

Written consultation: Selected Parts of Tender Material for Joint Nordic Tender 2028

(Purchasing period: 1 April 2028 – 31 March 2030, with an option to extend for up to two periods of up to 12 months each)

Amgros (DK), Sykehusinnkjøp (NO), Landspítali (IS), Region Skåne (SE) and HUS Group (representing the Southern Finland Collaboration Area, FI) would like feedback/comments from relevant stakeholders on the following themes:

1. Market division and List of Products:

In the upcoming Joint Nordic tender, Region Skåne and HUS Group join Amgros, Sykehussinnkjøp and Landspítali. However, not all five Nordic health procurers are buyers of all products in the tender. All products are for intravenous administration.

For each pharmaceutical, the procurement is expected to be divided into two clusters. The Contracting Authorities encourage Tenderers to submit tenders for both clusters; however, Tenderers may choose to submit a tender for only one cluster. The supplier awarded Cluster 1 will be encouraged to act as a replacement supplier for Cluster 2 in the event of a backorder, and vice versa.

The proposed market division is preliminary and has been developed with the aim of creating two clusters with volumes that are as comparable as possible, measured by number of vials.

All five buyers:

- **Ampicillin:**

Pharmaceutical form: Injection fluid; Strength(s): 1 g and 2 g

- Cluster 1: Denmark, Region Skåne and Southern Finland Collaboration Area (HUS Group)
- Cluster 2: Norway and Iceland

- **Ciprofloxacin:**

Pharmaceutical form: Infusion fluid; Strength: 2 mg/ml; Package: 100 ml and 200 ml

- Cluster 1: Denmark, Region Skåne and Southern Finland Collaboration Area (HUS Group)
- Cluster 2: Norway and Iceland

- **Benzylpenicillin**

Pharmaceutical form: Injection- and infusion fluid; Strength(s): 1 mio. IE, 2 mio. IE, 5 mio. IE, 10 mio. IE.; Package: Vial

- Cluster 1: Denmark, Region Skåne and Southern Finland Collaboration Area (HUS Group)
- Cluster 2: Norway and Iceland
- **Vancomycin**
Pharmaceutical form: Infusion fluid; Strength(s): 500 mg and 1000 mg
 - Cluster 1: Denmark and Iceland
 - Cluster 2: Norway, Region Skåne and Southern Finland Collaboration Area (HUS Group)

Amgros, Landspítali, Sykehusinnkjøp and HUS Group:

- **Piperacillin/beta-lactamase inhibitor**
Pharmaceutical form: Infusion fluid; Strength(s): 2 g + 0,25 g, 4 g + 0,5 g and 12 g + 1,5 g;
Package: Vial
 - Cluster 1: Denmark and Iceland
 - Cluster 2: Norway and Southern Finland Collaboration Area (HUS Group)
- **Cefuroxime**
Pharmaceutical form: Injection fluid; Strength(s): 250 mg, 750 mg and 1500 mg; Package: Vial
 - Cluster 1: Denmark and Iceland
 - Cluster 2: Norway and Southern Finland Collaboration Area (HUS Group)
- **Gentamicin**
Pharmaceutical form: Infusion fluid; Strength(s): 1 mg/ml and 3 mg/ml; Package: 80 ml and 120 ml of 3 mg/ml
 - Cluster 1: Denmark and Iceland
 - Cluster 2: Norway and Southern Finland Collaboration Area (HUS Group)
- **Metronidazol**
Pharmaceutical form: Infusion fluid; Strength: 5 mg/ml
 - Cluster 1: Denmark and Iceland
 - Cluster 2: Norway and Southern Finland Collaboration Area (HUS Group)
- **Meropenem**
Pharmaceutical form: Injection and infusion fluid; Strength(s): 500 mg and 1000 mg;
Package: vial
 - Cluster 1: Denmark
 - Cluster 2: Norway, Iceland and Southern Finland Collaboration Area (HUS Group)

Amgros, Landspítali, Sykehusinnkjøp and Region Skåne:

- **Paracetamol**

Pharmaceutical form: Infusion fluid; Strength: 10 mg/ml; Package(s): 10-50 ml and 100 ml.

- Cluster 1: Denmark and Region Skåne
- Cluster 2: Norway and Iceland

Amgros, Landspítali, Sykehusinnkjøp:

- **Ondansetron**

Pharmaceutical form: Injection fluid; Strength: 2 mg/ml; Package(s): 2 ml and 4 ml

- Cluster 1: Denmark
- Cluster 2: Norway and Iceland

- **Hydrocortisone**

Pharmaceutical form: Injection fluid; Strength: 100 mg

- Cluster 1: Denmark and Iceland
- Cluster 2: Norway

- **Fluconazole**

Pharmaceutical form: Infusion fluid; Strength: 2 mg/ml; Package(s): 50 ml, 100 ml and 200 ml.

