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Experience Report – Environment

Environmental Requirements for Pharmaceutical Procurements 2020-2022

SYKEHUSINNKJØP

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1 Introduction

1.1 Purpose

The purpose of the Experience Report is to summarise the environmental criteria that have been used in pharmaceuticals procurements up to now, and to present experience and results from the work.

2 Summary

A large number of evaluations have been conducted regarding the environmental requirements for the procurement of medicines for Norwegian hospitals. It is possible to streamline the evaluation process even more and include environmental requirements in more procurements.

It is even more important these days to continue working to reduce the carbon footprint of our nation's health trusts, to reduce waste and reduce emissions of harmful substances into the environment. There are several initiatives in place in and outside of Norway that can contribute to this.

3 General information

We have prioritised our goal of reducing the environmental impact of the health services. The procurement of medicines is an important part of this work.

A total of eight pharmaceutical procurements with environmental requirements have been completed in Norway, along with one procurement with environmental requirements in the joint Nordic cooperation with Denmark and Iceland. The product groups covered by the requirements are mainly anti-infectives, various chemotherapeutics and infusion and rinsing fluids. Experience gained from pharmaceutical product procurements forms a part of this report, even though these are not medicinal products. The reason why these areas were chosen as the starting point for environmental requirements in procurement is that they create the greatest challenges in production locally (antibiotics/oncology in India/China) or have a lot of packaging and involve voluminous transport and handling (nutritional products and rinsing fluids) and thus are a logical starting point for change/focus on emissions and use.

There are still not many other European procurement organizations that have set similar environmental requirements in the category of pharmaceuticals. The Norwegian Hospital Procurement Trust has gained valuable experience from setting environmental requirements for pharmaceuticals. There is strong interest from other countries around the world to introduce and further develop such requirements. The Norwegian Hospital Procurement Trust actively participates in dialogue with suppliers and shares its experience with other countries. The industry is very concerned that this is harmonised across national borders; the special Norwegian requirements are considered impossible to obtain, but if we act as a bellwether and others follow, that would be an important step. Our role in international opinion cannot be exaggerated. That is why it is so extremely important to stick to our demands and follow up on the procurements.

Each procurement has a specialist group with professional representatives from the health regions who participate in the design of the tender competition and evaluation, in addition to participants from the Norwegian Hospital Procurement Trust and the Norwegian Medicines Agency. The Nordic procurement is organized in a different way. The input and discussions in the groups have been based on our mandate and the group's opportunity to incur increased costs for the health trusts in the name

of the environment. That is why it is so important to obtain information about and create legitimacy around our actions in relation to environmental criteria in procurements to establish trust and confidence in these measures.

4 Experience

4.1 Completed procurements

The various procurements that have been completed so far have had different requirements and different numbers of requirements, in addition to a large variation between the number of products being procured and the number of bidders for the contracts. See Table 1.

For the areas anti-infectives and various chemotherapeutics, the requirements were directed at emissions into the environment. For the areas of medical nutrition products and infusion and rinsing fluids, the requirements were aimed at packaging and transport.

The Nordic procurement included requirements for transport, emission strategy and environmental certification.

No.	Name of procurement	Number of environmental requirements in the procurement	Number of specification requirements received with environmental responses	Number of evaluation forms filled out	Total number of requirements evaluated (not including the mandatory requirements)
2001a	Anti-infectives	14 suppliers	23		322
2201a	Anti-infectives	14 suppliers	30		394
2107g	Various chemotherapeutics, non-inj/inf	14 suppliers	11		154
2107j	Various chemotherapeutics, inj/inf	14 suppliers	18		266
2107g-1	Various chemotherapeutics, Mercaptopurine	14 suppliers	2		28
2107j-1	Various chemotherapeutics, Cabazitaxel	14 suppliers	5		70
2103	Infusion and rinsing fluids	3 suppliers 4-6 product	68 4 * supplier specification requirements 64 product specification requirements	16	120

2104	Tube feeding and other medicinal foods (this procurement does not include medicines)	3 suppliers 6 product			
	Nordic procurement	3 suppliers			

Table 1

*15 supplier specification requirements were submitted from 4 suppliers, but the responses were the same in each submitted specification requirement, and to give a more accurate picture of the evaluation, these are listed as 1 specification requirement per supplier.

