Environmental criteria for selected oncology products

Amgros, Sykehusinnkjøp and Landspitali wish to focus on the area of oncology and the environmental impact of these products in an upcoming Joint Nordic Tender. Therefore, the environmental criteria below have been prepared, on which we would like feedback/comments from relevant stakeholders.

We expect the tender to include the following products:

- Treosulfan
- Methrotrexate
- Cladribin
- Cytarabin
- Fluoruracil
- Vincristin
- Vinorelbin
- Vinflunin
- Etoposid
- Topotecan
- Trabectedin
- Daunorubicin
- Epirubicin
- Idarubicin
- Mitomycin
- Arsentrioxid
- Bendamustin

Criteria 1:

The offered product should be produced by an API manufacturer and a finished product manufacturer who have documented standard operating procedure(s) specifically to minimize the amount and concentration of the active substance related to the offered product in wastewater.

Answer options:

A	Both API and finished product manufacturers have standard operating procedures for minimizing active substances in wastewater
B	Only the API manufacturer has standard operating procedures for minimizing active substances in wastewater
C	Only the finished product manufacturer has standard operating procedures for minimizing active substances in wastewater
D	Information not available / Prefer not to disclose

Criteria 2:

The offered product should be produced by an API manufacturer and a finished product manufacturer who have documented standard operating procedure(s) for the handling, processing, and depositing of production waste related to the offered product, with the aim to eliminate or minimize emissions of the active substance into the environment.

Answer options:

A	Both API and finished product manufacturers have standard operating procedures for handling, processing, and depositing waste
B	Only the API manufacturer has standard operating procedures for handling, processing and depositing waste
C	Only the finished product manufacturer has standard operating procedures for handling, processing, and depositing waste
D	Information not available / Prefer not to disclose

Criteria 3:

The offered product should be produced by API manufacturer and finished product manufacturer who has implemented documented measures for managing and/or treating wastewater arising from the production of the offered product to achieve the predicted-no-effect concentration (PNEC) of the active ingredient.

Answer options:

A	Both API and finished product manufactures have implemented measures for achieving PNEC (Specify which PNEC-value is used and link to the source of reference or attach the source to the offer)
B	Only the API manufacturer has implemented measures for achieving PNEC (Specify which PNEC-value is used and link to the source of reference or attach the source to the offer)
C	Only the finished product manufacturer has implemented measures for achieving PNEC (Specify which PNEC-value is used and link to the source of reference or attach the source to the offer)
D	Information not available / Prefer not to disclose

Additional information regarding PNEC:

The PNEC value and the source of the PNEC value used in the routine for the active substance manufacturer and the finished product manufacturer must be specified to receive points. Routines for obtaining PNEC must be specified in an agreement with any third-party manufacturer. The routine must be documented upon request.

PNEC values are obtained from the product summary in the Joint Catalogue of Marketed Products (Felleskatalogen) if they have been submitted to FASS.se by the supplier and reviewed by the Swedish Environmental Institute in collaboration with FASS.se.

If the PNEC is not known for the active substance, analysis of the PNEC can be submitted to FASS.se during the agreement period for review by IVL Swedish Environmental Institute, or analysis of the PNEC can be submitted to a corresponding third party for review. (Submission to FASS assumes that the product has a product summary in FASS.se).

If the supplier wishes to submit analysis of the PNEC that is not already known to Fass or a corresponding third party for review, this will give credit for the requirement.

More information about PNEC: https://www.felleskatalogen.no/medisin/miljo/innledning.

Criteria 4:

The supplier should have implemented an environmental management system in active ingredient production for offered products, which covers risk assessments, environmental routines, environmental audits, and sanctions for violations of the agreement/environmental routine. For full benefit, the environmental management system must be certified by an accredited third party.

Answer options:

A	The supplier has implemented an environmental management system for risk assessments, environmental routines, environmental audits, and sanctions for violations of the agreement/environmental routine certified by an accredited third party for all offered products
B	The supplier has implemented an environmental management system for risk assessments, environmental routines, environmental audits, and sanctions for violations of the agreement/environmental routine not certified by an accredited third party for all offered products
C	The supplier has partly implemented an environmental management system
D	The supplier does not have an agreement with an accredited third party regarding environmental management
E	The supplier has not implemented an environmental management system
F	Information not available / Prefer not to disclose