

JOINT NORDIC TENDER SPECIFICATIONS

regarding

call for tenders for pharmaceuticals

(Amgros Tendering 2020 – 1.620.a)

A04AA01 Ondansetron

J01GB03 Gentamicin

N02BE01 Paracetamol

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1. THE CONTRACTING AUTHORITIES

Denmark, Iceland and Norway have entered into a cooperation regarding the procurement of pharmaceuticals for use in all three countries.

The contracting authorities will jointly procure and award framework agreements in order to ensure the supply of affordable pharmaceuticals.

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Customers and delivery addresses are listed in appendix 7, 8 and 9 to the framework agreement.

2. THE CALL FOR TENDERS

2.1 The call for tenders

This call for tenders is conducted as an open procedure in accordance with the Danish Procurement Act (*udbudsloven*). The procurement procedure is subject to Danish law and any complaints of the procurement procedure shall be lodged with the Danish Complaints Board for Public Procurement (*Klagenævnet for udbud*), cf. the Contract Notice section VI.4.3.

Tenders for the pharmaceuticals are invited so that Amgros, Sykehusinnkjøp HF, divisjon legemidler and Landspítali can enter into framework agreements for delivery of the pharmaceuticals requested in the list of products.

For this procurement group delivery to Iceland is an option, see paragraph 2.4

A framework agreement will cover delivery of the pharmaceuticals in Denmark and Norway. The agreement will also cover delivery to Iceland, if the Supplier chooses to submit a tender for this option.

The framework agreement is non-exclusive to the supplier. The customers are not obliged to use the framework agreement, see clause 1 of the framework agreement.

The call for tenders is organised with the purpose of entering into framework agreements that are assessed to be able to cover the requirements of the customers, taking into account the characteristics and application of each pharmaceutical.

Special circumstances may apply to some pharmaceuticals, and medical and patient safety considerations may therefore entail the use of specific pharmaceuticals or specific products. Where a requirement subject to such special circumstances is assessed not to be of an exceptional nature and modest in scale, the contracting authorities will endeavor to enter into framework agreement with multiple suppliers in order to purchase on the basis of a call for tenders, see paragraphs 6 and 7.

2.2 Tender documents

The full tender documents for procurement group 2020 – 1.620.a consist of these tender specifications with associated Annex 1:

Annex 1: Instructions for the European Single Procurement Document (ESPD) and documentation regarding absence of exclusion grounds

In addition, the tender documents consist of the following:

The Contract Notice, tender group 2020 – 1.620.a (issued on **UBK afsendelsesdato**)

Joint Nordic framework agreement, tender group 2020 – 1.620.a in two examples;

- I) Denmark, Norway and Iceland (if the Supplier gives a tender for Iceland)
- II) Denmark and Norway (if the Supplier choose not to give a tender for Iceland)

Appendices 7, 8 and 9 to the framework agreement

List of products, tender group 2020 – 1.620.a

The tender documents are available at Amgros' electronic tendering system at <https://levportal.amgros.dk>, and tenders must be submitted using that tendering system, see for more details paragraph 4.1.

Tenders must be submitted in conformity with the tender specifications for the relevant procurement group and the general guidelines for submission of tender provided in the tendering system, including the user guide. The user guide is a practical guide of a general nature, and in the event of discrepancy between the tender documents, especially the tender specifications for the relevant procurement group, and the user guide, the tender documents will prevail.

2.3 The period of the framework agreement

The period of the framework agreement and renewal periods thereof, if any, are set out in clause 18 of the framework agreement.

2.4 Options

Delivery to Iceland

For this procurement group delivery to Iceland is an option. The Supplier can choose to submit a tender for this option, see paragraph 4.1. If the Supplier is awarded a framework agreement the framework agreement will cover delivery of the pharmaceuticals in all three countries for the purchase period (see example I of the framework agreement, see paragraph 2.2).

If the Supplier chooses not to give a tender for the delivery to Iceland the framework agreement will cover delivery of the pharmaceuticals in Denmark and Norway for the purchase period (see example II of the framework agreement, see paragraph 2.2).

