

Guide on Sustainability criteria in the Dutch Preference Policy

Guide for users of the Preference Policy of
healthcare insurers in the Netherlands

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Contents

Contents	2
Introduction.....	3
Production location (PRK level)	4
Background criterion:	4
Explanation for answering the question:	4
Scoring and further development:	5
Criterion: Climate impact (company level).....	6
Background criterion:	6
Explanation for answering the question:	8
Scoring and further development:	9
Criterion: Water use in case of scarcity (PRK level)	10
Background criterion	10
Explanation for answering the criterion:.....	11
Scoring and further development:	12
Criterion: Drug production in accordance with EU standards (PRK level).....	13
Background criterion	13
Explanation for answering the question:	14
Scoring and further development:	15
Criterion: Pollution of production wastewater.....	16
Background criterion	16
Explanation for answering the question	16
Scoring and further development	18
Criterion: Circularity and packaging	19
Background criterion	19
Explanation for answering the question:	19
Scoring and further development:	19
Sources	20

Introduction

Dutch health insurers want to select more sustainably produced medicines for their policyholders. That is why, in the context of Zorgverzekeraars Nederland, they will take environmental sustainability into account in the selection of generic medicines for extramural use: their preference policy.

This document describes which sustainability criteria have been drawn up for this purpose, how they are requested and answered, and how this is included in the preference policy.

The five criteria cover different aspects of environmental impact and transparency in the pharmaceutical chain.

This Appendix, Guide on Sustainability Criteria in the Preference Policy contains the exact wording of the requested criteria, the detailed explanation and the answer options to be chosen as they will be requested are described in the database.

Note regarding translation: In this guide and in the database the terms 'PRK-level' and 'company level' are used to indicate whether a criterion is answered on product or company level. PRK is a Dutch abbreviation. PRK-codes are 'PRescriptie product Kenmerken', this translates as 'Prescription code'.

Production location (PRK level)

This information request indicates two specific locations, which the other criteria will reference to.

This question is not a real criterion, and there will never be a value attached to the answers given. However, this question will serve to validate other answers given.

Background criterion:

Pharmaceutical production chains consist of many different steps and the associated supply chains are not linear but consist of many connected branches. To keep this question answerable yet informative, we only ask about two specific steps: API production site and final product formulation site. An estimate can be made of the environmental risks present in the chain using this location data.

Explanation for answering the question:

Criterion request as formulated in database	Answer options as formulated in database	Scoring	Further development
01: What is the production location of the API?	Country [choice of dropdown with all countries] OR: ['no data available']	2026: Unanswered = exclusion from bid	In the long term, work towards GPS location. scoring will never become location-dependent, will remain in the future: Answered = exclusion from bidding
02: What is the production location of the final product (final product formulation)?	Country [choice of dropdown with all countries] OR: ['no data available']		

API production here means the last step where the production of the active ingredient (Active Pharmaceutical Ingredient, API) takes place.

'Formulation' here means the location where the final step of producing the end product (or semi-finished product) itself takes place, often referred to as 'formulation'.

If API production for your product takes place at multiple locations, enter here where the API production of the batches that will fall under the purchase conditions of this bid takes place. If this is not known: enter the API production location where the largest volume of the API is produced, if necessary, specified up to the last financial year.

If the finished product contains several active substances, only the data relating to the active substance that is used in the final product at the highest mass or concentration needs to be provided.

If your product consists of one or more semi-finished product(s), e.g. because it needs to be prepared for administration in the care chain: only provide location data of the semi-finished product with the highest active ingredient content in the product and indicate to which semi-finished product the data applies.

In the processing of the data in the database, the possible sensitivity of this information is taken into account when the production location is more specific.

If any of the requested information is not known, this can be indicated.

Scoring and further development:

In 2026, filling in the country(ies) of production will result in a positive score (inclusion in the bid), whilst leaving the question unanswered is grounds for exclusion from the bid. Indicating that no data is available is seen as an answer, and is not grounds for exclusion from the bid.

