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Experience Report Environment

Environmental Requirements for Pharmaceutical Procurements 2022-2023

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1. Introduction

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 our work. This is a follow-up to the work described in the corresponding report, published in 2022. Our experience with many types of environmental requirements in the field of pharmaceuticals will be used to identify suitable requirements in new procurements of pharmaceuticals, both nationally and internationally.

The work presented in this report can be beneficial in areas that are not relevant to evaluating a procurement through knowledge sharing and interaction across interest groups and countries. There are separate regulations for the pharmaceutical sector, which means that it is not always feasible to influence suppliers through procurements. Examples of environmental requirements that have proved more difficult to introduce than in other areas are: phasing out harmful substances, requirements for the proportion of recycled packaging and labelling of packaging.

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. There are approximately 2000 different drugs procured for Norwegian hospitals. These are distributed among approx. 30 different specialist groups within different disciplines. The largest procurement contains over 1100 different medicines. The specialist groups consist of professional representatives from the health regions who participate in the design of tenders and evaluations, in addition to the Norwegian Hospital Procurement Trust (Sykehusinnkjøp HF) and the Directorate for Medical Products (DMP). New in 2023 is that the four Medical Directors (one from each Regional Health Authority) has been appointed as the steering group for the procurements.

As of 01.01.2024, stricter requirements have been introduced in all public procurements in Norway stating that environmental requirements must be emphasised with 30% in procurement allocation criteria. Mandatory requirements can be used if they provide a better environmental benefit. The pressure to introduce environmental requirements in more pharmaceutical procurements in Norway is therefore greater now than before. So far, it has been most relevant to introduce environmental requirements in procurements where more criteria than price have already been introduced. The stricter requirements will mean that more criteria than price will be introduced in more procurements. The introduction is assessed specifically for the individual procurement and is explained and justified in the tender documents.

If the documentation requirements are found to be too time-consuming, or there is too high a risk of sanctions, suppliers may choose not to submit bids. Since pharmaceuticals are vital products, it is not immediately possible to set requirements that bidders do not accept. This means that expertise, targeted long-term work and close dialogue are key ingredients for achieving the goals.

2. Summary

The procurements that have been covered by environmental requirements with a 30% weighting are Antiinfectives, Off-patent oncology, Infusion and flushing fluids, Tube feeding and other medical foodstuffs, and Joint Nordic procurements. A mandatory appendix with a zero-emission plan has been introduced in several procurements.

A decision has been taken to phase out inhalers with greenhouse gases, and to phase out desflurane in the health trusts. These two measures alone are the most effective that can be implemented in the pharmaceutical field, with reductions in direct emissions of more than 6000 tons of CO_2 per year in hospitals. Other long-term measures going forward are also important. These will mainly have an effect on indirect emissions from the sector.

New environmental requirements that contribute to less development of resistance in connection with antibiotic production shall be used in all joint Nordic procurements of antibiotics, as well as local procurements for Norway, Denmark, Iceland and Finland. The requirements were launched in the spring of 2023 and have been adopted by Norway as the first country out, in spring and autumn of 2023. Other Nordic procurements will follow in 2024. The AMR Industry Alliance and BSI are key partners for the Nordic requirements. These are operators with an established global business enterprise in sustainable antibiotic production. There is a separate goal to encourage other European countries to adopt the same criteria.

There is strong interest from other countries around the world to introduce and further develop such requirements. Norwegian Hospital Procurement Trust participates actively in dialogue with suppliers and shares experiences with other countries and stakeholders, especially within Nordic cooperation. By participating in the dialogue and sharing experiences internationally, we also succeed in achieving effective benefits from our work on environmental requirements.

3. Experience

3.1. International cooperation

Stated support for the new antibiotic manufacturing certification scheme hosted by AMR Industry Alliance and the British Standards Institution (BSI) is an important measure in achieving the goal of reducing the global incidence of antibiotic resistance. Norway is collaborating with the Nordic Pharmaceutical Forum as a pioneer in this area. Below is a description of the process that has been completed.

A proposal for joint Nordic environmental requirements for antibiotics based on previous experience, as well as work carried out by the AMR Industry Alliance, was discussed in meetings organized by the Nordic Pharmaceutical Forum. AMR Industry Alliance and BSI provided much constructive input to the proposal.

The results of the collaboration were presented to the pharmaceutical industry in two dialogue meetings held by NHPT and AMGROS. Over two hundred people participated in the events, in person and digitally. The participants were the European Federation of Pharmaceutical Industries and Associations (EFPIA), government authorities and purchasing organizations from several countries. At the same meetings, AMR Industry Alliance and BSI launched a new certification scheme for the production of antibiotics, which aims to combat the development of antibiotic resistance at factories. In both dialogue meetings, there were many questions and discussions that AMR Industry Alliance and BSI actively participated in. AMR Industry Alliance and BSI are global operators. This close cooperation ensures that the new Joint Nordic environmental requirements have a greater impact outside the Nordic region.

The industry and several others asked for follow-up meetings in which they gave input, as well as answering written questions. The input has been positive, and broad support has been put forward for the requirements from many different parties.

Important discussion points in the process: affiliation requirements, transparency, environmental management systems and how to assess responses and different situations. The approach of not excluding bidders, but that the requirements may become stricter in the long term, was also discussed in depth.

It will be up to each procurement to assess whether requirements for third-party certified environmental management systems and sustainable antibiotic production are included in the framework agreement, or whether there will be evaluation requirements based on whether relevant bidders meet this or not. The same applies to transparency about production sites.

Since its launch, several purchasing organizations in other countries have contacted us with a desire to apply the same requirements. For purchasers new to this type of assessment requirement, it requires extra planning. There may be a need for increased expertise and appropriate tools to implement the change in several places.

3.2. Market dialogue

Developing targeted requirements requires close dialogue over time.

Environmental requirements have been addressed in all procurement dialogue meetings with more criteria than price. These procurements comprise approximately 90% of the drugs used by the health trusts, measured in number of units. Approximately 80 different suppliers participate actively in these procurements. At least one joint dialogue meeting is held in each procurement, possible theme meetings and each supplier can request a dialogue meeting. 30 minutes are set aside for each supplier that requests it. Everyone is encouraged to submit written input. One-on-one meetings are often better suited for dialogue and input than joint meetings. The environment is a topic that piques everyone's interest. There are many good discussions and much knowledge sharing, both in formal and informal contexts.