4.2 Market dialogue

The first environmental requirements that were set in Procurement 2001a Anti-infectives were set up after a long preliminary process in collaboration with the Norwegian Pharmaceutical Industry Association. The main focus of the requirements was emissions into the environment.

The same requirements were then used for a subsequent procurement (2201a Anti-infectives), as well as for four procurements for various chemotherapeutics. Some guidelines were added at this time to keep the requirements as similar as possible for the first round of procurements. Therefore, only minor adjustments were made to the requirements, and these were sent out for consultation to suppliers who provided good input.

For the procurements 2103 Infusion and Rinsing Fluids and 2104 Tube Feeding and Other Medical Foods, the requirements were prepared through several dialogue meetings with the suppliers, and with support from the environmental managers at the Norwegian Hospital Procurement Trust who have experience from medical professions other than pharmaceuticals. The requirements were sent out for consultation to the suppliers, where several good written input documents were received which contributed to the requirements working well for all parties.

The health trusts were represented in the specialist group for all procurements, and were also given the opportunity to provide input through consultation hearings.

After the announcement of the tender competition, all questions were answered in writing by question and answer sheets that were sent to all the stakeholders. The largest proportion of the questions on environmental requirements concerned practical considerations and an understanding of how to meet the specification requirements, which documentation should or should not be attached and which languages could be used.

4.3 Preparation of specification requirements and implementation of the competition

For the anti-infective and chemotherapeutic procurements, all environmental requirements were related to the supplier's routines and strategies for environmental follow-up, and the requirements were weighted with 30% in the allocation criteria in accordance with current regulations. For 2103

and 2104, environmental requirements for suppliers were weighted with 20% and environmental requirements related to the properties of the products offered were weighted with 10%. This was when we discovered that the requirements for environmental certification of production sites (among others) would provide greater value, even though there were fewer requirements.

The vast majority of requirements were MUST requirements (scored with 0-10p), and two requirements were SHOULD requirements that had to be met for the bidder to have the opportunity to participate in the tender competition. Also see the list of requirements in the separate section below.

Today, most of the evaluation and bidding is done using excel, which has some limitations. There is a need to develop more efficient systems for collecting data for preparing competitions, evaluation and follow-up. This will further contribute to the health trusts reaching their goals, and hopefully also simplify supplier work in submitting tenders and further follow-up processes.

There is a great desire from suppliers to have the specification requirements translated into English, so this was done. Some suppliers wanted to submit their responses in English, but this was not approved out of consideration for capacity, resources and responsibility for conducting a good evaluation. The design and further standardisation of the specification requirements will probably be important to make it easier to submit responses in Norwegian in the future.

4.4 Evaluation

The evaluation work was most demanding in the Anti-infectives and Various Chemotherapeutics procurements. This was largely due to the design of the specification requirements, where the response alternatives are entered as YES or NO, in addition to the descriptive text having to be filled in. There were no clear guidelines for what the supplier should answer. There were also a large number of responses and a large number of requirements – so completing the evaluation took a significant amount of time. In later procurements, other response alternatives than yes/no will be prepared. There was great variation in whether the bidders were able to meet the requirements; see Figure 1.