In the future, answering that 'data is not available' will no longer be sufficient in the long run. We will also work towards answering at Global Positioning System (GPS) location level. This phasing in will always be applied proportionally.

There will never be a value attached to the answers given to this question.

Criterion: Climate impact (company level)

This criterion is requested to enable selection of (in the long term) the product that is produced with the least climate impact. The information request will start in 2026 at company level and will be developed, proportionally phased, at product level in accordance with international developments.

Background criterion:

Greenhouse gas emissions have a disruptive warming effect on the Earth's climate. The cause of change in emissions to the atmosphere is primarily a result of human activity. International co-operation agreements were put into effect worldwide in 2015, under the United Nations Paris climate agreement. Central to this agreement is the limitation of the volume of emissions that are released into the atmosphere, to prevent the climate warming by more than 2 degrees centigrade, based on pre-industrial levels, with warming to 1.5 degrees as a safe limit. Based on this, all countries have been given quotas expressed in CO₂ emission equivalents. For companies, there is the SBTi (Science Based Targets initiative) that helps to translate the Paris target at company level.

Climate impact, risk and the disclosure of CO₂ emissions are included in all international ESG/sustainability reporting frameworks. Below are the three most important standards where CO₂ emissions are a part:

1. In the European Sustainability Reporting Standard (ESRS), this is the first subject that must be reported and is fully mandatory. ESRS is the reporting standard prescribed by the Corporate Sustainability Reporting Directive (CSRD).
2. Global Reporting Initiative (GRI) is the standard from the UN Global Compact and the oldest and most widely used standard for sustainability reporting.
3. Sustainability Accounting Standards Board (SASB). Investor-led reporting framework that takes a specific approach to each sector and its unique financial-material topics.

All major pharmaceutical companies report according to one or more of these standards and therefore have insight into (part of) their emissions. In addition, CO₂ emission reporting and reduction is an important sustainability criterion internationally when purchasing medicines:

- National Health Service (NHS) the UK's UK health insurance company: *Net zero – achieve the targets set on the NHS Net Zero Supplier Roadmap and net zero targets for the supply chainⁱ*. The figure below shows the phasing from company to product level that NHS maintains. These requirements also apply to pharmaceutical procurement processes by NHS.
- Sustainable Procurement Index for Health (SPIH). A tool developed by the United Nations Development Program (UNDP) and Health Care without Harmⁱⁱ
- Noorwegen: Norwegian Hospital Procurement Trustⁱⁱⁱ a hospital procurement^{iv}
- France: The government has published a method for evaluating the CO₂ impact of medicines to help the pharmaceutical industry achieve emission reductions. ^v

