REPORT

PROCURING FOR GREENER PHARMA

Health Care Without Harm

CONTENTS

INTRODUCTION

MEDICINES ARE ESSENTIAL TOOLS FOR TREATING AND ALLEVIATING SYMPTOMS OR PREVENTING DISEASE. SCIENTIFIC ADVANCES HAVE MADE IT POSSIBLE FOR MEDICINES TO CURE PREVIOUSLY INCURABLE DISEASES AND SAVE LIVES. HOWEVER, EVERY MEDICINAL PRODUCT THAT IS USED TO TREAT A PATIENT HAS THE POTENTIAL TO HARM ENVIRONMENTAL AND HUMAN HEALTH, AND THIS SHOULD BE CAREFULLY CONSIDERED BEFORE ITS PURCHASE AND USE.

The nature of a pharmaceutical product's impact on the environment depends on a number of different factors. Some pharmaceuticals use a large amount of energy that results in high carbon emissions.[1] Other products have a high toxicity that when entering the environment could lead to harmful effects on human health, including accelerating antimicrobial resistance (AMR).[2] Some produce considerable amounts of waste requiring treatment and processing: in the EU, waste from unused medicines represents 10% of wastewater pollution.[3]

Pharmaceuticals can enter the environment at all stages of their life cycle, production, use, and disposal. Pharmaceutical residues have been detected in surface water, sewage effluents, groundwater, drinking water, manure, soil, and other environmental matrices globally.[4][5][6] Whilst the environmental impacts of most Active Pharmaceutical Ingredients (API) are not fully understood, several APIs are known to persist and accumulate in the environment, which can severely affect animal and plant life.[7][8][9][10]

The discharge of pharmaceuticals into the environment has been linked to the development of AMR, which kills an estimated 1.27 million people every year.[11][12] Uncontrolled discharges from pharmaceutical manufacturing have devastating impacts on water systems, including humans and animals coming into contact with the resulting resistant bacteria. Several studies show that polluting factories, where resistant bacteria grow, are exporting to EU markets and directly selling drugs to EU-based healthcare providers and buyers.[13]

Public procurement can support healthcare institutions to make sustainable choices and reward good practices when purchasing medicinal products. Globally, public procurement accounts for 29% of total general government spending, and health is the second largest spending area with over 9% of the GDP.[14] In the EU, an average of 8% of national GDP is spent on healthcare.

The EU Public Procurement Directive seeks to ensure a greater inclusion of common societal goals in the procurement process. In practice, it provides a legal framework that can be used to prioritise the procurement of pharmaceutical products with a lower environmental impact.

This report builds on the experience of the Nordic countries, which have implemented sustainability criteria in pharmaceutical procurement. Through interviews with key stakeholders (including procurers and pharmaceutical companies) and an analysis of selected case studies, this report seeks to examine the opportunities and challenges associated with the sustainable public procurement of pharmaceuticals.

SUSTAINABLE PHARMACEUTICAL PROCUREMENT IN EUROPE

IN 2022, HCWH EUROPE CONDUCTED INTERVIEWS WITH A RANGE OF STAKEHOLDERS INVOLVED IN THE SUSTAINABLE MANAGEMENT OF PHARMACEUTICALS. THESE STAKEHOLDERS INCLUDE NATIONAL PROCUREMENT AGENCIES, REPRESENTATIVES OF PHARMACEUTICAL COMPANIES AND REPRESENTATIVES OF PHARMACEUTICAL CONGLOMERATES.

The Nordic countries have pioneered the use of sustainability criteria in pharmaceutical procurement in Europe (see pages 7 and 8). Their work with pharmaceutical companies in recent years gives us a better understanding of how the landscape of sustainable production of pharmaceuticals is changing and where the pharmaceutical sector stands on this issue.

Over the last five years there has been a fundamental shift in the mindset of pharmaceutical companies regarding sustainability issues, which are now a key consideration for large pharmaceutical companies. Consequently, pharmaceutical manufacturers have switched from a position of "*why* should we do this?" to "*how* should we do this?".

