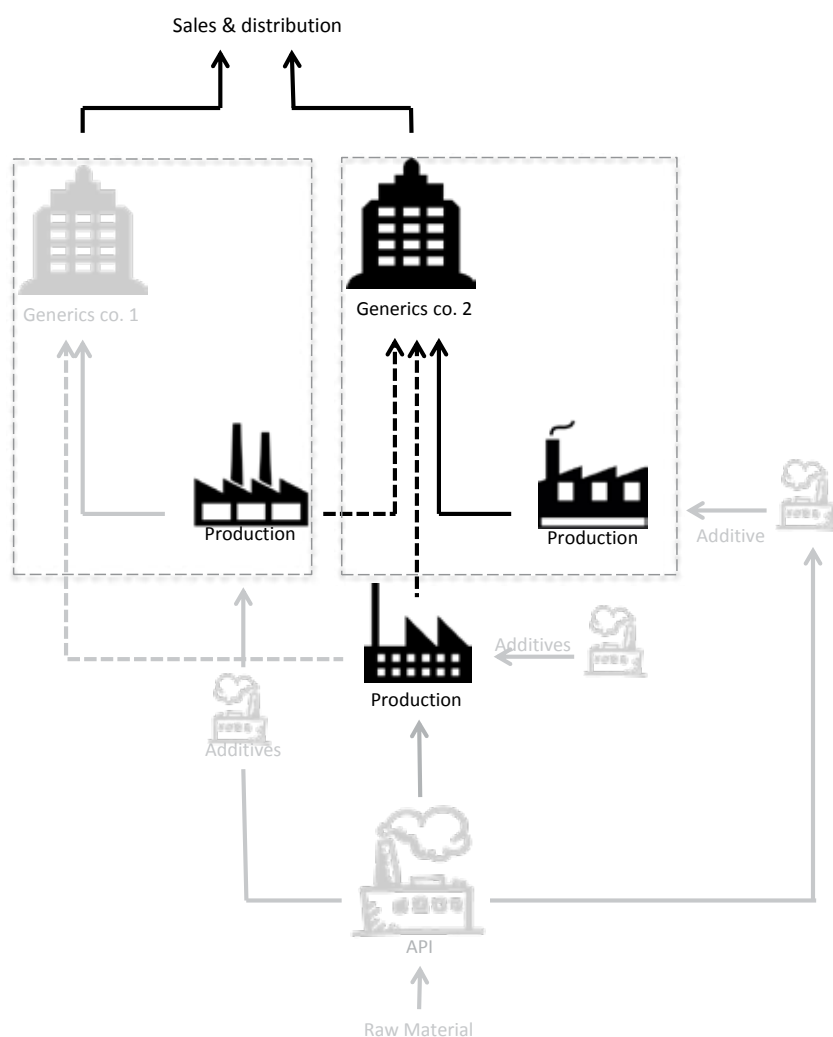
The generic pharmaceuticals often stem from a more complex supply chain consisting of both in-house and third-party manufacturers (Figure 8). It is quite common for the companies to purchase products or constituents from competitors but offering them to the market under different brand names.

Getting access to sustainability-related information requires that competitors share information about their processes and manufacturing chains, which they can be reluctant to do for reasons described below. The same problem applies to parallel distributors who purchase their pharmaceuticals directly from competitors. The pharmaceutical industry is characterised by tough competition, and there is therefore good reasons why companies want to protect their intellectual property and are reluctant to permit full transparency in relation to their manufacturing processes. The pharmaceuticals research industry, which plays an important role in the creation and development of new pharmaceuticals, wants to keep sensitive information confidential and internal

in order to retain competitive advantages. Both the generics industry and parallel importers contribute to the dynamics on the market by pushing prices. These two last actors therefore tend to promote a levelled playing field where sustainability information is openly accessible on the market, so that competition can be based purely on price. However, as of today the industry is permeated by a high level of secrecy, which makes sustainable procurement more difficult. The principle of public access to official records also contributes to suppliers being reluctant to share information with the County Councils and other procuring agencies as shared documents may become publicly available.