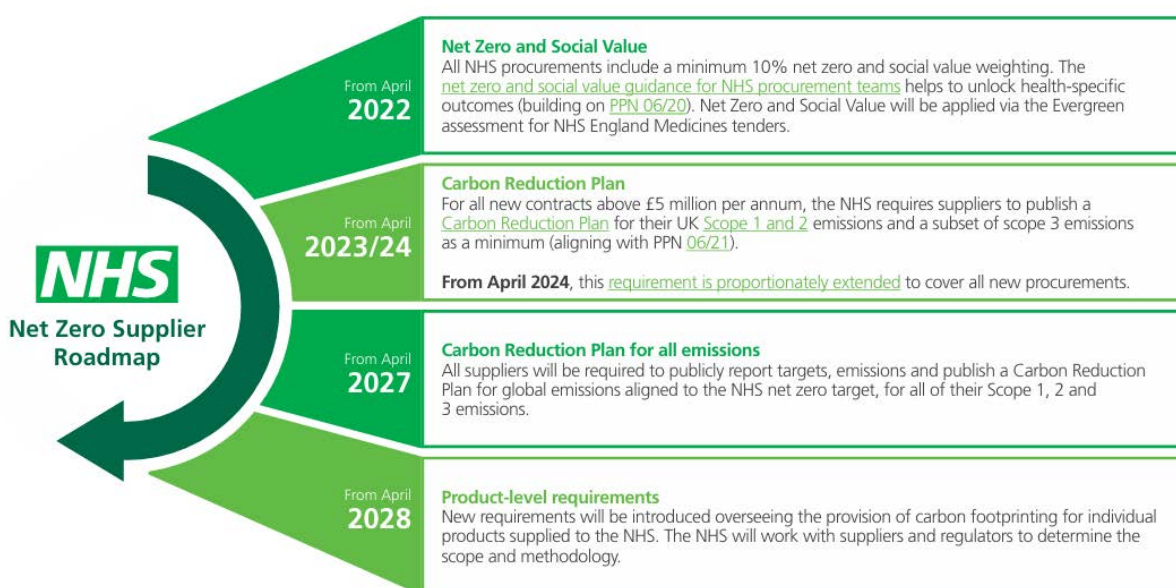
This criterion takes into account the experience gained and the progress of the above procurement projects, with which internationally operating companies will also be familiar.

The important starting point for this criterion is that reporting is done in accordance with the Greenhouse Gas Protocol. The following definitions are important here:

- Scope 1: direct emissions
- Scope 2: emissions from energy consumption (including electricity and heat)
- Scope 3: emissions from the value chain (especially customers, transport and suppliers)

Example NHS and its phasing of CO2 emission requirements for pharmaceutical procurement, among other things:

NHS Net Zero Supplier Roadmap



Explanation for answering the question

	Criterion request as formulated in the database	Answer options as formulated in database	Scoring	Further development
Climate impact of production (company)	03: Are scope 1, 2 and 3 emissions measured at the farm level?	a. Yes, scope 1 and 2 completely and of scope 3 at least more than 80% of the estimated scope of scope 3 b. Partially, scope 1 and 2 completely and scope 3 not (or less than 80% of the estimated size) c. No	2026: Leaving unanswered = exclusion from bidding	This question goes to product level by requesting emissions per dose (product carbon footprint) in accordance with international guidelines Future: Scoring answers
	04: Is there a company-level reduction target for scope 1, 2 and 3 emissions compared to a base year?	a. Yes [insert the reduction target in question 5] b. No		
	05: The reduction target and baseline year are: (= follow-up to question 4)	[Reduction target expressed as a percentage] [Year]		

This is a criterion defined at company level in accordance with the GHG protocol, noting that in sustainability reports, CO₂ emissions from one's own organization (scope 1 and 2) are a basic requirement. If your organisation has a sustainability report in accordance with ESRS, GRI or SBAB, scope 1 and 2 will be reported. Relatively little effort is therefore required to achieve this.

Scope 3 is more complex, but also a requirement in most sustainability reports such as ESRS (CSRD). If scope 3 has not been calculated at all or for less than 80% of the estimated size, answer b. must be chosen.

Whether or not there is a reduction target is also an important element in all reporting standards. This maps out the ambition of a company in question 4.

The percentage target for CO₂ emission reduction compared to the baseline year with which the calculation is made is requested. Both the percentage and the year must be entered in question 5.

Scoring and further development:

In 2026, leaving the question unanswered is grounds for exclusion from the bid. Indicating that no data is available is seen as an answer.

In the future, a scoring will be developed that assesses more favourably drugs with lower production emissions.

In order to get a picture of the emissions for a specific product, CO2 emissions will be further developed at product level. For example, a Product Carbon Footprint or Life Cycle Assessment can be determined for the expression of CO2 emissions at product level, e.g. in line with the PAS 2090:2025. As of 2025-2026, this will be introduced in various countries in medicine procurement processes.

This phasing will always be applied proportionally.