Delivery in a pre-agreement and post-agreement period

Clause 1 of the framework agreement provides for an option for delivery in a pre-agreement period (i.e. before the purchase period begins) and an option for delivery in a post-agreement period (i.e. after the purchase period). The two options may be exercised on the terms and conditions stipulated in the framework agreement. The option for delivery in the pre-agreement period may only be exercised when final marketing authorization for the relevant country is in place and the pharmaceutical is included in the list at "medicinpriser.dk" (Denmark), "Farmalogg" (Norway) or "Lyfjaverðskrá" (Iceland).

3. LIST OF PRODUCTS, INCLUDING REQUIREMENTS FOR THE PRODUCTS PUT UP FOR TENDER

3.1 The list of products in general

The pharmaceuticals put up for tender are given a consecutive lot number in the list of products. Each lot number is considered a separate lot for the pharmaceutical indicated and is put up for tender independently of the other lot numbers. This means that a supplier may submit tender for one, several or all lot numbers (lots), and that framework agreements will be awarded separately for each lot number. However, only one framework agreement will be entered into with each supplier per procurement group; the procurement group comprises all the lot numbers that the supplier is awarded under the procurement group concerned.

In the list of products, the pharmaceuticals put up for tender (under each lot number) are specified in terms of ATC code and generic name (the active ingredient), pharmaceutical form, strength and, where appropriate, requirements for package form and/or stated package sizes.

Under certain lot numbers, a pharmaceutical may be further specified by requiring specific ingredients or pharmaceutical formulation.

A lot number may comprise the active ingredient in different forms, e.g. different pharmaceutical forms/strengths/packages (indicated by multiple lines under the relevant lot number). These are different products to be delivered by the same supplier, and the supplier is thus required to submit tender for the pharmaceutical in all the forms stated under the lot number in question. This means that the supplier's tender must include at least one product per line under a lot number. Depending on the layout of the list of products, a tender may include several products in the same line under a lot number, see in this respect the guidelines set out in paragraph 3.3 and/or 3.4 below.

The list of products thus specifies the specific requirements for the product to be offered under the individual lot number, see for more details paragraphs 3.2 - 3.4 below. The framework agreement generally only covers the products offered (specified by product numbers in Appendix 1 of the framework agreement). However, the contracting authorities may agree, on a case-by-case basis, to include other products under

the framework agreement in the term of the framework agreement in accordance with the provisions of clause 3 of the framework agreement.

Where a tender comprises multiple products in the same line under a lot number, such products must have the same product name (trade name) in each country.

Where the product list is designed so that there are multiple lines under the same lot number, the requirement for the same product name (trade name) applies to the products offered in all the lines under the lot number, so that only products with one product name (trade name) are offered under the lot number concerned.

3.2 Pharmaceutical form

Requirements regarding a specific pharmaceutical form for the pharmaceuticals put up for tender are stated with the customary designation of the pharmaceutical form in question.

It should be noted that the contracting authorities defines the pharmaceutical forms as follows:

Injection fluid means "injection fluid, emulsion"; "injection fluid, solution" and "injection fluid, suspension".

Infusion fluid means "infusion fluid, emulsion"; "infusion fluid, solution", and "infusion fluid, suspension".

3.3 Strength

Requirement for specific strength

Where a specific strength is required in the list of products under a lot number, the supplier must offer the pharmaceutical in the strength indicated.

3.4 Packages

No requirement as to a specific package size

Where under a lot number no specific package size is required, the supplier must offer the pharmaceutical in customary packages. Customary packages mean packages that are customary in the trade of the pharmaceutical in question, including bulk packages with several of the package sizes indicated.

Where no package size requirement is stated, the contracting authorities would prefer that the supplier offers several package sizes, but that is not a mandatory requirement.

Package sizes indicated as a range

If the package size under a lot number is indicated as a range, the supplier must submit tender for at least one package within the range stated.

Where package size is indicated as a range, the contracting authorities would prefer that the supplier offers several packages within the range, but that is not a mandatory requirement.