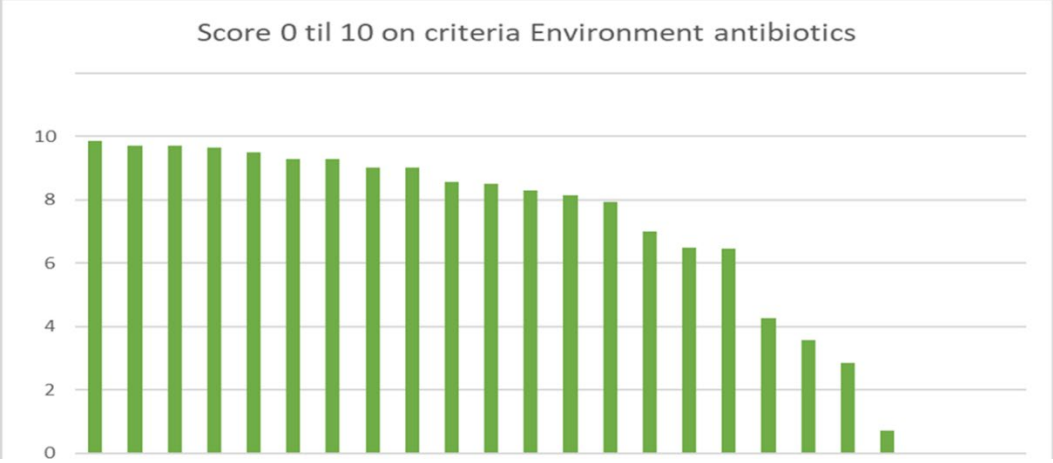

Figure 1

For procurements 2103 and 2104, there were fewer bidders, and evaluating requirement fulfilment by suppliers went quickly. Only one supplier had not provided documentation for ISO 14001 certification, and otherwise there were small variations in how the requirements for eco-friendly transport and water reduction were fulfilled. Evaluating the environmental requirements for products based on submitted samples was done together with the specialist group. There was sufficient time to carry out all the evaluations at the whole-day meeting that had been set aside for the specialist group, but some of the evaluations were not completed on the same day due to the extra quality assurance work required afterwards. The requirements for products that were to be assessed on the basis of the supplier's responses were done in advance, prior to the specialist group meeting. Three of the requirements could be calculated mathematically based on the bidder's response, and it is thus entirely possible to perform an effective evaluation without manual operations if you have good technical solutions.

Example of calculating the score for transport of air for a received bid; see Table 2

Unit	Number of smallest unit	Number of smallest unit per 190cm pallet (as stated in the bidder's response)	Number of pallets	Total pallets	Score for transport of air [(Total for best offer)/(Total offer X)]*10 = Grade for offer X
500 ML	48 643	1210	40,20082645	355,070065	9,29162121
1000 ML	209 915	672	312,3735119		
250 ML	4 672	1872	2,495726496		

Table 2

Environmental certification requirement
Most suppliers and production sites were environmentally certified through ISO 14001. This is therefore a requirement that can be made mandatory in several procurements in the future. The extent to which this can be regulated by relevant third parties must, however, be taken into account in order for it to have a real value.

The requirements for Certification and Environmental Management are also not enough to understand what the individual supplier actually contributes to, so this must be followed up more closely, e.g. by setting other specific requirements, and by contract follow-up.

Water reduction
This requirement was included as a result of input from suppliers who are already working closely with the problem. Specific goal achievement by the bidder was evaluated, but whether they had goals for water reduction or not. It is conceivable that you can develop a standard to also assess the consumption of water, but it will probably be some time before a measurement method is developed that can be used to evaluate this.

Emissions of harmful substances into the environment
Some suppliers have facilities that ensure zero-discharge of API (active pharmaceutical ingredient) into the environment, through the incineration of waste-water. This indicates that there is great potential to be extracted within the areas where large emissions of harmful substances into the environment is a risk factor.

There is extensive use of third-party manufacturers in the pharmaceutical industry, and there is a great need for environmental work to be clearly regulated in collaboration agreements. Bidders have different approaches to transparency in their supply chains, and increased transparency will be an

important focus in the future. This can be achieved e.g. by rewarding bidders who state the API country of production or production sites when submitting a tender.

Training

There are different levels of training of third-party suppliers in environmental procedures. Some participate in their own programmes for sharing their experiences, while others only inform about expectations in their collaboration agreements. Competence within the environmental field is on the rise, and it will be necessary for further progression to also include manufacturers/producers in other countries in this rise in competence. In the completed procurements, the only question asked was whether training has been completed, but in the future it will be possible to specify the type of training and competence you want a third party to be able to document that they have achieved, such as during a visit to the factory.

Transport

Questions were asked as to whether the carriers/transporters used were bound by environmental standards, and calculations of the transport of air were also carried out.

Different suppliers use different transport routes, have different transport distances and different packaging design, which are important factors for emissions during transport. The Norwegian Hospital Procurement Trust does not know of any tools that make it possible to calculate comparable, real emissions, so evaluating eco-friendly transport has a large degree of discretion. In order to increase the probability of receiving comparable responses, the transport distance to be evaluated was limited to transport between the place of production of the finished product (not raw materials) until reaching the customer. In Norway, such products are mainly delivered to 1-2 delivery locations, which makes this scenario somewhat easier than in other countries, where delivery takes place directly to the individual hospitals.

The zero-emissions goal will be the focus in the future, and thus parameters such as transport distance and real energy consumption will not be decisive for the degree of goal fulfilment.

The number of pallets is a specific measure that can easily be used to give points and which is well suited for discerning among suppliers and motivating more efficient packaging designs and reducing transport volume.