Criterion: Water use in case of scarcity (PRK level)

The purpose of this criterion is to select medicines for which, water consumption during production processes in water-scarce areas, is reduced to a minimum by applying water-saving measures..

Background criterion

A lot of water is used in the production of medicines: 63% of the total freshwater use of the Dutch healthcare sector is for medicines and chemicals^{vi}. Common industrial processes that use of fresh water include not only the production of medicines but also the cleaning of production installations. Water is normally extracted or purchased locally, and in water-scarce areas, this can lead to drought in the areas around production locations, affecting the environment and local communities.

In an area with water scarcity, many people and animals depend on the same remaining water source(s). If the groundwater around factories is too polluted and/or has become too scarce, clean drinking water for the factories and local residents must be supplied by tankers. This mainly affects vulnerable local residents and causes additional environmental impact.



All companies within the scope of the CSRD must report on ESRS E3, if their double materiality assessment identifies water resources or marine ecosystems as material for their business. ESRS E3 will be particularly relevant for companies that:

1. Heavily dependent on water sources
2. Operating in water stress areas
3. Have a significant impact on marine environments
4. High water consumption or significant wastewater discharge

Experience with this criterion in other countries:

Water use is part of the SPIH tool developed by Healthcare without Harm (HCWH) & United Nations Development Program (UNDP), as part of the Resource Depletion module. It asks:

- Is the water use of the final production phase / entire production chain measured?
- Are water-saving measures applied?

Norway (Norwegian Hospital Procurement Trust) has requested the following criteria for a limited group of medicines (Infusion and rinsing fluids, tube feeding and other drug feeding):

- The supplier's production sites must have water reduction targets
- The supplier must have a system in place to control access to water in and around the production sites for the product(s) offered.

CSRD (ESRS) Definition: Water stress includes quantity or availability (related to water scarcity) along with water quality and accessibility, and provides a broader measure of watershed pressure.

Global indicators (with associated datasets) and related thresholds to assess whether an area has water stress include:

- a) basic water stress – equal to or higher than 'High': 40–80% (WRI);
- b) water deficit – greater than 'High': 25–75% (seasonal) (Brauman et al.);
- c) basic water depletion – equal to or greater than 'High': 50–75% (WRI); and
- d) WEI+ (Water Exploitation Index plus) – equal to or greater than 40% (EEA).

While these global indicators take into account water stress in terms of the amount of available water resources (related to water scarcity), a comprehensive assessment of water stress covers all its dimensions (quantity, quality, and accessibility). The assessment of whether an area is exposed to water stress is usually carried out at least at the basin level. Tailored methodologies can be used to assess whether an area is exposed to water stress and can leverage local knowledge.

Explanation for answering the criterion:

	Criterion request as formulated in database	Answer options as formulated in database	Scoring	Further development
Water use in case of scarcity (PRK)	06: Does production of the API and/or the end product take place in an area with high water stress? (WRI basic water stress greater than or equal to 40-80%)	a. Yes, API production and final product formulation take place in an area with high water stress [continue to question 7] b. Partly, one of the two locations in an area with high water stress [continue to question 7] c. No, both are not in an area with high water stress d. No information available	2026: Leaving unanswered = exclusion from bidding	Future: Scoring answers
	07: Are measures being taken to reduce water use in production? (= follow-up to question 06)	a. Yes b. No c. No information available		

The criterion requests information about production in an area of high water stress. This is defined according to the definition of the World Resource Institute ([World Resources Institute - Research for People & Planet](#)) as: The base water stress measures the ratio of total water demand to the available renewable surface and groundwater resources. The water demand includes domestic, industrial, irrigation and livestock farming. Available renewable water supplies include the impact of upstream

consumption water users and large dams on the availability of water downstream. Higher values indicate more competition between users. High water stress is defined as 40%-80%.