Requirements for specific package size

Where requirements for a specific package size are indicated in the list of products, the supplier must submit tender for the pharmaceutical in a package of the package size indicated (e.g. 100 ml) or in packages of several of this package size, however only in customary sizes of such bulk package (e.g. 5 x 100 ml, 10 x 100 ml or similar). The supplier may choose to submit tender for a package of the package size indicated and/or for one or several bulk packages of the pharmaceutical concerned.

Several different packages under one lot number

Where, pursuant to the above guidelines, the supplier chooses under a lot number to submit tender for several different packages of a pharmaceutical in one specific pharmaceutical form and one specific strength (i.e. multiple products in the same line under a lot number), specific requirements apply for setting prices for such different packages (same price per unit), see paragraph 4.2.a below.

3.5 Units

For every lot number in the list of products, a unit is specified. The unit may correspond to DDD (Defined Daily Dose specified by WHO) or another unit specified.

The unit is used for comparison of prices offered under a lot number, see paragraph 5 below. The unit stated in the list of products is used for allowing products under the same lot number (e.g. for comparison of tender prices for two different package sizes) being given a true and fair comparison of the package prices offered by applying a price per unit as a benchmark.

The unit of a pharmaceutical stated in the list of products is furthermore the basis for calculating the same price per unit in connection with pricing of multiple products where that requirement applies, see paragraph 4.2.a below.

3.6 Expected consumption

In the list of products, the contracting authorities have under "quantity in units" indicated the expected yearly consumption of the pharmaceuticals put up for tender among other things on the basis of historical consumption.

It should be noted that the expected consumption indicated is based on a historical consumption and that the hospitals' need for pharmaceuticals and purchase of various pharmaceuticals to cover that need is influenced by a number of factors, including a possible change of or new use of the pharmaceuticals in the period of the framework agreement. Hence, the estimate is non-binding, and the suppliers must expect that the actual purchase under a framework agreement may differ significantly from the estimate.

When entering into framework agreements, the contracting authorities, after consultation with the customers, will draw up a new estimate of the expected purchase of the various pharmaceuticals, which is also a non-binding estimate, see clause 2 of the framework agreement. The contracting authorities will make efforts during the term of the framework agreement, including during a possible extension of the framework agreement, to inform the supplier of adjustments, if any, of the estimate.

For pharmaceuticals in respect of which the contracting authorities, on entering into the framework agreement, have indicated the expected purchase to be 0 (indicated by a 0 in Appendix 1 of the framework agreement), the framework agreement will be entered into without a delivery obligation for the supplier, see clause 2 of the framework agreement. For such pharmaceuticals, the supplier may choose to accept an order and deliver the pharmaceutical pursuant to the terms of the framework agreement. The supplier is not subject to liability in damages pursuant to clause 12 of the framework agreement if the supplier chooses not to accept such an order.

4. CONTENT OF THE TENDERS

4.1 Submission of tenders

Suppliers must submit tender via Amgros' electronic tendering system at <https://levportal.amgros.dk> before expiry of the deadline stated in paragraph 14. Tenders must be in conformity with the tender specifications for the specific procurement group and the general guidelines for submission of tender stated in the tendering system, see paragraph 2.2.

Submission of tenders under the individual lot numbers and indication of price must furthermore be in accordance with the provisions of paragraph 4.2.

The supplier's tender must furthermore include the information set out in paragraphs 4.4.

The tender and the documentation for the information submitted in the ESPD must be in Danish, Swedish, Norwegian or English.

If the contract is awarded to a group of suppliers, each participant must undertake joint and several liability and appoint a joint representative.

4.2 Indication of price for the products offered

The supplier's tender must indicate the pharmaceuticals (lot numbers) for which tenders are submitted; the supplier must furthermore provide the information requested in the tendering system about the products offered, including the price of the products offered.

Tenders for products under each lot number must be submitted in accordance with the provisions of paragraph 3. The price must be specified as a fixed net price per product in EURO and as stated below.

a. A tender comprising multiple products under one lot number

Depending on the layout of the list of products, a tender must - or may - comprise multiple products under one lot number, see paragraphs 3.1, 3.3 and 3.4. This means that the supplier's tender must include at least one product per line under a lot number and may, if appropriate, include multiple products in the same line under the lot number.

If in one tender under one lot number, a tender is submitted for multiple products, the requirements below regarding indication of price apply.