There has also been dialogue with other parties such as DMP, the Norwegian Pharmaceutical Compendium, FASS, the regional health authorities and the Norwegian Directorate of Health. International dialogue is described in the section on International Cooperation.

The market dialogue has revealed that there are major gaps in environmental information on the various medicines, and also that there are some regulatory obstacles to achieving specific environmental objectives.

PNEC (predicted no-effect concentration) is not known to most old pharmaceuticals except antibiotics. Nor is there any information for prescribers about the environmental risks of pharmaceuticals, or how to take environmental perspectives into account when prescribing. Although many medicines have a harmful effect on the environment, there is no information about this in the Summary of Product Characteristics (SmPC) or package leaflets. The Norwegian Pharmaceutical Product Compendium (NPC) cooperates with Swedish FASS to publish identified environmental information. NPC and FASS have no information related to greenhouse gases such as apaflurane, norflurane and desflurane or CO2 footprints in general.

It will require a great deal of work ahead to obtain information on PNEC and CO_2 footprints for all medicines. It is also necessary to work with EU pharmaceutical authorities to achieve environmental goals more quickly – such as removing harmful substances from packaging, removing paper package inserts, introducing greater use of recycled materials and improving recycling. For new medicines, an environmental risk assessment (ERA) is submitted to the authorities upon approval of the medication, but these risk assessments have no practical consequences. This is likely to change in the future.When introducing new environmental requirements, a supplier reported that over 20 people were involved in obtaining information for the tender submission. Even though there is still a great deal of work to be done in the pharmaceutical field, there is a lot of commitment and desire from suppliers, customers and other partners to solve environmental problems.

3.3. Greenhouse gas decision

In 2023, two environmental issues were decided in the RHF Discipline Directors' Meeting (the steering group) on the procurement of pharmaceuticals.

It was decided that inhalers that emit greenhouse gases should be replaced with inhalers with alternative options, mainly administration via nebulizer. The decision will enter into force on 01.02.2025. The signal effect is great, and hopefully the measure will help out-of-hospital health services reduce the consumption of greenhouse gas inhalers.

The second decision is that the footprint of inhalational anaesthetics shall be minimised, by switching from desflurane to sevoflurane and using collecting equipment. The Norwegian Directorate of Health has proposed an end date for desflurane as soon as possible. The consumption of desflurane is declining, and each individual health trust is responsible for phasing it out. Similar decisions have been made in other countries. The final completion date has been adopted by the EU in 2026.

The two decisions together result in a cut of 6000 kg of CO_2 in direct emissions per year in hospitals. Only 10 product lines account for the largest emissions.

Line items with the highest greenhouse gas footprint:

Name	KG CO2* footprint
Suprane Liquid for inhalation vapour	4 697 046
Sevoflurane Solvent for inhalation vapour 100% v/v	682 781
Isoflurane Liquid for inhalation vapour	243 779
Sevorane Liquid for inhalation vapour	195 789
Ventoline Inhalation Aerosol, suspension 0.1 mg/dose	110 664
IsoFlo vet Liquid for inhalation vapour 100% w/w	56 215
Atrovent Inhalation Aerosol, solution 20 µg/dose	41 232
Sevoflurane Solvent for inhalation vapour 100% v/v	21 458
Trimbow Inhalation Aerosol, solution 87 µg/dose/5 µg/dose/9 µg/dose	16 027
Airomir Autohaler Inhalation Aerosol, suspension 0.1 mg/dose	10 416
Total top 10 product lines	**6 075 407**
Sum all inhalations	**6 113 165**

*KG CO_2 is calculated according to one year's consumption in Norwegian hospitals (2022). For inhalers, the value is estimated at 120g CO_2 per dose. Real figures per dose vary from product to product.

3.4. Zero Emissions Plan

Although setting requirements for CO_2 footprints has been discussed for many years now, we have not come far enough in developing standard analytical methods that allow comparison of CO_2 footprints between two equivalent drugs. Few pharmaceutical suppliers have prepared life cycle analyses for their products.

As part of NHPT's (Pharmaceuticals Division) follow-up strategy, a decision was made in 2022 to introduce requirements to submit a Zero Emissions Plan as part of the framework agreement for all procurements. The plan was introduced in 2023 for most drugs and will be introduced in 2024 for the remaining procurement.

The plan will provide health trusts with information on providers' plans to reach net zero emissions by 2050 as part of the health trusts' own climate target of net zero emissions by 2045. Scope 1, 2 and 3 shall be mentioned in the plan. Most vendors have submitted the plan along with the quote. The responses provide good overall insight into the individual suppliers' plans, and can be used actively in the follow-up of the environmental goals that have been set.

Scope	Guidance	Plan to reach zero emissions by 2050
Scope 1 - all direct GHG emissions from a company.	Enter a primary description, not a detailed plan.	
Scope 2 - Indirect company GHG emissions from the consumption of purchased electricity, heat, or steam.	Enter a primary description, not a detailed plan.	
Scope 3 - All indirect emissions that occur in the value chain of a company (excluding Scope 2), including both upstream and downstream emissions.	Enter a primary description, not a detailed plan.	

3.5. Completed procurements

The table lists the various procurements, as well as the number of environmental requirements and the number of evaluations. For more information on specific requirements, see List of Environmental Requirements.

No.	Name of procurement	Number of environmental requirements in the procurement (Organisational = one answer for all products)	Number of specification requirements received with environmental responses	Number of evaluation forms (competitions)	Total number of requirements evaluated (not including the mandatory requirements)
2001a	Anti-infectives	14 organisational	23		322
2201a	Anti-infectives	14 organisational	30		394
2501a	Anti-infectives	2 organisational 4 products	30 organisational 93 products	18	432
2107gj	Off-patent oncology*	14 organisational	36		518
2407gj	Off-patent oncology	2 organisational 3 products	40 organisational 130 products	33	510
2103	Infusion and rinsing fluids	3 organisational 4-6 products	4 organisational 64 products	16	120
2403	Infusion and rinsing fluids	4 organisational 3-4 products		13	
2104	Tube feeding and other medicinal foods**	3 organisational 6 products		19	
2404	Tube feeding and other medicinal foods**	3 organisational 6 products		24	
2020	Nordic procurement	3 organisational			
2022	Nordic procurement	3 organisational			

*The acquisition(s) have changed their name from 'Miscellaneous chemotherapeutics'. In the previous report, the figures were divided between the 4 different procurements carried out in this area.