- Cluster 1: Denmark
- Cluster 2: Norway and Iceland
- Alternative: One cluster of Denmark, Norway and Iceland (multiple winners)

- **Aciclovir**

Pharmaceutical form: Infusion fluid; Strength: 25 mg/ml

- Cluster 1: Denmark
- Cluster 2: Norway and Iceland

- **Methotrexate**

Pharmaceutical form: Infusion fluid; Strength: 100 mg/ml; Package(s): 10 ml and 50 ml.

- Cluster 1: Denmark and Iceland
- Cluster 2: Norway
- Alternative: One cluster of Denmark, Norway and Iceland (multiple winners)

2. Qualitative criteria:

The Contracting Authorities expect the upcoming tender to be evaluated on the basis of the best price-quality ratio, with quality consisting of environmental and security of supply criteria.

For the purpose of this written consultation, only the proposed criteria, response options and score are presented. More detailed information, including definitions, documentation requirements, scoring methodology, verification procedures and contractual provisions, will be included in the final tender documents.

2.1 Environmental criteria for antibiotics (weighting 30%)

The purpose of the four sub-criteria is to achieve the lowest possible environmental impact in the manufacturing processes of the products and to prevent antimicrobial resistance resulting from the production of the offered product. Sub-criteria 1 and 2 each account for one-third of the total weight assigned to the criterion *Combating antibiotic resistance*, while sub-criteria 3 and 4 each account for one-sixth of the total weight. This distribution reflects the relative importance the Contracting Authorities places on each element within the criterion *Combating antibiotic resistance*.

Sub-criterion 1: Production standard for combatting antimicrobial resistance

The supplier complies with the WHO Guidance, AMRIA Antibiotic Manufacturing Standard, or similar production standard that combats antimicrobial resistance throughout the full supply chain for the offered product. To obtain the highest score, compliance with this standard must be certified by an independent third party, or the certification process must have been initiated.		
Response options:		
a)	The supplier complies with WHO guidance, the AMRIA Antibiotic Manufacturing Standard or similar standard throughout the full supply chain for the offered product, and this is certified by an independent third party, or the certification process has been initiated and will be finalized within 12 months.	(6 points)
b)	The supplier complies with the AMRIA Antibiotic Manufacturing Standard or similar standard throughout the full supply chain for the offered product, but only parts of the supply chain are certified by an independent third party, or the certification process has been initiated and will be finalized within 12 months.	(5 points)

c)	The supplier complies with WHO guidance, the AMRIA Antibiotic Manufacturing Standard or similar standard in parts of the supply chain for the offered product, and this has been certified by an independent third party, or the certification process has been initiated and will be finalized within 12 months.	(3 points)
d)	The supplier complies with WHO guidance, the AMRIA Antibiotic Manufacturing Standard or similar standard throughout the full supply chain or in parts of the supply chain for the offered product, but this has not been certified by an independent third party, and no certification process has been initiated.	(1 points)
e)	The supplier does not comply with WHO guidance, the AMRIA Antibiotic Standard or similar standard for the offered product.	(0 point)
f)	Don't know / Prefer not to disclose	(0 points)

Sub-criterion 2: Measures to achieve PNEC (Predicted No Effect Concentration)

The offered product must be manufactured by an API manufacturer and a finished product manufacturer that have implemented measures for the handling and/or treatment of wastewater from the production of the offered product to achieve a predicted no effect concentration (PNEC) of the active substance.		
Response options:		
a)	Both the API manufacturer and the finished product manufacturer have implemented measures to achieve PNEC.	(6 points)
b)	Only the API manufacturer has implemented measures to achieve PNEC.	(3 points)
c)	Only the finished product manufacturer has implemented measures to achieve PNEC.	(2 points)
d)	None of the manufacturers have implemented measures to achieve PNEC	(0 points)
e)	Don't know / Prefer not to disclose	(0 points)