One of the fundamental prerequisites for sustainable procurement is transparency. It is vital to understand and gain insight into the supply chain to be able to assess risks and there through develop relevant requirements. The lack of transparency in the pharmaceutical industry and the degree of supply chain complexity makes risk assessments difficult. Suppliers did in the study request more specific requirements and responsibilities, but this in turn requires the industry to be more transparent about their processes.

Figure 8: Supply chain(s) generic drugs (Lonaeus 2015)



Sustainable public procurement: recommendations



Need identified and task assigned by operations | The County Councils have a political mandate to promote sustainable development through public procurement. They do so by working to ensure that goods and services procured by County Councils are produced under responsible conditions. The preliminary study³⁰ indicated that the goals are far too abstract to absorb and that they are too unspecific to apply.

Recommendation:

- While the vision for sustainable procurement is clear, it needs to be broken down into tangible goals and strategies. The strategy needs to be communicated internally and externally.



Market analysis/Business environment analysis/Spend analysis | A product's social and environmental impacts should be analysed at this stage of the procurement process. The market analysis should to a greater extent include social and environmental assessments in order to increase the relevance of the sustainability requirements. It is important that sustainability aspects are an integral part of the overall strategy. For example, in the study³¹ there was criticism that the requirements are not sufficiently well adapted to the subject of contract and that there is insufficient consideration of what effects certain environmental requirements might have on product characteristics. Furthermore, the study revealed that the industry would like to see that the requirements are more adapted to their level of maturity with regards to sustainable development. Furthermore, both the industry and procurement practitioners realize that the lack of transparency and the complexity of the supply chain is a challenge that needs to be addressed. In addition, the limited opportunities for parallel distributors to comply with requirements have been highlighted as a potential hinder for sustainable public procurement. For competitive reasons, parallel distributors will not receive

information with regards to production processes that the original company possesses. The parallel distributor's supply chain is limited to the repackaging of the finished product. By requiring information that concerns production processes that the parallel distributor does not have access to, procurement officers risk excluding this particular segment of the industry, which would considerably impact price levels on the market.

Recommendations:

- Sustainability aspects should be part of the market analysis and an integral part of the strategy.
- Social and environmental risk related to the subject of contract should be mapped. These risks should be juxtaposed and weighed against the product's strategic importance, and any effects of potential sustainability requirements on the product's effectiveness should be considered.
- When developing sustainability requirements, some consideration should be taken to the industry's level of maturity as well as other contextual circumstances. Transparency of the industry is encouraged.



Procurement (implementing sustainability requirements) | A number of challenges have been identified with regards to the implementation of sustainability requirements in public procurement. First of all, there is a need to clarify the legal framework for sustainable public procurement, in other words, what is allowed and what is not. There is a need to sort out in which instances a supplier may be excluded on social or environmental grounds. Furthermore, a clarification is needed regarding parallel distributors and what is feasible with regards to this segment of the market. Requirements must not discriminate against an entire segment of the market, and if requirements concern the production of the pharmaceutical, there is a risk that parallel distributors will be excluded.

General requirements versus Specific requirements |

There is a request from suppliers for requirements to be clearer and more specific. Several participants in the study³² mentioned requirements on PVC free products as a best practice example. Participants felt that these requirements were specific and concrete and that the purpose with them was clear. However, sustainability re-