** The procurement does not include pharmaceuticals

3.6. Preparation of specification requirements and implementation of the competition

No complaints have been received about any of the environmental evaluations. Providers want to gain greater insight into how they can improve, and they get this through the justifications. There have been a number of dialogue meetings on the results of environmental evaluations at the request of suppliers. It shows that the requirements contribute to cooperation and dialogue, which provides increased knowledge and opportunities for improvement at the individual supplier.

The general rule of 30% emphasis on the environment has been followed in all procurements that have had environmental requirements. Standardised response alternatives have been introduced for most requirements. Standardised response alternatives enable additional automation. Response alternatives make it easier and less time-consuming for providers to answer questions precisely. This makes it easier to conduct consistent evaluations across procurements, it reduces random errors in the evaluation, while significantly speeding up the evaluations. The requirement specification is set up to allow for different requirements for different product groups in the same procurement. This ensures that the requirements are targeted, even where there is great variation in the environmental footprint within each product group.

During the question-answer period of the competition, technical questions often arise as to how the evaluation is conducted. In particular, there is a need for translation of environmental requirements into English.

The largest procurements where environmental weighting has not been introduced are Injection infusion medicines and Non-injection infusion medicines. For these drugs, there are many monopoly situations, little competition and low contract coverage. Fewer requirements make tender submission easier. The introduction of more requirements must be weighed against the risk of losing bidders.

3.7. Evaluation

See also sections List of Environmental Requirements and Results from Evaluations (figures).

3.7.1. Major Accomplishments

The average discount has increased in the procurements, and for the procurement Off-patent oncology, the gain is MNOK 90 per year compared with the previous contract period.

We have an example of an increased discount compared to the previous contract period, even though the cheapest product did not win the competition. This shows that suppliers are interested in competing on price, even if environmental criteria are included in a procurement. The increase in the discount is due to the fact that we have implemented measures over several years to make it more predictable for suppliers at all stages of the procurement process. It is also nice that suppliers say they are interested in participating in the competition because Norway appears to be a pioneer on this topic.

The main reason the price level has not been increased is that there were already quality requirements in all procurements where environment is weighted. Some winners have achieved a higher price for their drug as a result of a good response to the environmental requirements. This shows that the requirements have the intended effect of reducing price pressure in a competition.

The environmental evaluations have taken 1-2 days in each procurement. An extra day was spent assessing environmental management systems for the first time. This is because the requirements encompass many different situations that require the supplier to provide additional information in order to obtain a a weighted score. Careful reading of the responses and extra quality assurance were necessary to ensure that identical cases were treated equally.

The number of requirements has been reduced in some procurements. Fewer requirements make each requirement more decisive, and it is of great importance that one can expect beneficial environmental effects from the requirements imposed. Some requirements are easier to gain points on, so that there are few suppliers who get zero points on everything. Many suppliers deliver very well on environmental requirements. These set the premises for what level is expected in the future.

Total contract coverage has gone up when we look at value. The number of bidders is about equal. In cases where we lose bidders on essential medicines, we contact our suppliers and consider long-term measures.

3.7.2. Technical execution

A single evaluation form (Excel) is generated for each subcontract with multiple bids.

All responses received are compiled (Excel). Each standardised response alternative has a score (0-10) that is the starting point for the evaluation. These are identified via a query formula. For some requirements where the answer is a numeric value, the score can be calculated via a relative formula.

All the answers within a requirement are reviewed before the final determination of points is made. A deduction from the score is given if the answer is incomplete or contains conflicting information, an increased score is given if information supports it. Excel provides the ability to filter one response alternative at a time, which helps ensure equal treatment. Most often, this work will take approx. 2 days in a large procurement with many submitted answers.

The evaluation form generates a comprehensive justification text for each bidder based on differences in each evaluation. After all evaluations have been carried out, the results and justifications are compiled in an evaluation report, where forecasts are also entered.

Many different worksheets complicate the process. So far, this has been solved through continuous improvements in Excel.

3.7.3. Quality Assurance

The most important quality assurance occurs in the formulation of the requirements. Therefore, it is recommended that one uses requirements that have developed over time, through broad dialogue and knowledge of the products you are going to purchase.

The score and justification are reviewed by 1-2 qualified persons after the evaluation. It is possible to request a post-submission of documentation for requirement fulfilment, but the score is always determined based on information in the response submitted at the deadline.

Proof of fulfilment may be enclosed with the bid or forwarded upon request. It can be time-consuming for suppliers to obtain documentation, especially for requirements imposed for the first time. The supplier is bound by the responses submitted in the tender, so that in some cases documentation requirements can best be followed up after signing the agreement or prior to award.

It is typical of the evaluation of entirely new requirements that one is presented with cases of which one had no prior knowledge and therefore did not take into account when planning the evaluation. For the next evaluation, one will have better knowledge of how the various responses are progressing and one can take this into account in the planning.

4. Contract follow-up and further work

More extensive environmental requirements require more extensive contract follow-up.

In the previous period, we followed up four suppliers in the form of a meeting where we reviewed the status of environmental work in the organizations at a general level. Both international and national representatives of the suppliers participated in the meetings.

In the next period, we want to build on this, and to expand follow-up somewhat through reporting and follow-up meetings.

When several countries have introduced common environmental requirements, a more international approach may be possible, such as different countries being responsible for following up different suppliers. This can also be seen in the context of the EU's initiatives for several joint procurements and in future expansions of joint Nordic procurements.

There is a great need to increase knowledge about the environmental impact of pharmaceuticals. NHPT will help to disseminate relevant knowledge and be an active partner for the health trusts to achieve their climate and environmental goals. In this context, there is a need to set up more analyses than are presented in the chapter Results from Evaluations (figures).