Whether a location is located on a geographical locations where water stress is a factor can be viewed at address level on this site of WRI: [Aqueduct Water Risk Atlas](#)

For more background on water stress and water scarcity, see [Water scarcity - Wikipedia, the free encyclopedia](#).

Given the importance of water and ongoing water shortages, question 7 asks about measures to reduce water consumption.

Scoring and further development:

In 2026, leaving the question unanswered is grounds for exclusion from the bid. Indicating that no data is available is seen as an answer.

In the future, a scoring will be developed in which medicines that are produced with least detrimental effect on water availability in areas with water scarcity are assessed more favourably than medicines that do.

This phasing will always be applied proportionally.

Criterion: Drug production in accordance with EU standards (PRK level)

The purpose of this criterion is to encourage the selection of medicines that have been produced with an environmental impact comparable to that which we consider acceptable in Europe for pharmaceutical production.

Background criterion

Drug production is associated with negative environmental impact on many different parameters. When it comes to ecological aspects of production location, the biggest impact does not come from the distance that a resource is transported. Multiple sources such as LCAs and Sustainability Reports from companies show that the climate impact of transport is very small (marginal) compared to the climate impact of the production steps themselves.

Both the Nordics and IZAAZ ask suppliers whether products are produced in the EU. Manufacturing in the EU has geopolitical, socially sustainable, supply-side and environmentally sustainable advantages over manufacturing outside Europe. However, this set of criteria only describes ecological aspects; other aspects have not been taken into account.

In Europe, the production of chemical products must comply with the Industrial Emissions Directive, best available techniques (BAT) must be applied to prevent harmful emissions to the environment and limits set in BAT Conclusions must be met for those emissions. In Europe, this is how it has been determined what is acceptable environmental pollution from a chemical process such as pharmaceutical production.

A product that is produced outside Europe, but meets the requirements described in the above documents, should also meet the requirements to be selected as a 'more sustainable medicine'. Therefore, this set of criteria does not aim at selection based on geographical location of production, but whether it is produced in accordance with EU environmental legislation.

Explanation for answering the question:

	Criterion request as formulated in database	Answer options as formulated in database	Scoring	Further development
Medicine Production according to EU normen (PRK)	08: Drug production in Europe must meet environmental requirements as described in BREF documents, thus limiting the impact on the environment to acceptable standards. But production of the API or the end product can also take place outside Europe under such environmental requirements. Does the production of the API and the end product take place under environmental measures comparable to the European ones by applying best available techniques (BAT) in accordance with BREFs OFC, SIC and WGC?	a. Yes, API production <u>and</u> final product formulation take place in accordance with BREF documents for all described categories by applying BBTs. b. In part, API production takes place in accordance with BREF documents for all described categories by applying BAT s. c. In part, final product formulation takes place in accordance with BREF documents for all described categories by applying BAT s. d. No, neither site produces in accordance with BREF documents for all described categories by applying BAT s. e. No information available	2026: Leaving unanswered = exclusion from bidding	Future: Scoring answers

Specifically, it is asked whether the European environmental measures apply in the final step in API production AND/OR the final step of formulating the end product. In which part of the production is the requirements as described in the Industrial Emissions Directive (IED) (specifically Appendix 1 under Category 4.5) met by applying Best Available Techniques (BAT) and associated Conclusions (BATC) for the applicable categories B BREF OFC (2006) - Organic Fine Chemicals, BREF SIC (2007), Inorganic Fine Chemicals and BREF WGC - Waste Gas Treatment Chemical Sector.

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If production takes place in Europe, this would in principle be met, and an affirmative answer can be given.

NB: When this criterion was drawn up, contact was made with the helpdesk of the Living Environment Information Point (IPLO). The IPLO helpdesk said that providers can also contact the helpdesk via iplo.nl/contact/vragenformulier/ if they have technical questions about these requirements and the accompanying documents.

Scoring and further development:

In 2026, leaving the question unanswered is grounds for exclusion from the bid. Indicating that no data is available is seen as an answer.