³⁰ Lonaeus, 2015

³¹ Lonaeus, 2015

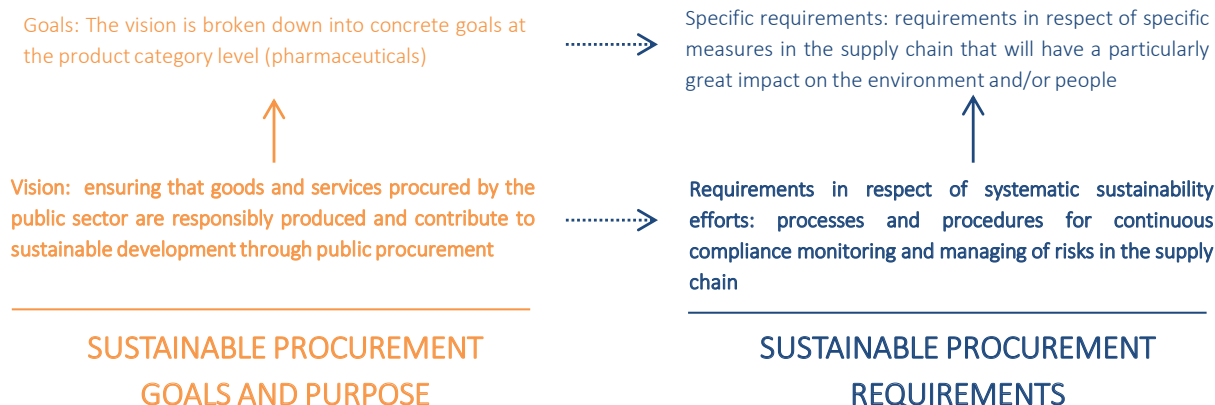
³² Lonaeus, 2015

requirements are more easily managed when they concern the product itself and do not address specific processes; requirements concerning the manufacturing processes places greater demand on specificity and requires insights into the supply chain. Again, supply chain transparency is vital. It is for example important to specify to which tiers of the supply chain the requirements apply.

The cases mentioned above refer to very specific requirements in relation to specific products, processes or actors in the chain. General requirements are instead universal and can be applied to any procurement, as they address a supplier's management systems, i.e. their internal systems to manage sustainability issues. These can include requirements on the supplier having a policy commitment, a clear division of responsibilities, methods for risk analyses, methods for forwarding information and knowledge about sustainability in the supply chain, methods for monitoring compliance in the supply chain, and procedures for handling non-compliances. The general criteria ought to be the point of departure in any procurement where sustainability requirements are included, as this is a way to encourage a more systematic approach to managing sustainability in the supply chain.



Figure 9 Requirements: from management systems to specific requirements



In order to inspire long-term improvements, any specific requirements should be anchored in procedures and processes that exist to systematically identify risks and take measures to mitigate them. Furthermore, it is important that specific sustainability requirements stem from established long-term goals so that suppliers can feel confident in investing in the identified areas. It therefore becomes particularly important to return to the goals of sustainable/green procurement and to embed the requirements in these goals. This gives suppliers the opportunity to look beyond selective measures and work systematically towards a common goal. Furthermore, it is important to remember that even though procuring agencies want to rectify unsustainable behaviours further up the chain, the requirements set in procurements address the contracting party. The contracting party can manage the supply chain through solid management systems but does usually not have direct control over manufacturing- or other processes. Sustainability must therefore be formulated in such a way that they target the contracting party's responsibilities to control risks in the supply chain.

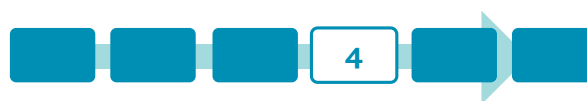
Monitoring | In order for requirements to be credible, it is important that they are monitored. It is therefore vital to plan for how to follow up on the requirements already in the tendering process. When deciding on the possibilities for following up on requirements, resources and length of contract should be taken into account. Following up on sustainability requirements takes time, skill and money, and must be budgeted for. The length of the contract (maximum 3 years) determines how much time is available for follow-up activities and thus limits what can be done. Monitoring compliance should have a more central role when deciding on which criteria to include in procurement, and should not be dealt with in retrospect.

Carry on a dialogue with various stakeholders | It is important to engage relevant stakeholders when developing and implementing sustainability requirements. Three stakeholder groups are particularly important in this context: the industry and supply chain actors, other procuring organisations and agents, and sustainability experts and other stakeholders within the sustainable procurement community.