Return scheme

The Norwegian Hospital Procurement Trust (pharmaceutical division) has a long tradition of demanding membership in a recycling and return scheme (Green Dot, or its equivalent) as a contractual requirement. Bidders with products that are not Norwegian can document this requirement by showing agreements with the contract wholesalers of the hospitals.

Amount of waste

In the Medical Foodstuffs procurement, the amount of waste was evaluated, including how much space the packaging takes up in the waste and what possibility there is for compaction. These are mainly hard plastic bottles and large containers where there is great potential for waste reduction. This was not assessed for products that contain or may contain drugs, but it should be considered whether there are other areas where the amount of waste is relevant to evaluations in this area.

The health trusts in Norway have limited storage space, and requirements for reduced waste volumes and reduced transport of air will indirectly be able to contribute to the health trusts being able to utilise their storage capacity significantly better.

Energy consumption
Some suppliers have carried out life cycle analyses for their products, but these are too few to have a sufficient basis for comparison at present to assess energy consumption as a separate parameter in procurements for pharmaceuticals or medicinal foods. You can encourage several suppliers to do their own analyses, but it also requires that there is agreement among bidders and the client regarding standardised measurement methods. The most realistic way is to watch what is being done in other areas to see how this can develop further.

Packaging
Suitability for packaging recycling and requirements for labelling with recycling symbols proved to be easy to assess and have great potential for improvement among bidders, but this requires some adaptations to the specification requirements in order for the evaluation to be more effective.

4.5 Profit realisation

Summary overview of budget/quality outcomes:
For all the procurements, the project group reviewed preliminary expectations for price developments in the procurement; the same was done after the procurements were done. At the beginning, we were worried that the environmental requirements could lead to significantly price increases in the procurements, but it was difficult to find evidence for this. It turns out, however, that setting other demands than prices had a price-altering effect that was clear and also significant. By comparing what we have seen regarding prices from Denmark, we see it clearly. They only utilise price in their procurements, while we have different sets of requirements and this creates higher prices.
But we were not able to see how environment alone versus the other requirements we set for the product increased prices to any particular degree.
We thus concluded that we do see an effect on prices when setting requirements for products, obviously, but that environmental requirements as such do not overturn the cart in relation to costs. But this is an element we will take a closer look at over time, to get a better understanding of this conclusion.

4.6 Contract follow up

Due to the corona pandemic, it has not been possible to follow up the agreements signed as of 01.02.2020 using physical visits to selected suppliers. The plan was to visit 2-3 suppliers to gain experience and broaden our basis for evaluation.

The visits will therefore be done once new agreements are signed, and for future contract periods.

5 Further work

A number of initiatives are underway at the Norwegian Hospital Procurement Trust, at the regional health trusts and in the health services internationally, and the focus of our future work will be to implement environmental requirements in several procurements, as well as look at what

requirements are set in other countries and increase competence in this area. The labelling schemes that are developed in other areas (e.g. by the Nordic Swan Ecolabel) will be monitored to see if there are any relevant issues and tools that can be transferred to the category of pharmaceuticals.

Inhalation anaesthetics, inhalers and hormones are examples of relevant areas where no targeted work has been done with environmental requirements in Norwegian hospitals, yet, but where targeted measures are underway in other countries that are logical to build on in future procurements. Work will also be done to further develop the requirements that have already been implemented, such as to help reach the goal of zero emissions during transport. We also have a goal to find targeted and truly effective requirements, rather than having as many requirements as possible.

6 List of environmental requirements used

6.1 Procurements for anti-infectives and various chemotherapeutics

See Table 3.

The supplier should have an overall environmental strategy that includes its entire portfolio. If necessary, also state which parts of the portfolio you do not have an environmental strategy for.	The supplier is asked to provide a summary and concrete description. The supplier shall not enclose other documents.
The supplier should have an overall environmental strategy that includes the entire value chain from raw materials to finished product. If necessary, also state which parts of the value chain you do not have an environmental strategy for.	The supplier is asked to provide a summary and concrete description. The supplier shall not enclose other documents.
Will the supplier be willing to state in what/which country the API/raw material production for offered products takes place, if the Norwegian Hospital Procurement Trust requests such information?	The supplier is asked to answer Yes/No. The supplier shall not enclose other documents.
Does the environmental strategy include the factory(ies) that complete the ready-to-sell packages?	The supplier is asked to answer Yes/No. The supplier shall not enclose other documents.
Does the environmental strategy include API/raw material producer(s)?	The supplier is asked to answer Yes/No. The supplier shall not enclose other documents.
Does the environmental strategy include treatment plants for API/raw material producer(s)?	The supplier is asked to answer Yes/No. The supplier shall not enclose other documents.