The changes to be made to environmental requirements in the future will depend on regulatory decisions made by EU, increased level of knowledge and speed of development of suppliers and products. Many of the requirements adopted so far can be made stricter, extended to more pharmaceuticals or removed if they are replaced by regulatory requirements.

Phasing out harmful substances, life cycle analyses, PNEC values, zero emissions and circular economy are major topics to address in this area in the years ahead. Developments will be followed closely through continued cooperation and dialogue at several levels both nationally and internationally, and more directly through contract follow-up within individual procurements.

5. List of Environmental Requirements

Grey Requirements are mandatory requirements; others are Evaluation Requirements.

No.	Requirement	Additional information	Procurements where the requirement is used
1	The supplier should have implemented an environmental management system for active ingredient production for offered products, which safeguards risk assessments, environmental routines, environmental audits and sanctions in the event of breach of agreement/environmental routine. For a a weighted score, the environmental management system must be certified by the third party.	State the response alternative. If necessary, specify which third-party certification has been used, what is not covered (risk assessment, routines, environmental audits and/or sanctions), and whether there is an agreement on the implementation of an environmental management system with any third-party manufacturer or whether the supplier owns the production itself. If you do not own production or have an agreement with the manufacturer on the implementation of an environmental management system, the requirement will be awarded points. The purpose of the requirement is to achieve the least possible environmental impact in the production of the offered product.	Anti-infectives Off-patent oncology Similar requirements for Infusion and rinsing liquids Tube feeding and other medicinal foodstuffs
2	The supplier should have implemented an environmental management system for finished product production for offered products, which safeguards risk assessments, environmental routines, environmental audits and sanctions in the event of breach of agreement/environmental routine. For a a weighted score, the environmental management system must be certified by the third party.	State the response alternative. If necessary, specify which third-party certification has been used, what is not covered (risk assessment, routines, environmental audits and/or sanctions), and whether there is an agreement on the implementation of an environmental management system with any third-party manufacturer or whether the supplier owns the production itself. If you do not own production or have an agreement with the manufacturer on the implementation of an environmental management system, the requirement will be awarded points. The purpose of the requirement is to achieve the least possible environmental impact in the production of the offered product.	Anti-infectives Off-patent oncology Similar requirements for Infusion and rinsing liquids Tube feeding and other medicinal foodstuffs
3	The supplier's carrier(s) should use the most eco-friendly transport (zero	Describe which means of transport the supplier's carrier will use and the country from which the finished product will be	Nordic procurement

No.	Requirement	Additional information	Procurements where the requirement is used
	emissions) possible for the offered products.	released. This applies to transporting finished products from supplier to customer.	Infusion and rinsing fluids Tube feeding and other medicinal foodstuffs
4	The supplier's production sites for The offered product should have water reduction targets.	Specify response alternatives and, if necessary, specify the starting point (baseline), objectives and degree of goal attainment on the last measurement, as well as how this is regulated in agreements with any third-party suppliers. This is to achieve the least possible water consumption in production. In the future, the requirement will be set per smallest unit, but it is considered that few suppliers can provide information on water consumption per product in 2023.	Infusion and rinsing fluids Tube feeding and other medicinal foodstuffs
5	The supplier should have a system in place to check water access at and around production sites for the offered product(s).	Indicate the response alternative and, if applicable, a list of procedures relating to water access at and around the production site and how this is regulated in agreements with any third-party suppliers. The purpose of the requirement is to ensure that the production does not result in reduced water access for areas around the production site that have consequences for the population and the environment in the area.	Infusion and rinsing fluids Tube feeding and other medicinal foodstuffs
6	The offered product should be manufactured by a supplier that can demonstrate compliance with the AMRIA Antibiotic Manufacturing Standard or similar manufacturing standard that combats antimicrobial resistance throughout the supply chain. To achieve the highest score, this must be certified by a third party or the certification process must have started.	State the response alternative. The purpose of the requirement is to achieve the least possible environmental impact in the production processes of the products and to avoid antibiotic resistance resulting from the production of the offered product. Compliance with the AMRIA standard can be proven by independent third-party certification, through programmes such as the Antibiotic Resistance Manufacturing certification programme by BSI. The standard set by AMRIA is found here: https://www.amrindustryalliance.org/shared-goals/common-antibiotic-manufacturing-framework/ Read more about this here: BSI certification.	Anti-infectives

No.	Requirement	Additional information	Procurements where the requirement is used
7	The offered product should be produced by the active ingredient manufacturer and the finished product manufacturer that have routines for handling and/or treating wastewater from production in order to achieve the presumed-no-effect concentration (PNEC) of the active substance.	State the response alternative. The PNEC value and the source of the PNEC value used in the routine for the active ingredient manufacturer and the finished product manufacturer shall be specified in order to obtain a weighted score. Procedures for achieving PNEC must be specified in an agreement with any third-party manufacturer in order to obtain a weighted score. Routines must be documented on request. Additional information on PNEC values: https://www.amrindustryalliance.org/wp-content/uploads/2023/02/AMR-Table-1-Update-20230222.pdf PNEC can be active substance specific PNEC-ENV or PNEC-MIC (lowest value). If an antibiotic is not listed in the table, a reading can be made to a similar antibiotic based on its chemical structure or mode of action. Alternatively, based on a statistical assessment of all available data, in the absence of both a PNEC-ENV and PNEC-MIC of 0.05 µg/L, a standard PNEC can be used as a measure. When available, a compound-specific PNEC-ENV, PNEC-MIC or the lower of both values should be used. If no data are available, a standard PNEC of 0.05 µg/L should be used.	Anti-infectives
8	The offered product should be produced by the active ingredient manufacturer and the finished product manufacturer who have routines for minimising the amount and concentration of active substance in wastewater.	The offered product should be produced by the active ingredient manufacturer and the finished product manufacturer that have routines for minimising the amount and concentration of active substances in wastewater.	Anti-infectives Off-patent oncology
9	The offered product should be produced by the active ingredient producer and the finished product manufacturer that have routines for	State the response alternative. Routines for handling, treatment and disposal of waste must be specified in an agreement with any third-party manufacturer in order to be weighted. Routines must be documented on request. The purpose of the requirement is	Anti-infectives Off-patent oncology