Recommendations:

- Continuity and a long-term approach should guide sustainable procurement.
- As a first step, requirements concerning systematic approaches for sustainability management should be set, but these can then be supplemented with more specific product/process requirements.
- Requirements, monitoring of compliance and improvement efforts should in the first instance target the contracting party.
- Monitoring possibilities should be taken into account when including sustainability requirements in procurements.

- Involve stakeholders for the development and coordination of requirements:
 - The industry: The industry has expertise in the manufacturing chain and expert knowledge about the challenges that exist in terms of addressing sustainability risks. These challenges ought to be taken into account when setting requirements in order for the actors to jointly take ownership over sustainable development initiatives. Furthermore, it is important to understand the degree of maturity of the industry and to ensure that the requirements are based on the conditions and circumstances that exist, so that achievable goals are set in order to increase commitment.
 - Experts, environmental and social responsibility: It is also important to involve experts in the area of environmental and social responsibility in order to ensure that relevant and current global challenges are addressed.
 - Other purchasing actors: Last but not least, other purchasing actors ought to be involved in order to coordinate the requirements that are set on the industry. This is important in order to become more influential and in order to facilitate for suppliers to respond to the requirements. Also, it is important to create stability through harmonisation.



Contracts | Sustainability requirements must be given greater attention when tenders are evaluated and contracts awarded. Today, suppliers experience that these requirements are given too little importance in the decision-making process. Clarification is needed regarding the priority that sustainability requirements are given in evaluation processes in relation to other requirements, and in relation to price. As things stand today, suppliers do not experience these requirements as credible since the lowest price is still the decisive factor when awarding contracts.

Recommendation:

- Clarify the role of sustainability requirements in the evaluation of tenders
- To the extent possible, make sustainability aspects more influential when awarding contracts, and do not exclusively award contracts based on lowest price.



Orders and delivery | Orders and delivery are carried out in accordance with the contract.



Contract management, compliance monitoring and capacity-building |

In order to monitor compliance with requirements that target suppliers' management systems for sustainability, generally a desktop audit is carried out. During a desktop audit, different documents, certificates and policies are reviewed to evaluate processes the supplier has in place for identifying and managing risks connected to sustainability. This type of audit should be carried as a first monitoring step, before any on-site or other in-depth audits are conducted. Desktop audits have proven to be time-consuming and challenging when it comes to assessing the documentation. Many suppliers experience the requirements and the questions as unclear, which leads to the suppliers generally submitting large quantities of documentation in order to ensure that the specified areas are covered. Procuring agencies then have an obligation to assess all documentation that have been sent in, which in turn demands both time and resources. Besides the requirements themselves needing to be clearer, it is therefore important to specify what type of evidence are required for the audit.