Does the strategy include weight assessment/mass balance calculations and/or monitoring emissions and corresponding environmental risk assessments?	The supplier is asked to answer Yes/No. The supplier shall not enclose other documents.
The supplier should carry out environmental audits on the procurement, production and waste management of API/raw materials, and be asked to describe the scope of such audits, including the frequency of performing the audits.	The supplier is asked to provide a summary and specific description of scope and frequency. The supplier shall not enclose other documents.
The supplier should be willing to share results from completed environmental audits, including who has performed the audits, and is asked to describe the extent to which such results can be presented at the request of the pharmaceutical division at the Norwegian Hospital Procurement Trust.	The supplier is asked to provide a summary and concrete description. The supplier shall not enclose other documents.
The supplier should provide a table of contents for its environmental procedures for waste management of API, or an overview of the procedures for auditing waste management at API manufacturers, in cases where the supplier does not have the API production.	The supplier is asked to provide a table of contents for environmental procedures (title) for waste management of API. The supplier shall not enclose other documents.
The supplier should have an environmental procedure that applies to both the supplier's factory(ies) and/or API/raw material producer(s). In cases where the supplier does not have its own factories, the supplier should have procedures for environmental audits of factories.	The supplier is asked to provide a table of contents of environmental procedures or procedures for environmental audits (title) where it states which are for factory(ies) and/or API/raw material producer(s). The supplier shall not enclose other documents.
The supplier should provide third-party manufacturers with training in the supplier's environmental procedures.	The supplier is asked to provide a summary and concrete description. The supplier shall not enclose other documents.
The supplier should, as part of the supplier's environmental risk assessment, carry out sampling of waste-water from API/raw material producer(s).	The supplier is asked to provide a summary and concrete description. The supplier shall not enclose other documents.
The supplier should, as part of the supplier's environmental risk assessment, carry out weight assessment/mass balance calculations of waste-water from API/raw material producer(s).	The supplier is asked to provide a summary and concrete description. The supplier shall not enclose other documents.

Table 3

6.2 Infusion and Rinsing Fluids and Tube Feeding and Other Medicinal Foods

See Table 4. Gray requirements are MUST requirements, others are evaluation requirements

Environmental requirements at supplier level (ML)	
The supplier's production sites should be certified by an accredited third party in accordance with ISO 14001, EMAS or the equivalent.	Enter the number of production sites and the number of those that have such a certification. For this to count on the criterion, a copy of the certification must be attached.
The supplier's production sites should have a strategy for water reduction, with targets for reduction.	Briefly describe the strategy, action plan and point of departure (baseline)/goals. For the highest possible calculation of the criterion, specific information should be provided.
The supplier's transporter(s)/carrier(s) should be required to use Euro 6 vehicles.	Enter the number of carriers and the number of carriers where this is a requirement. Applies to transporting finished products from supplier to customer.
Environmental requirements for at product level (MP)	
Offered product must not have packaging that contains PVC or PVDC.	Must be confirmed
Offered product must have outer packaging that can be recycled (source-sorted and recycled).	Must be confirmed. Outer packaging here means the transport packaging around the product.
Offered products should have packaging suitable for recycling. Packaging in the most homogeneous material possible is desired, and for plastic preferably PE, PP or PET.	State the material(s) in the packaging and whether it is homogeneous packaging.
Offered products should have inner and outer packaging with text and symbols for recycling.	Enter the text and the source sorting symbols the product is marked with.
The product offered should have outer packaging with a high percentage of recycled material, which does not come at the expense of the packaging's function.	Enter the percentage of recycled material as a percentage
Offered products should have the lowest possible transport volume (minimising the transport of air).	Enter the transport volume as the number of smallest units that can be transported per pallet at a height of 190 cm. Stated per offered item line.
Offered products should have inner packaging and possibly a cover bag where appropriate, which takes up as little space as possible in the waste.	Evaluated on the basis of a sample submitted to Norwegian Hospital Procurement Trust. 1 unit is submitted as described in the tender documents. If necessary, describe how the product can be compressed.
Offered products should have inner packaging of low weight.	Enter the weight of the inner packaging per unit in number of grams.

Table 4