No.	Requirement	Additional information	Procurements where the requirement is used
	handling, treating and disposal of waste so that emissions of active substances into the environment are eliminated or minimised.	to achieve the least possible environmental impact in the production of the offered product.	
10	The offered product should be produced by the active ingredient manufacturer and the finished product manufacturer that have routines for handling and/or treating wastewater from production in order to achieve the presumed-no-effect concentration (PNEC) of the active substance.	State the response alternative. The PNEC value and the source of the PNEC value used in the routine for the active ingredient manufacturer and the finished product manufacturer shall be specified in order to obtain a weighted score. Procedures for achieving PNEC must be specified in an agreement with any third-party manufacturer in order to obtain a weighted score. Routines must be documented on request. If PNEC is not known for the active substance, an analysis of PNEC may be submitted to FASS during the term of the agreement for investigation by the Swedish Environmental Institute, or analysis may be provided to an equivalent third party. (Submission to FASS assumes the product has a product review in FASS.se.) More information about PNEC: https://www.felleskatalogen.no/medisin/miljo/innledning. Specific PNEC values are stated in the Summary of Product Characteristics in the Norwegian Pharmaceutical Product Compendium for Marketed Products if they are known and examined by the Swedish Environmental Institute in collaboration with FASS.se. The purpose of the requirement is to achieve the least possible environmental impact in the production of the offered product.	Off-patent oncology
11	The offered product 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 product line. 190cm is the height from which the calculation is made. It is not necessary that the actual pallet height of the product be 190cm. The euro pallet of 15 cm is included in the 190cm.	Infusion and rinsing fluids Tube feeding and other medicinal foodstuffs Off-patent oncology (some)

No.	Requirement	Additional information	Procurements where the requirement is used
12	The offered product should have an outer packaging that takes up as little space as possible in waste.	Evaluated on the basis of a submitted sample. The packaging may be empty and must be marked with which sub-contracts it applies to. Specify a description of how the packaging can be compressed and, if applicable, a picture of empty/compressed packaging. It is the packaging of the sales unit (not the transport packaging) that is evaluated.	Infusion and rinsing fluids Tube feeding and other medicinal foodstuffs Off-patent oncology (some)
13	The product offered should have outer packaging with a high percentage of recycled material.	Enter the percentage of recycled material as a percentage. It is the packaging of the sales unit (not the transport packaging) that is evaluated.	Infusion and rinsing fluids Tube feeding and other medicinal foodstuffs Off-patent oncology (some)
14	The offered product must not have packaging that contains PVC or PVDC.	Packaging refers to inner and outer packaging.	Infusion and rinsing fluids
15	The offered product must not have packaging that contains PVC or PVDC.	Packaging refers to inner and outer packaging	Infusion and rinsing fluids
16	The offered product should have outer packaging printed with text and a sorting symbol for source separation and recycling that corresponds to the Norwegian/Nordic/European labelling scheme. This is to make the packaging as easy as possible to be recycled.	Evaluated on the basis of the bidder's response, as well as a picture of the labelling and information about the composition of the product/packaging. See: https://sortere.no/sorteringsmerker for Norwegian brands.	Infusion and rinsing fluids Tube feeding and other medicinal foodstuffs
17	The offered product should have packaging suitable for recycling. Packaging in the most homogeneous material possible is desired, and for plastic preferably HDPE, LDPE, PP or PET.	State the material(s) in the packaging and whether it is homogeneous packaging.	Infusion and rinsing fluids Tube feeding and other medicinal foodstuffs
18	The offered product should have inner packaging of low weight.	Enter the weight of the inner packaging per unit in number of grams. If the offered product is delivered with an outer bag/cap,	Infusion and rinsing fluids

No.	Requirement	Additional information	Procurements where the requirement is used
		this must be included in the evaluation of inner packaging.	Tube feeding and other medicinal foodstuffs
19	The offered product must not contain greenhouse gas as an additive.	The health authorities have decided to switch from greenhouse gas inhalers, preferably to administration via nebulizer, starting on 01.02.2025. This is to reduce greenhouse gas emissions from the health trusts. Examples of greenhouse gases to be phased out are apaflurane and norflurane.	Non-injection infusion medicines (inhalations)
20	The supplier should state the country and name of the company(ies) producing the finished product of the product offered.	Enter the response alternative and specify (if applicable) country, name, address (coordinates) or Global Location Number (GLN code) of the company. The purpose of the requirement is to assess the risk of delivery failure, as well as plan and implement possible measures to ensure stable delivery over time.	Off-patent oncology Anti-infectives Injection infusion medicines
21	The supplier should state the country and name of the company(ies) producing the finished product(s) of the product offered.	Enter the response alternative and specify (if applicable) country, name, address (coordinates) or Global Location Number (GLN code) of the company. The purpose of the requirement is to assess the risk of delivery failure, as well as plan and implement possible measures to ensure stable delivery over time.	Off-patent oncology Anti-infectives Injection infusion medicines