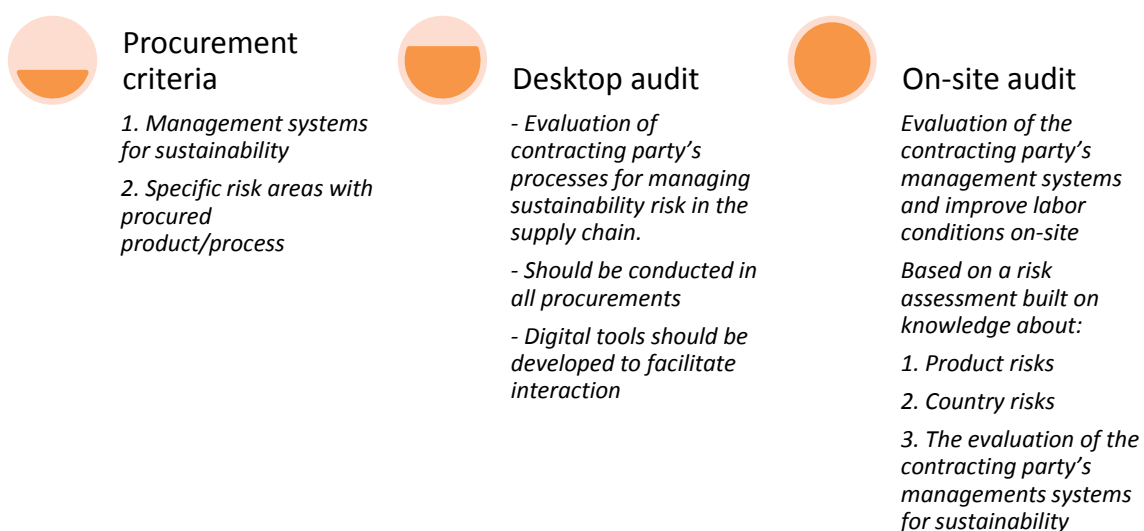
On-site audits are usually conducted by a third-party auditing firm at a production facility, where risks and management thereof- are assessed. One purpose of the audit is to assess the conditions on-site; another purpose of the on-site audit is to evaluate the effectiveness of the contracting party systems to manage sustainability in the supply chain. In line with previous arguments, any issues found further upstream in the chain need to be dealt with in the procurement context, meaning between the contracting parties. On-site compliance monitoring has

proven to be complex in many respects. The purchasing agency finds that tools and procedures for this kind of monitoring are lacking, and additional resources are needed in order to build up an internal organisation to deal with criteria and compliance monitoring. The industry would prefer longer notice to plan for on-site audits. The industry feels there is little understanding for how lengthy the process of getting access to subcontractor sites can be. Specifying which tier and/or actor of the supply chain the requirements apply to could facilitate this, since it would allow suppliers to know at an early stage which facilities might be affected by the monitoring of compliance with that specific requirement. The choice of facility for on-site audits can also to a greater extent be made based on dialogue and joint risk assessments between the contracting parties, so that efforts are synchronized. However, it is also important to remember that part of the compliance monitoring process is to evaluate the supplier's systems for risk assessment, so this has to be accounted for in these dialogues.

Recommendations

- Besides the need to clarify the criteria for sustainable public procurement, specifying what type of documentation is required for a desktop audit can facilitate for the supplier as well as for the procuring agent.
- Develop easy-to-use tools for risk assessment, supervision and monitoring of supplier compliance.
- Longer processing times for on-site compliance monitoring.
- Specifying which tier in the supply chain the requirement applies (where applicable) to facilitates compliance monitoring.
- Desktop audit of the contracting party should always be conducted prior an on-site audit further up the chain. On-site audits are conducted to get insight into labour conditions in a factory, but also to assess the effectiveness of a contracting party's management systems.

Figure 10: The auditing process



Equally important as having an established process for compliance monitoring is developing clear guidelines to follow in case non-compliances are detected in the supply chain. There needs to be greater consensus among regions and county councils on how to reprimand suppliers that don't comply with the requirements; the greater the degree of cohesion, the greater the influence.

Caution should be exercised in excluding suppliers on sustainability grounds as this might have legal implications. First, this puts greater pressure on the procuring agency to do follow-ups on all suppliers and all facilities, otherwise this might seem unjust to suppliers. Furthermore, in the pharmaceutical industry, suppliers might be supplying from the same subcontractor or from each other, which means that other suppliers may be purchasing from that same subcontractor but only one supplier is excluded for purchasing from it. Another reason for avoiding exclusion is that it hinders the opportunity to work with improvements through capacity-building. Exclusions rarely improve conditions in factories, which is why it is better to instead collaborate and share knowledge on how to conduct business sustainably. In cases where serious non-compliances risk damaging the procuring county council in terms of reputation or otherwise, it would be better to take action in the form of freezing the contract until the situation is remedied and then put an action plan into place. In the particular case a supplier repeatedly demonstrates an unwillingness to work with and address sustainability issues, the purchasing agency could consider the option of excluding the supplier from procurements.