The momentum of carbon reduction efforts is one of the main drivers of this changing mindset within many pharmaceutical companies. The pharmaceutical industry has a significant carbon footprint, producing more emissions than the automotive sector, making it one of the single largest contributors to the healthcare sector's carbon footprint.[1] It's also a relevant issue among European countries, which generally target carbon emissions as a first step towards addressing other sustainability issues (see page 8).

The drive towards decarbonisation of pharmaceutical supply chains is reflected in the changing structure of pharmaceutical companies – many have now developed sustainability departments to focus primarily on the environmental and social impact of their products.

THE CHALLENGES OF SUSTAINABLY PROCURING PHARMACEUTICALS

WASTEWATER MANAGEMENT

During the manufacturing process of medicines, unknown amounts of waste enter the environment through water.[15] Furthermore, up to 90% of orally administered pharmaceuticals are excreted as active substances into wastewater. As wastewater treatment plants do not have the capacity to eliminate all of these substances they are released into the environment and, as a result, APIs enter the water cycle. For this reason wastewater makes a significant contribution to pharmaceutical pollution and can contribute to the acceleration and spread of AMR.[16]

According to interviewees, sustainable procurement has not yet had a direct impact on reducing APIs in water. This task is made more difficult due to a lack of transparency on the part of pharmaceutical producers. With limited data on the concentration of different drugs in waterways it is difficult for procurers to design measures to address the issue. There is an urgent need for joint work with the pharmaceutical industry and procurement agencies to begin measuring the levels of certain drugs in wastewater effluents, and then to establish discharge targets in an effort to reduce them. Developing criteria to reduce the concentration of antibiotics in the environment should be a priority.

THE RISK OF DIFFERING STANDARDS

Without a standardised, harmonised approach towards sustainable procurement of pharmaceutical products in Europe, drafting sustainability criteria falls to individual procurement agencies and other stakeholders involved in the purchase of pharmaceuticals. Many organisations are therefore developing their own criteria to procure sustainable pharmaceuticals. This piecemeal approach makes it challenging for pharmaceutical companies to adapt to varying criteria from different clients and could ultimately discourage them from responding to tenders.

The procurement agencies interviewed suggested that these criteria should be harmonised at the EU level. They recommend other procurement agencies try to incorporate already successfully implemented criteria before start building their own. This approach can help procurement officials take decisions based on initiatives that have already been tested and that are working in other European countries. It also helps pharmaceutical companies to adapt their production smoothly.

LACK OF TRANSPARENCY IN SUPPLY CHAINS

Procurers often find it difficult to access some of the data they need from pharmaceutical companies. Similarly, pharmaceutical companies claim that compiling data for tenders is also a challenge for them due to a lack of transparency from their own suppliers and excessive internal bureaucracy.

In some cases, it might be impossible to access the requested information, particularly when working with operators from outside Europe that operate under alternative environmental regulatory systems. Capacity building and awareness-raising exercises are usually helpful to enable suppliers to understand the benefits of sharing data and instate sustainability criteria.

Many tenders are carried out at regional or national level, however, some important data are collected at the global level, meaning they are not available to regional branches that are responding to tenders. Procurement officers can ask pharmaceutical companies to incorporate transparency mechanisms to overcome business confidentiality and make pharmaceutical supply chains more transparent.

FAIR COMPETITION

There is a significant gap between small and large companies in terms of their capacity to respond to sustainable procurement tenders. Whereas larger companies tend to have sustainability departments, smaller companies might be focusing their resources on developing other lines of business.

Setting the bar too high could result in exclusionary practices, meaning smaller companies may not be capable of participating in the tendering process. Procurers should guide small companies to make their production more sustainable and engage with them during the procurement process to gather their views and understand which aspects might be more challenging for them to comply with. A flexible approach with special conditions for small companies that might have more issues complying with certain criteria could help them green their production or supply chains and participate in the procurement process.

CASE STUDIES

ENVIRONMENTAL REQUIREMENTS FOR PHARMACEUTICALS (NORWAY)

The Norwegian Hospital Procurement Trust, (Sykehusinnkjøp HF), is a hospital procurement agency jointly owned by Norway's four regional health organisations. The institution manages all joint procurement agreements and creates savings for hospitals through joint procurement.