6. Results from Evaluations (figures)

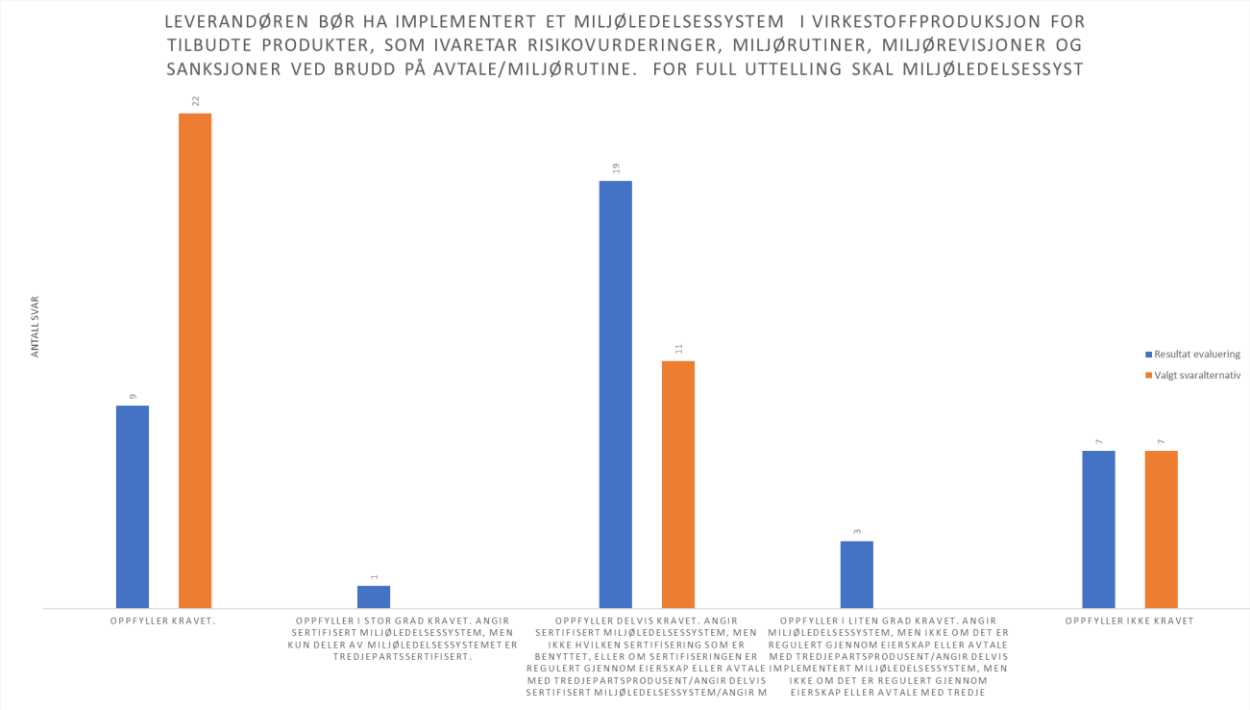
The figures below are made using an inventory of what different suppliers have chosen as a response alternative (orange colour), and how NHPT has evaluated the requirement fulfilment (blue colour).

For some requirements, there is a 1:1 relationship between response and result, while for other requirements there is great variation. Common to the requirements with great variation is that it is not sufficient to choose a standard response alternative in order to get the weighted score, but the bidder must also provide additional information.

The analysis can illustrate how time-consuming it is to submit and evaluate responses for the various requirements, as well as the proportion of suppliers that respond well or poorly.

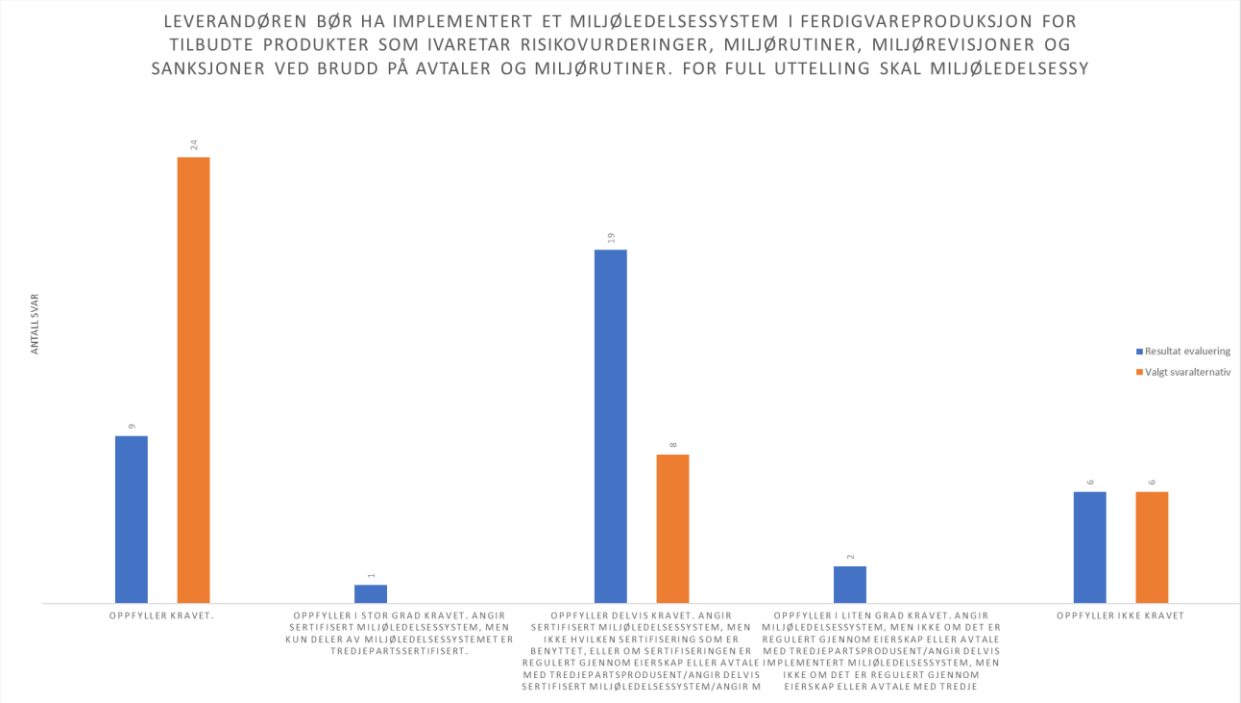
The results presented for Requirements 1, 2, 8, 9 and 10 are from the Off-patent oncology procurement. At the time of publication, there are no corresponding analyses of other requirements for other procurements.