Recommendations

- Develop clear internal guidelines for action in case non-compliances are detected in a contracting party's supply chain.
- Exclusion of suppliers on ethical grounds can have complex consequences and ought therefore to be avoided. Instead, in cases of non-compliances, county councils should work out action plans for capacity-building and work on improvements that contribute to sustainable development.
- Continuous improvement and capacity building should be the focus in cases of deviations from the requirements.
- Where serious non-compliances from requirements are discovered, contracts can be frozen until the non-compliance is remedied.

Conclusions and next steps

Continuity and a long-term approach are fundamental to achieving change through public procurement. It is therefore important to be systematic; from setting goals, via the requirements, to risk assessment, compliance monitoring and capacity building. Clear national guidelines can both help create a coherent process for sustainable procurement and can facilitate coordination of work.

Furthermore, it is important that the procuring agencies work from a clear vision and adopt a comprehensive approach in addressing sustainable development through public procurement. Goals should be broken down into objectives so that purchasing agencies, together with their suppliers, are able to manage risks in the supply chain in a practical way. By putting words into action in an organised way and working actively in close cooperation with stakeholders, the Swedish public sector can create become influential in promoting sustainable development through public procurement.

As a next step in developing strategies for introducing sustainability requirements into public procurement, the cluster group recommends the following additional actions:

- Investigate the possibilities for pharmacies to include sustainability requirements when purchasing pharmaceuticals,
- In dialogue and cooperation between the County Councils, regions, the industry and other stakeholders, develop a process for sustainable procurement of pharmaceuticals by:
 - Creating a platform for cooperation (preferably hosted the National Agency for Public Procurement)
 - Develop clear and common criteria for sustainable procurement of pharmaceuticals
 - Develop a clear and common strategy for compliance monitoring based on goals, risks and management of non-compliance.