Sub-criterion 3: Standard procedure for wastewater

The offered product must be manufactured by an API manufacturer and a finished product manufacturer, that have standard operating procedures (SOPs) in place to minimize the amount and concentration of antibiotics that end up in the wastewater.		
Response options:		
a)	Both the API manufacturer and the finished product manufacturer have standard operating procedures (SOPs) for minimizing antibiotics in wastewater.	(6 points)
b)	Only the API manufacturer has standard operating procedure(s) (SOPs) for minimizing antibiotics in wastewater.	(3 points)
c)	Only the finished product manufacturer has standard operating procedures (SOPs) for minimizing antibiotics in wastewater.	(2 points)
d)	None of the manufacturers have standard operating procedures (SOPs) for minimizing antibiotics in wastewater.	(0 points)
e)	Don't know / Prefer not to disclose	(0 points)

Sub-criterion 4: Standard procedure for waste handling

The product offered must be manufactured by an API manufacturer and a finished product manufacturer, that have standard operating procedures (SOPs) for the handling, processing and depositing of production waste in order to eliminate or minimize the emission of antibiotics into the environment.		
Response options:		
a)	Both the API manufacturer and the finished product manufacturer have standard operating procedures (SOPs) for the handling, processing and depositing of production waste.	(6 points)
b)	Only the API manufacturer has standard operating procedures (SOPs) for the handling, processing and depositing of production waste.	(3 points)
c)	Only the finished product manufacturer has standard operating procedures (SOPs) for the handling, processing and depositing of production waste.	(2 points)
d)	None of the manufacturers have standard operating procedures (SOPs) for the handling, processing and depositing of production waste.	(0 points)
e)	Don't know / Prefer not to disclose	(0 points)

2.2 Environmental criteria for non-antibiotics (weighting 30%)

The purpose of the four sub criteria is to achieve the lowest possible environmental impact in the manufacturing processes of the offered product. Sub-criteria 1 and 2 each carry one third of the total weight assigned to the criterion *Environmental management*, while sub-criteria 3 and 4 each carries one sixth of the total weight. This distribution reflects the relative importance the Contracting Authorities places on each element within the criterion *Environmental management*.

Sub-criterion 1: Environmental management system for API production

The Active Pharmaceutical Ingredient (API) manufacturing site(s) for the offered product should operate an environmental management system that meets requirements equivalent to those of ISO 14001 or Eco-Management and Audit Scheme (EMAS). The highest score will be awarded where all relevant sites are covered by a valid ISO 14001 certificate, EMAS registration or equivalent certification issued by an accredited independent third party. The scope of the certificate or registration must cover the relevant API manufacturing activities.		
Response options:		
a)	All relevant API manufacturing sites for the offered product are covered by a valid ISO 14001 certificate, EMAS registration or equivalent certification issued by an accredited independent third party.	(6 points)
b)	One or more, but not all, relevant API manufacturing sites for the offered product are covered by a valid ISO 14001 certificate, EMAS registration or equivalent certification issued by an accredited independent third party. The remaining relevant site(s) operate an environmental management system and will obtain such certification or registration no later than 12 months after the start of the purchasing period.	(5 points)
c)	One or more, but not all, relevant API manufacturing sites for the offered product are covered by a valid ISO 14001 certificate, EMAS registration or equivalent certification issued by an accredited independent third party. The remaining relevant site(s) do not operate a certified or registered environmental management system.	(3 points)
d)	None of the relevant API manufacturing sites are currently covered by such certification or registration. However, all relevant sites operate an environmental	(3 points)

	management system and will obtain such certification or registration no later than 12 months after the start of the purchasing period.	
e)	None of the relevant API manufacturing sites operate an environmental management system, and the tenderer does not commit to obtaining the certification or registration described above within 12 months after the purchasing period.	(0 points)
f)	Don't know / Prefer not to disclose	(0 points)

Note: If the API manufacturing of the offered product is limited to one (1) manufacturing site, answer options b) and c) are not applicable.

Sub-criterion 2: Environmental management system for finished product production

The finished product manufacturing site(s) for the offered product should operate an environmental management system that meets requirements equivalent to those of ISO 14001 or Eco-Management and Audit Scheme (EMAS). The highest score will be awarded where all relevant sites are covered by a valid ISO 14001 certificate, EMAS registration or equivalent certification issued by an accredited independent third party. The scope of the certificate or registration must cover the relevant finished product manufacturing activities.		
Response options:		
a)	All relevant finished product manufacturing sites for the offered product are covered by a valid ISO 14001 certificate, EMAS registration or equivalent certification issued by an accredited independent third party.	(6 points)
b)	One or more, but not all, relevant finished product manufacturing sites for the offered product are covered by a valid ISO 14001 certificate, EMAS registration or equivalent certification issued by an accredited independent third party. The remaining relevant site(s) operate an environmental management system and will obtain such certification or registration no later than 12 months after the start of the purchasing period.	(5 points)
c)	One or more, but not all, relevant finished product manufacturing sites for the offered product are covered by a valid ISO 14001 certificate, EMAS registration or equivalent certification issued by an accredited independent third party. The remaining relevant site(s) do not operate a certified or registered environmental management system.	(3 points)