Result for Requirement 1



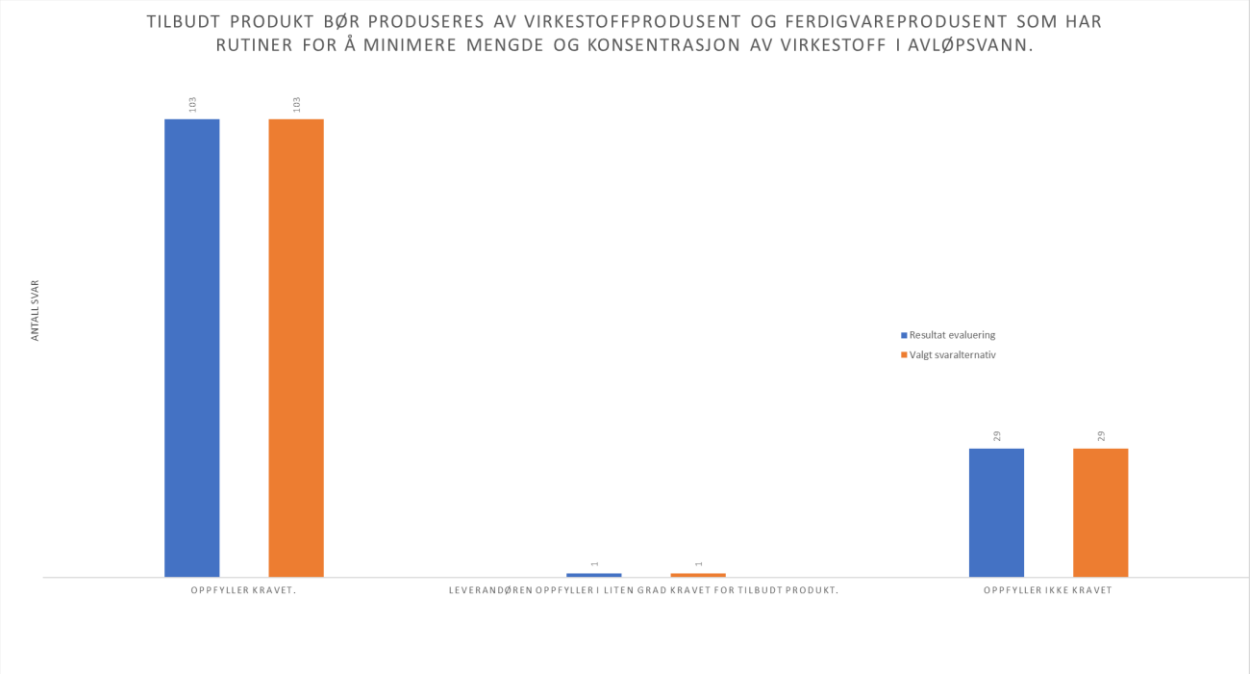
Selected response alternatives (orange)	Number of responses	Results from Evaluations (blue)	Number of responses
Implemented environmental management system for risks, routines, audits and sanctions certified by third parties. (specify which third-party certification has been used, and ownership of/agreement on environmental management).	22	Fulfils the requirement.	9
		Largely fulfils the requirement. State the certified environmental management system, but only parts of the system are third-party certified.	1
Implemented environmental management system not certified by third party/Partially implemented environmental management system	11	Partially fulfils the requirement. Specifies certified environmental management system, but not which certification has been used, or whether the certification is regulated through ownership or agreement with a third-party manufacturer/State partially certified system/state system that is not certified by third party.	19
		Slightly fulfils the requirement. State the environmental management system, but not whether it is regulated through ownership or agreement with third-party manufacturer/State partially implemented system, but not whether it is regulated through ownership or agreement with third-party manufacturer.	3
Does not have an agreement with third-party manufacturers for environmental management system/Has not implemented the system/Do not know.	7	Does not fulfil the requirement	7

Result for Requirement 2



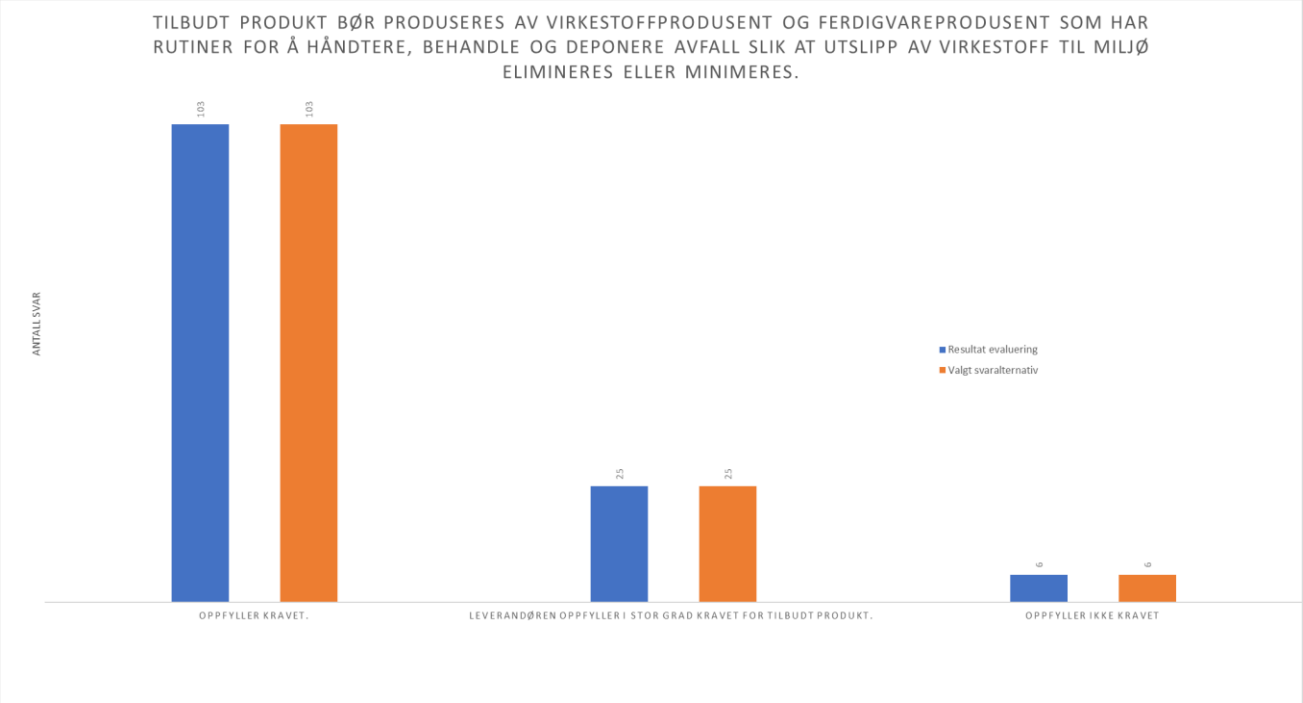
Selected response alternatives (orange)	Number of responses	Results from Evaluations (blue)	Number of responses
Implemented environmental management system for risks, routines, audits and sanctions certified by third parties. (specify which third-party certification has been used, and ownership of/agreement on environmental management).	24	Fulfils the requirement.	9
		Largely fulfils the requirement. State the certified environmental management system, but only parts of the system are third-party certified.	1
Implemented environmental management system not certified by third party/Partially implemented environmental management system.	8	Partially fulfils the requirement. Specifies certified environmental management system, but not which certification has been used, or whether the certification is regulated through ownership or agreement with a third-party manufacturer/State partially certified system/State system that is not certified by third party.	19
		Slightly fulfils the requirement. State the environmental management system, but not whether it is regulated through ownership or agreement with third-party manufacturer/State partially implemented system, but not whether it is regulated through ownership or agreement with third-party manufacturer.	2
Does not have an agreement with third-party manufacturers for environmental management system/Has not implemented the system/Do not know.	6	Does not fulfil the requirement	6