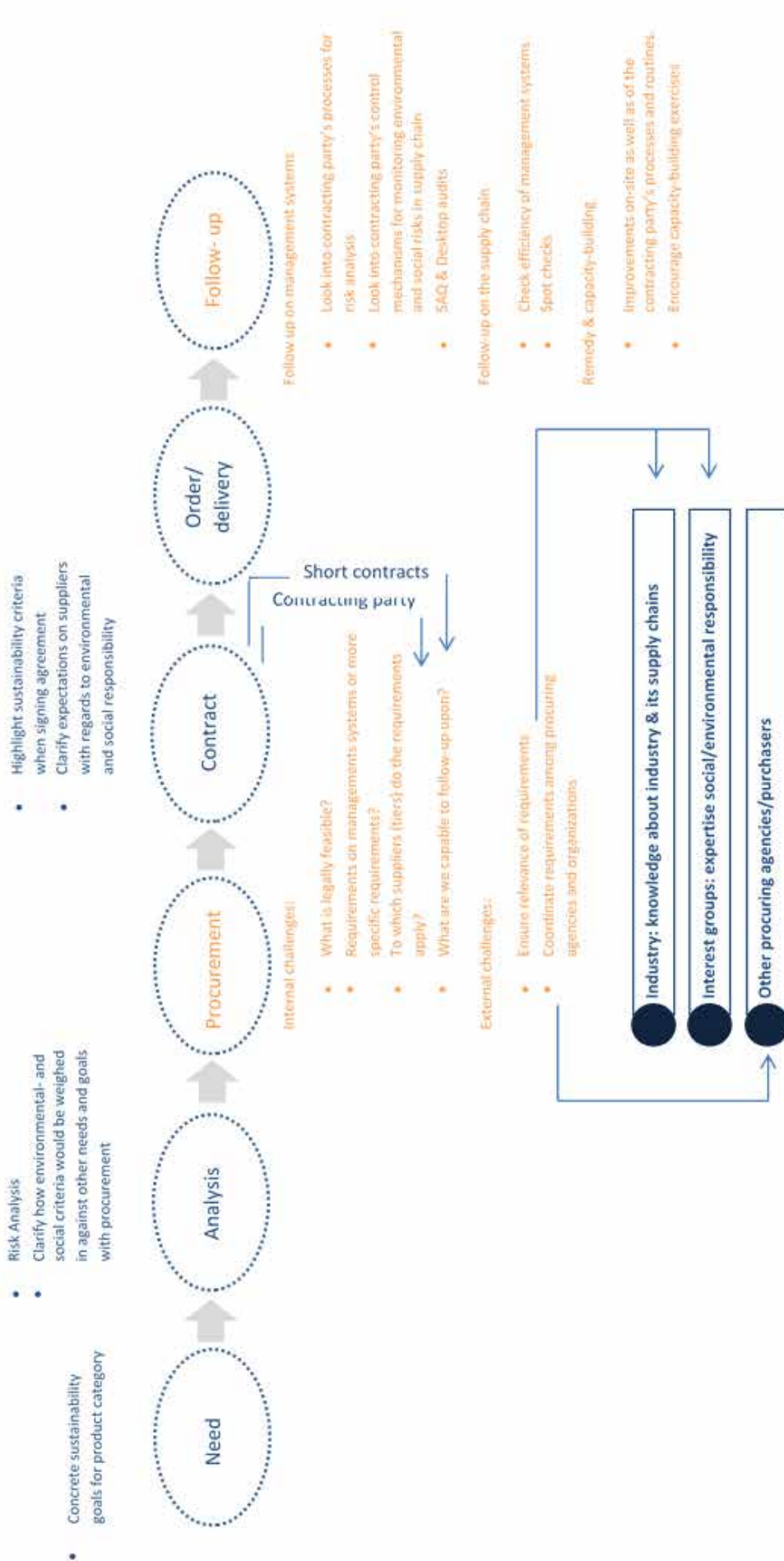
- Develop a risk assessment- and compliance monitoring tool for sustainable procurement
- Investigate the legal framework with regards to transparency and the principle of public access to official records,
- Clearly define and communicate the legal framework for sustainable public procurement to procurers and practitioners
- Communicate goals and purpose of sustainable public procurement (from vision to the specific goals of sustainable procurement of pharmaceuticals)
- Cooperating with leading international actors in the sustainable procurement of pharmaceuticals (including researchers, NHS, UNDP, HCWH, WHO).

In order to take the next steps, the group is also of the opinion that further legal aspects need to be investigated:

- How can we develop and set sustainability requirements concerning production of pharmaceuticals without disadvantaging parallel distributors?
- How can suppliers share business critical information without it becoming publicly accessible as part of the public record?
- When do sustainability conflict with the Swedish PPA?

Sustainable procurement of pharmaceuticals 2016: Other on-going Swedish projects

- In 2016, the National Agency for Public Procurement will update and develop new requirements for pharmaceuticals (existing requirements will be reviewed)
- Sweden's county councils and regions will be continuing their national efforts in monitoring compliance with sustainability requirements in contracts. During 2016, the region of Västra Götaland, Blekinge County Council and Sörmland County Council are responsible for this compliance monitoring. Two audits have been conducted by the region of Västra Götaland and a report from these will be communicated.
- SIS TK 478 is developing a new standard for sustainable procurement (ISO 20400, Sustainable procurement – Guidance)



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About the clustergroup Water and Pharmaceuticals

SIWI Swedish Water House has brought together Swedish experts and stakeholders in pharmaceuticals and water management. The aim was to promote recommendations for more effective implementation of environmental regulations limiting pharmaceutical pollution. Representatives from SIWI Swedish Water House, Apotek Hjärtat, Pfizer Health AB, Fresenius-Kabi, The Research-Based Pharmaceutical Industry (LIF), Stockholm County Council (SLL), Swedish Environmental Research Institute (IVL), Käppalaförbundet, Uppsala University Hospital and Uppsala County Council were core members of the group.

APOTEK 




KÄPPALA



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