In 2019, the agency introduced criteria to reduce the environmental impact of pharmaceutical products, which they first applied to antibiotics procurement.[17] In these criteria, environmental requirements for producers were weighted at 30%.

Between 2020-2022 they launched eight pharmaceutical procurement processes with environmental requirements attached. They primarily targeted anti-infectives, chemotherapeutics, and infusion and rinsing fluids. These products were selected because they present the greatest challenges in the countries they are produced (such as the production of antibiotics or oncology products in China and India), or because their import involves voluminous transport and the use of heavy packaging that results in increased emissions.

The agency has a constant dialogue with pharmaceutical companies and other stakeholders, including the Norwegian Pharmaceutical Industry Association. Once drafted, the provisional criteria were open to feedback from all stakeholders through an open consultation.

The Norwegian Hospital Procurement Trust intends to draft environmental requirements for other pharmaceutical products that could not be addressed in the first phase, such as inhalation anaesthetics, inhalers, and hormones.

SUSTAINABILITY CRITERIA FOR MEDICINAL PRODUCTS (SWEDEN)

The National Agency for Public Procurement of Sweden was founded in 2015 to strengthen the strategic importance of public procurement. The agency's economic impact is more than 800 bn krona (approx. €721 bn) each year, which accounts for almost one fifth of Sweden's GDP.[18]

The Agency has focussed on procurement criteria for medical products for patient care, with a strong emphasis on sustainability. These criteria help collect information on the location of the manufacture and formulation of active pharmaceutical substances and improve access to available environmental information. This approach makes the identification and prioritisation of environmental and social risks easier and also improves follow-up efforts.

Users can access the proposed criteria through an easy-to-use online tool.[a] The agency proposes five 'award criteria' and four 'special contract terms'. For each award criterion there is proposed text and guidance on how to verify correct fulfilment, as well as guidelines on the proposed follow-up. Using the same tool, users are able to compare up to three criteria simultaneously.[b]

Even though these criteria have been designed to help procurers identify sustainable products, the access to environmental information can also be useful for the work of other bodies, such as pharmaceutical committees.

CARBON FOOTPRINTING HEALTH PRODUCTS (FRANCE)

Building on lessons learnt during the COVID-19 pandemic concerning the availability of medicines and medical devices, the French Ministry of Health has drafted a strategy to strengthen the provisioning capacities of the country. This strategy will not only address availability criteria, but will also consider other societal challenges that can be directly impacted by health products, such as environmental issues.

In addition, the Ministry of Health has announced that from 2023 all strategic health products, including medical devices and medicines, will require a carbon footprint report.[19] This requirement will help health procurers to better assess the environmental impact of products.

The ministry may also ask producers to provide the rate of production waste. Actions pursuing the reduction and recycling of the packaging of these medical products will be scored positively under this new policy. The French Health Ministry also foresees 'significant penalties' in case of noncompliance with the criteria.

a These criteria can be used in procurement to set requirements for sustainability www.upphandlingsmyndigheten.se/en/criteria/nursing-and-care/medicinal-products

b Comparing different criteria helps users decide which are best for their procurement. www.upphandlingsmyndigheten.se/en/criteria/compare-criteria

SUSTAINABLE PROCUREMENT INDEX FOR HEALTH (UNDP)

The Sustainable Procurement Index for Health (SPIH)[c] allows policy makers, manufacturers, suppliers, procurers, and healthcare facilities to maintain an environmental and social sustainability record of their medical products. The SPIH tool has been designed to accelerate sustainable procurement in the health sector.

The general SPIH tool targets general healthcare commodities, such as medical gloves and biomedical devices. In parallel, there is a specifically oriented pharmaceutical edition that targets pharmaceutical products only, such as malaria medication, with specifically tailored criteria. The index includes guidance that monitors four different impacts of medical products:

- Greenhouse gas emissions
- Resource depletion (water, energy, and material consumption)
- Chemical/toxic impact on human health and environment
- Human, labour rights, and gender equality.

The SPIH is formed by a structured set of questions and criteria, organised around the key sustainability themes mentioned above, which can be used to identify the sustainability credentials of a supplier and its products. Each module contains weighted questions. Depending on the scoring in each module, an overall score for the supplier can be determined.