d)	None of the relevant finished product manufacturing sites are currently covered by such certification or registration. However, all relevant sites operate an environmental management system and will obtain such certification or registration no later than 12 months after the start of the purchasing period.	(3 points)
e)	None of the relevant finished product manufacturing sites operate an environmental management system, and the tenderer does not commit to obtaining the certification or registration.	(0 points)
f)	Don't know / Prefer not to disclose	(0 points)

Note: If the finished product manufacturing of the offered product is limited to one (1) manufacturing site, answer options b) and c) are not applicable.

Sub-criterion 3: Standard procedure for wastewater

The offered product must be manufactured by an API manufacturer and a finished product manufacturer, that have standard operating procedures (SOPs) in place to minimize the amount and concentration of active substance that end up in the wastewater.		
Response options:		
a)	Both the API manufacturer and the finished product manufacturer have standard operating procedures (SOPs) for minimizing active substance in wastewater.	(6 points)
b)	Only the API manufacturer has standard operating procedure(s) (SOPs) for minimizing active substance in wastewater.	(3 points)
c)	Only the finished product manufacturer has standard operating procedures (SOPs) for minimizing active substance in wastewater.	(2 points)
d)	None of the manufacturers have standard operating procedures (SOPs) for minimizing active substance in wastewater.	(0 points)
e)	Don't know / Prefer not to disclose	(0 points)

Sub-criterion 4: Standard procedure for waste handling

The product offered must be manufactured by an API manufacturer and a finished product manufacturer, that have standard operating procedures (SOPs) for the handling, processing and depositing of production waste in order to eliminate or minimize the emission of active substance into the environment.		
Response options:		
a)	Both the API manufacturer and the finished product manufacturer have standard operating procedures (SOPs) for the handling, processing and depositing of production waste.	(6 points)
b)	Only the API manufacturer has standard operating procedures (SOPs) for the handling, processing and depositing of production waste.	(3 points)
c)	Only the finished product manufacturer has standard operating procedures (SOPs) for the handling, processing and depositing of production waste.	(2 points)
d)	None of the manufacturers have standard operating procedures (SOPs) for the handling, processing and depositing of production waste.	(0 points)
e)	Don't know / Prefer not to disclose	(0 points)

2.3 Security of Supply criteria for both antibiotics and non-antibiotics (weighting 20%)

The purpose of the three sub-criteria is to support the resilience and security of supply of the offered product. The criteria are designed to reduce the risk of supply disruptions by encouraging, manufacturing capacity located within the EU/EEA, reduced dependency on third-country production capacity located outside the EU/EEA, and diversified manufacturing structures capable of maintaining supply in the event of disruptions affecting individual facilities. Sub-criteria 1 and 2 each account for 25% of the total weighting of the Security of Supply criterion, while Sub-criterion 3 accounts for the remaining 50%.

Tenderers shall provide the information and documentation requested under each sub-criterion. Where the requested information is not provided or cannot be verified, the Contracting Authority will award 0 points for the relevant sub-criteria.

Sub-criterion 1: Location of Active Pharmaceutical Ingredient (API) Manufacturing

The proportion of the API manufacturing capacity for the offered product is located within the EU/EEA.		
Tenderers shall identify all API manufacturing sites used for the offered product and indicate the proportion of API manufacturing capacity attributable to each site.		
Share of API manufacturing capacity located within the EU/EEA:		
a)	100 %	(6 points)
b)	75 % or more but less than 100 %	(5 points)
c)	50 % or more but less than 75 %	(4 points)
d)	More than 0 % but less than 50 %	(3 points)
e)	0 %	(0 point)

Sub-criterion 2: Location of Finished Product Manufacturing

The proportion of the finished product manufacturing capacity for the offered product is located within the EU/EEA.		
Tenderers shall identify all manufacturing sites responsible for production of finished offered product and indicate the share of manufacturing capacity represented by each site.		
Share of Finished Product manufacturing capacity located within the EU/EEA:		
a)	100 %	(6 points)
b)	75 % or more but less than 100 %	(5 points)
c)	50 % or more but less than 75 %	(4 points)
d)	More than 0 % but less than 50 %	(3 points)
e)	0 %	(0 point)

Sub-criterion 3: Diversification of Manufacturing Capacity

The extent to which the offered product can be manufactured at multiple approved manufacturing sites in the event of a disruption affecting a primary manufacturing site.