It is furthermore a requirement that multiple products under the same lot number must have the same product name (trade name) in each country, see paragraph 3.1.

Several different packages in the same line under a lot number

Where the supplier under a lot number chooses to submit tender for several different packages of a pharmaceutical in one particular pharmaceutical form and in one particular strength (in the same line under the lot number in question, see the instructions in this respect in paragraph 3.4) it is a requirement that the price per package is determined so that the price per unit is the same for these different packages.

Possible correction of prices indicated

Where the tender comprises multiple products under one lot number, the supplier must thus be aware that the price of certain of the different products must be determined so that the price per unit is the same for such products, and that the contracting authorities will correct the tender price if the price per unit is not the same, see paragraph 5. As described above, this applies to all tenders offering multiple products in one line under a lot number.

If the supplier should erroneously indicate prices for such different products without the required conformity between the converted prices per unit for the products, the contracting authorities will correct the prices so that the requirement is complied with, see paragraph 5 below.

b. Fixed net price

The tender must include a fixed net price in EURO excl. VAT for each of the products offered under the lot in question.

The offered price must apply for all the countries covered by the framework agreement. This means that the tender price shall be the same price in EURO for Denmark and Norway – and for Iceland, if the Supplier chooses to submit a tender for the option regarding Iceland. The price will be converted to the national currency for Denmark and Norway as described in the framework agreement, clause 10. If Iceland is part of the framework agreement, purchase for Iceland will be made at the tender price in EURO, see the framework agreement (example I), clause 10 and 11.

The price offered must not be made dependent on the turnover of the pharmaceutical or be based on the Pharmacy Purchase Price (referred to by its Danish abbreviation "AIP") as published by the Danish Medicines Agency (*Lægemiddelstyrelsen*) "Farmalogg" (Norway) or "Lyfjaverðskrá" (Iceland) or similar. The price offered must not be dependent on or based on offers of other services, nor must the prices offered under different lot numbers be interdependent.

4.3 Information about marketing authorization

It is not required that marketing authorisations for the pharmaceuticals offered are in place at the time of submission of tender, but final marketing authorisation for Denmark, Norway and Iceland (if part of the framework agreement) must be in place so that the pharmaceuticals have marketing authorisation and are indicated in the Danish Medicines Agency list at "medicinpriser.dk", "Farmalogg" (Norway) and "Lyfjaverðskrá" (Iceland, if part of the framework agreement) not later than the date stated in clause 4 of the framework agreement.

If the Supplier fails to comply with the requirement regarding admission to the lists as stated above, the Supplier will be deemed to be on back order

4.4 The European Single Procurement Document and documentation regarding absence of exclusion grounds

The tenderer must use the European Single Procurement Document (ESPD) for the declaration stated in section III.1.1 of the Contract Notice. Further information on the completion and application of the ESPD in the tender process is available in the "Instructions for the European Single Procurement Document (ESPD) and documentation regarding absence of exclusion grounds" which is part of the tender documents.

Specific requirements apply to the tenderer's documentation of the information on absence of exclusion grounds submitted by the tenderer in the ESPD. A tenderer with whom the contracting authorities intends to enter into a framework agreement will before the award be requested to submit documentation of the information that the tenderer has submitted in the ESPD, see for more information "Instructions for the European Single Procurement Document (ESPD) and documentation regarding absence of exclusion grounds".

5. THE CONTRACTING AUTHORITY'S EVALUATION OF TENDERS IN ACCORDANCE WITH THE AWARD CRITERION

For each lot number, the contracting authorities will enter into a framework agreement with the supplier having submitted the most economically advantageous tender evaluated in accordance with the award criterion "price" on the basis of the lowest tender price per unit.

The price offered per package will thus be converted to a comparable unit price. The unit price will be calculated as price per unit on the basis of the unit stated in the list of products for the lot number in question.

As stated in paragraph 4.2.a, it is a requirement that the price of multiple products in one line under a lot number is determined so that the price per unit is the same for these products. If the offered prices per product in those instances entail that there is not the required consistency between the converted prices per unit for the products in question, the evaluation of the tender will be based on the lowest converted price per unit. If a framework agreement is entered into with the supplier in question, the contracting authorities will be entitled to purchase the products in question on the basis of the lowest converted price per unit.