Result for Requirement 8



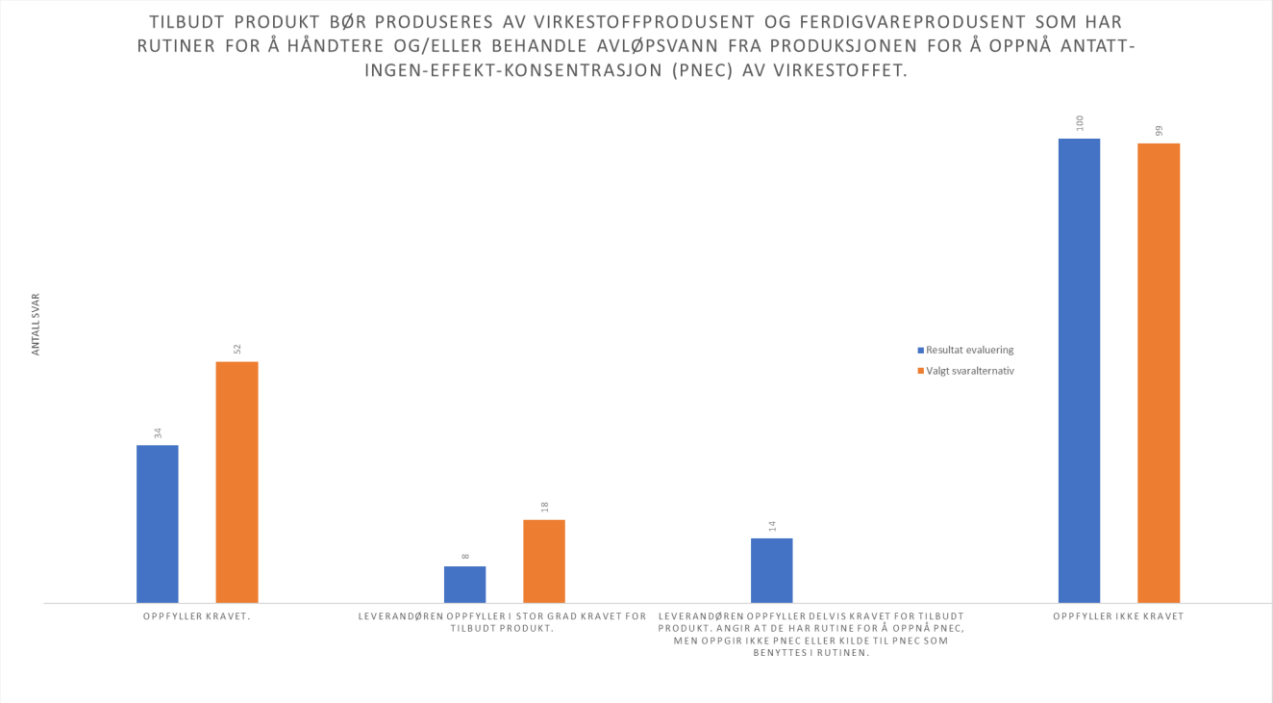
Selected response alternatives	Number of responses	Results from Evaluations	Number of responses
Both the active ingredient manufacturer and the finished product manufacturer have routines for wastewater.	103	Fulfils the requirement.	103
Only the finished product manufacturer has routines for wastewater.	1	The supplier does not fulfil the requirement for the offered product to any great extent.	1
Does not have a routine for wastewater/Does not know what routines are followed for wastewater.	29	Does not fulfil the requirement	29

Result for Requirement 9



Selected response alternatives	Number of responses	Results from Evaluations	Number of responses
Both the active ingredient manufacturer and the finished product manufacturer have routines for achieving PNEC (Specify PNEC and source of PNEC used).	103	Fulfils the requirement.	103
Only the finished product manufacturer has a routine for achieving PNEC. (Specify the PNEC and source of PNEC used)/Only the active ingredient manufacturer has a routine for achieving PNEC/Does not have routines for achieving PNEC, but analysis of PNEC will be delivered to third parties during the agreement period. (Indicate the expected date for delivery of the analysis, and which third party is used)	25	The supplier largely fulfils the requirement for the offered product.	25
Does not have a routine to achieve PNEC/Don't know.	6	Does not fulfil the requirement	6

Result for Requirement 10



Selected response alternatives (orange)	Number of responses	Results from Evaluations (blue)	Number of responses
Both the active ingredient manufacturer and the finished product manufacturer have routines for achieving PNEC (Specify PNEC and source of PNEC used).	52	Fulfils the requirement.	34
Only the finished product manufacturer has a routine for achieving PNEC. (Specify the PNEC and source of PNEC used)/Only the active ingredient manufacturer has a routine for achieving PNEC/Does not have routines for achieving PNEC, but analysis of PNEC will be delivered to third parties during the agreement period. (Indicate the expected date for delivery of the analysis, and which third party is used)	18	The supplier largely fulfils the requirement for the offered product.	8
		The supplier partially fulfils the requirement for the offered product. State that they have a routine for achieving PNEC, but does not provide the PNEC or source of PNEC used in the routine.	14
Does not have a routine to achieve PNEC/Don't know.	99	Does not fulfil the requirement	100

7. References

https://www.sykehusinnkjop.no/siteassets/dokumenter/legemidler/miljorapport/erfaringsrapport-miljo.pdf

https://www.sykehusinnkjop.no/49612e/siteassets/dokumenter/legemidler/miljorapport/erfaringsrapport-miljo_en.pdf

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