For the purpose of this sub-criterion, an alternative manufacturing site means an operational manufacturing facility capable of manufacturing the same Active Pharmaceutical Ingredient (API) and/or the finished product.

Tenderers shall identify all approved manufacturing sites available for the offered product.

Number of alternative operational manufacturing sites:

a)	Multiple approved manufacturing sites exist for both API and finished product	(6 points)
b)	Multiple approved manufacturing sites exist for either API or finished product	(4 points)
c)	Only one approved manufacturing site exists for API, and only one approved manufacturing site exists for the finished product	(1 points)
d)	Information not provided or not verifiable	(0 points)

3. Implementation of the Urban Wastewater Treatment Directive (UWWTD)

The Contracting Authorities would welcome stakeholders' views on an appropriate contractual approach to the implementation of the Urban Wastewater Treatment Directive (UWWTD).

As the Joint Nordic Framework Agreement is a cross-border agreement, the implementation of the Directive may vary between the participating countries. National legislation may differ with regard to different effective dates, the scope of pharmaceutical products covered, documentation requirements, and other regulatory obligations.

These differences may affect suppliers' costs and obligations during the term of the Framework Agreement. The Contracting Authorities are therefore considering how such changes should be addressed contractually.

Possible approaches could include:

- allowing price adjustments where implementation of the Directive results in documented additional costs; however, such a solution may entail a significant administrative burden for both suppliers and Contracting Authorities due to varying national implementation requirements, documentation standards and effective dates across the participating countries; and/or
- allowing termination of the Framework Agreement, in whole or in part, with reasonable notice (e.g. 9–12 months), where continued performance is materially affected by the implementation of the Directive.

The Contracting Authorities would appreciate feedback on these options, including the administrative implications of a price adjustment mechanism, as well as any alternative approaches that stakeholders consider appropriate.

4. Verification of qualitative criteria and Consequences of non-compliance

The Contracting Authorities are considering introducing provisions governing the ongoing verification of the qualitative criteria offered by the Supplier and evaluated as part of the award procedure. The purpose is to ensure that the performance levels and characteristics forming the basis of the contract award are maintained throughout the Purchasing Period.

The draft clause below outlines a possible mechanism whereby verified non-compliance may result in a reassessment of the Supplier's awarded score and a corresponding adjustment of the contract price.

“Verification of criteria and price adjustment in case of non-compliance:

The Products shall throughout the Purchasing Period, including any extensions thereof, comply with the criteria and performance levels offered by the Supplier in its Tender and set out in Appendix Y.

The Contracting Authorities shall be entitled at any time during the Purchasing Period to verify the Supplier's compliance with the criteria. Such verification may include review of documentation, certifications, declarations, reports or other relevant information, including verification by an independent third party.

If such verification demonstrates that the Supplier does not comply with one or more criteria at the level set out in Appendix Y, the Supplier shall reimburse all documented costs incurred in connection with the verification. If the verification demonstrates that the Supplier complies with the relevant criteria, such costs shall be borne by the Contracting Authority that initiated the verification.

If a verification demonstrates non-compliance, the Contracting Authority shall recalculate the Supplier's score for the relevant award criterion based on the circumstances verified and the evaluation model applied in the procurement procedure.

If the assessment shows that the Supplier would have received fewer points for the relevant award criterion than those originally awarded, the price for the relevant Product shall be reduced as follows:

- If the Supplier would have received more than 0 and up to 1 point less, the price shall be reduced by 3%.
- If the Supplier would have received more than 1 and up to 3 points less, the price shall be reduced by 5%.
- If the Supplier would have received 3 points or more less, the price shall be reduced by 7%.

The reduced price shall apply to all orders placed after the verification result has been notified to the Supplier.

The reduced price shall remain in effect for the rest of the Purchasing Period, including any extensions thereof, or until the Supplier, at its own expense, provides new documentation demonstrating that the relevant criteria once again comply with the level set out in Appendix Y. However, the reduced price shall apply for no less than two (2) months from the date on which the price reduction takes effect. The reduced price shall cease to apply only after the Contracting Authority has accepted such documentation.”

Please submit your input to udbud@amgros.dk no later than October 30, 2026. Please include JNT2028 in the subject line.