Feedback from buyers and suppliers suggests that the index should be used during a specific purchase rather than as a market monitoring or contract performance tool.[20]

RESPONSIBLE ANTIBIOTICS MANUFACTURING PLATFORM (RAMP)

Pharmaceutical manufacturing is a stage of the pharmaceutical value chain that poses particular risks to the environment and public health. To help stakeholders minimise this risk, in 2020 the Stockholm International Water Institute (SIWI) launched the Responsible Antibiotics Manufacturing Platform (RAMP).[d]

This platform aims to lead industry transformation towards responsible antibiotics manufacturing to reduce the spread of antimicrobial resistance. RAMP engages a wide range of stakeholders across the supply chain to demonstrate sustainable, cost-effective solutions. Following this approach, all stakeholders take part in defining higher standards for reducing emissions that are verified, demand-driven, and scientifically sound.

According to Nicolai Schaaf, Senior Manager at SIWI, this approach is revolutionary since it has led stakeholders to co-create the business-case for sustainably produced antibiotics. Until now the lack of information for procurers to develop strict environmental criteria was a barrier that left the commitment to raise environmental standards of antimicrobial production almost solely in the hands of pharmaceutical manufacturers.

c The SPIH, is an adaptable procurement measurement tool, developed by HCWH and UNDP www.noharm-europe.org/content/global/sustainable-procurement-index-health

d RAMP sets a new standard for the pharmaceutical industry. www.siwi.org/amr-ramp

CONCLUSION

MEDICINES USED TO TREAT PATIENTS HAVE AN ENVIRONMENTAL IMPACT THAT ALSO AFFECTS PEOPLE'S HEALTH AND WELL-BEING. INCLUDING SUSTAINABILITY CRITERIA IN THE TENDERING OF THESE PRODUCTS CAN HAVE A POSITIVE EFFECT ON REDUCING THE IMPACT OF PHARMACEUTICALS ON ENVIRONMENTAL AND HUMAN HEALTH.

Through a series of interviews with national procurement agencies and pharmaceutical companies, combined with a case study analysis, we have identified a number of challenges and areas for consideration and improvement that any organisation planning to implement sustainable procurement criteria for pharmaceuticals should consider.

Firstly, there is a need to carefully monitor the emissions of APIs to effluent wastewater. This would drive procurers to include more impactful criteria. Secondly, sustainability criteria need to be harmonised as much as possible between different European countries to avoid the risk of conflicting or piecemeal standards at the EU level. In parallel, it is necessary for pharmaceutical companies to implement policies that encourage transparency among their suppliers to better understand the impact of APIs in the environment. Finally, procurers must ensure throughout the process that sustainable procurement criteria do not create a competitive barrier that disadvantages smaller companies; the focus of healthcare procurers should be on facilitating the transition of all pharmaceutical companies to a model that prioritises the sustainability of their products.

Based on these conclusions, we propose a series of recommendations for procurers to facilitate the transition of pharmaceutical companies to a more sustainable model:

RECOMMENDATIONS TO PROCURERS OF PHARMACEUTICALS THAT WANT TO START IMPLEMENTING SUSTAINABILITY CRITERIA:

- **Benchmark other available criteria.** Harmonise currently available criteria so that it is easier for pharmaceutical companies to meet the requirements.
- **Target the most important APIs first.** Prioritise these substances and avoid drafting broad criteria trying to cover many products.
- **Be clear with the questions for suppliers.** Make it easy for companies to understand which data they need to provide.
- **Ask companies to measure water pollution.** Data regarding concentration of pollutants in water is difficult to obtain. Pharmaceutical companies could help by asking suppliers to measure the levels of certain APIs in wastewater in order to set meaningful thresholds for reduction.
- **Involve hospital pharmacists in procurement.** Pharmacists are usually aware of the availability and necessity of key products. Their contribution is essential to avoid issues, including shortages.
- **Don't exclude companies.** Criteria that are too demanding may discourage smaller companies from responding. Your goal should be to guide pharmaceutical companies to a more sustainable production model, which may require a more flexible approach for companies that need to implement more significant changes to their production processes.

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