In the future, a scoring will be developed in which medicines that are produced in accordance with EU standards, regardless of geographical location, are assessed more favourably than medicines that do not meet these standards. This is the reason that a value is never attached to the specified geographical location of production as asked in questions 1 and 2. This phasing will always be applied proportionally.

Criterion: Pollution of production wastewater

The purpose of this criterion is to select medicines for which the wastewater is treated during production in such a way that it does not cause harmful effects on the environment into which the wastewater is discharged.

Background criterion

Pollution of the environment from wastewater at production sites are a major cause of the negative environmental effects of drug production, resulting in damage to human, animal and ecosystem health^{vii}.

PNEC stands for *predicted no effect concentration*. This is a value that indicates the concentration below which a substance must remain in order not to have any effects on (present) organisms. The PNEC value is therefore important to gain more insight into the environmental effects of medicines in the water and how these effects should be limited.

In toxicology, both the terms PNEC-MIC and PNEC-ENV are used as an expression of effect limit. The MIC stands for antimicrobial resistance value and only applies to antibiotics. In this criterion, the PNEC-MIC is not taken into account and only the PNEC-ENV is considered.

A PNEC is a value that differs per substance, but can also have a different value in a different environment because of different living organisms present. This question asks for the PNEC-ENV at production location of the API or the PNEC-ENV at "after use" locations, which in this case is the Netherlands. If a PNEC is known for the substance, it is expected to monitor this not only at post-use locations but also at the production sites.

This can be achieved through sufficiently effective treatment processes for production wastewater. In that case, sufficiently effective means that PNEC is monitored and that the aim is to keep pollutants below this value.

It was decided to specifically request pollutants in wastewater (and not pollutants in air/gaseous or solid form) because water pollution has direct negative effects on the environment (such as the availability of clean drinking water and damage to ecosystems) and concrete and measurable parameters can be requested for this.

Explanation for answering the question

	Criterion request as formulated in database	Answer options as formulated in database	Scoring	Further development
Pollution of production wastewater (PRK)	09: Does the API and end product production take place at a production site where routines have been implemented for processing and/or	a. Yes, routines have been implemented at both production sites to get wastewater contamination at or below the PNEC [fill in the specific PNEC-ENV and the source of the PNEC used in question 10].	2026: Leaving unanswered = exclusion from bidding	Future: Scoring answers

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	treating production wastewater that prevent the amount of active substances in the production wastewater from exceeding the <i>presumed no effect on environment concentration</i> (PNEC-ENV) of the active substance?	b. Partly, only at the API production site routines have been implemented to get contamination of the wastewater at or below the PNEC [fill in the specific PNEC-ENV and the source of the PNEC used in question 10]. c. Partly, only at the end product production site, routines have been implemented to get contamination of the wastewater at or below the PNEC [fill in the specific PNEC-ENV and the source of the PNEC used in question 10]. d. Partly, no routines have been implemented at both production sites to get wastewater pollution specifically at or below PNEC (e.g. because the PNEC is not (yet) in possession), but at one or both locations the production wastewater is treated or processed in such a way to limit wastewater pollution to an alternative standard [insert the source of the other standard used and a brief description of the method to achieve it in question 10] e. There are no agreements with the third-party manufacturers on routines to get wastewater pollution at or below PNEC f. No wastewater treatment steps take place at either site g. No information available		
	10: The PNEC-ENV of the API is: (= follow-up to question 9)	[Open input field: Fill in parameter PNEC-ENV in µg/L, the source used (open input field for URL or reference) and possibly description of alternative method]		

This criterion corresponds to the survey already carried out by the Scandinavian countries and the hospital procurement groups, where it is asked whether purification processes are used in the production of the API and the end product to achieve the PNEC. For a growing number of active substances, a PNEC-ENV value is known from the ecotoxicological field.

If no PNEC-ENV value is known for the substance, answers a, b and c cannot be filled in for question 9. If a PNEC-ENV is not known, several rationales can be taken into account to the answer the question.

- For generic products, which are offered in the preference policy, PNECs will not always be available because this ERA extension to before 2006 was made not long ago. As long as a substance is still in the catching-up procedure, only alternative standards can be used. In question 10, enter the chosen alternative standard and source that is used.
- If the PNEC-ENV is known but not in your possession, please choose the appropriate alternative answer and fill in the alternative standard and source used in question 10, if applicable, stating 'PNEC not in our possession'
- It is possible that no PNEC-ENV will be disclosed for some APIs because no extensive PNEC calculation was found to be required for the API on the basis of the phase 1 screening. If purification steps are taken to stay below an alternative standard, enter the alternative standard used (e.g. the standard standard) and source in question 10.
- If the API or the final product is produced at a site with which no agreements have been made to treat wastewater below the PNEC, choose answer e.
- If it is confirmed that no purification steps are taken to purify the wastewater from production so that it has no effects on organisms, up to any possible standard, choose answer f.
- If no information can be retrieved that leads to any other answer, choose answer g.

Scoring and further development

In 2026, leaving the question unanswered is grounds for exclusion from the bid. Indicating that no data is available is seen as an answer.

In the future, a scoring will be developed in which medicines that are produced in a way that does not have a harmful effect on the environment are judged more favourably than medicines that do. In the further development, it will be investigated in which steps it is necessary to move towards this approach, taking into account the availability of information derived from answers to this criterion over time. This phasing will always be applied proportionally.

Criterion: Circularity and packaging

Sustainability criteria on circularity and packaging aim to stimulate the reduction of the use of raw materials for (the packaging of) medicines. This can be achieved in different ways, the way in which can differ per medicine.

Background criterion

The packaging, composition and form of administration of medicines can play a role in achieving a reduction in CO2 emissions or raw material use required for the medicines. For example, because waste of the medicine or packaging material is prevented, or because the total product has a lower environmental impact.

Variables that influence the circularity and use of raw materials of medicines that can be considered are the type and composition of packaging material, additives such as PFAS lubricants used during packaging, shelf life, (refrigerated) storage conditions and duration, relative quantity of packaging material per medicine, etc.

In 2026, insufficient ground has yet been found for a procurement criterion for medicines in the preference policy that is measurable, distinctive and proportionate.

Explanation for answering the question:

	Criterion request as formulated in database	Answer options as formulated in database	Scoring	Further development
Circularity and packaging	-	-	-	Future: develop a criterion on which scores can be achieved for packaging and/or application form(s) with lower CO2 emissions or raw material use

In 2026, no question will be asked for the Circularity and packaging criterion

Scoring and further development:

The aim of the further development of this criterion is to bring the various parameters that play a role into line with each other. Recommendations in professional guidelines are monitored.

A criterion will be developed whereby a score can be achieved for packaging or application form(s) where the production is associated with less CO2 emissions or lower raw material use than the alternatives. This phasing will always be applied proportionally.

Sources

- ⁱ [NHS England » Sustainable procurement](#)
- ⁱⁱ [Sustainable Procurement Index for Health | Health Care Without Harm - Global](#)
- ⁱⁱⁱ [erfaringsrapport-miljo-2023_engelsk-versjon.pdf](#)
- ^{iv} [Status of the roadmap for net zero - Sykehusinnkjøp HF](#)
- ^v [Methodology for assessing the carbon footprint of medicines | Directorate-General for Enterprise](#)
- ^{vi} <https://www.rivm.nl/publicaties/effect-van-nederlandse-zorg-op-milieu-methode-voor-milieuvoetafdruk-en-voorbeelden-voor>
- ^{vii} <https://changingmarkets.org/report/impacts-of-pharmaceutical-pollution-on-communities-and-environment-in-india/>