If under a lot number there are multiple tenders with the (exact) same lowest price, the choice between those tenders will be based on a drawing of lots functionality in Amgros' tendering system.

6. SELECTION OF MULTIPLE TENDERS

Under each lot number in this procurement group, a framework agreement will only be entered into with one supplier.

7. PURCHASE UNDER ONE FRAMEWORK AGREEMENT WITH MULTIPLE SUPPLIERS

A framework agreement will not be concluded with multiple suppliers under the individual lot numbers in this procurement group.

8. FRAMEWORK AGREEMENT - RESERVATIONS AND VARIANTS - FORMAL REQUIREMENTS

The contracting authorities has drawn up the enclosed framework agreement.

As stated in the Contract Notice, the tenderer is not entitled to submit variants.

Nor is the tenderer entitled to make reservations regarding provisions in the draft framework agreement or provisions in the appendices thereof.

Furthermore, the tenderer is not entitled to draw up its tender so that terms and conditions in the tender specifications are derogated from, unless expressly provided for in the tender specifications.

As for the formal tender content requirements set out in the tender documents, the contracting authorities may choose, on a case-by-case assessment, not to reject the tender for non-compliance with these requirements but instead choose to remedy or disregard the errors/defects to the extent provided for in procurement law. In this context, the contracting authorities will be entitled to obtain additional information, including a missing ESPD.

9. AMBIGUITIES

The tenderer may clarify any ambiguities by requesting further information on the tender specifications (written questions), see paragraph 14.

Written questions must be submitted in English in the tendering system under the procurement group to which the question pertains. Questions will be answered in English.

Written questions and the related answers will be published in Amgros' tendering system in anonymized form under the procurement group in question.

The contracting authorities points out that continuing notices will not be submitted to the businesses having indicated an interest in a particular call for tenders. Hence, it is the responsibility of the tenderer to keep updated on additional information regarding the tender; such information may be published until 6 days before the expiry of the deadline for submission of tenders. Reference is furthermore made to the descriptions in the tendering system and the related guidelines.

10. PERIOD OF VALIDITY OF TENDERS

By submitting its tender, the tenderer has accepted to keep open its tender for acceptance until the expiry of the period of validity of the tender set out in paragraph 14.

11. PROCESSING OF TENDERS, ETC.

The tenderers are not permitted to attend the opening of the tenders. Tenders will be registered upon receipt, and tenders received on time will be opened collectively at a specified time after expiry of the deadline for submission of tenders. With the notice regarding the tender evaluation, the tenderers will receive a comprehensive overview of the businesses having submitted compliant tenders. The overview may not be obtained at any earlier point in time.

The contracting authorities are not obliged to return the tender to the tenderer.

The contracting authorities will not consider the tender process concluded until the framework agreement has been signed and reserves the right, in accordance with procurement law, to cancel the tender process in whole or in respect of certain lot numbers. On a case-by-case assessment, the tender process may be cancelled, inter alia, if the contracting authorities on the basis of the number of tenders and the prices received assesses that the order has not been the subject of sufficiently effective competition, including in the light of market conditions.

There may, as the case may be, be such a link in the use of different pharmaceuticals under several different lot numbers that the contracting authorities, on a case-by-case assessment, may choose to cancel several lot numbers within the same therapy area if certain lot numbers need to be cancelled. The cancellation of a lot number may thus be based on the fact that a re-tender of the pharmaceutical at the time of a re-tender of other pharmaceuticals is assessed, on a case-by-case basis, to comply the most with fundamental procurement law principles.

Even though the framework agreement is awarded to another tenderer, the tenderer is bound by its tender, but not longer than the date specified in paragraph 10 for the tender to remain open for acceptance.

The costs of the tenderer in connection with this tender are of no concern to the contracting authorities, including if the contracting authorities may have to cancel the tender process or lot numbers without conclusion of a framework agreement.

12. NEGOTIATIONS

When preparing the tender, the tenderer should be aware that the contracting authority is not allowed to negotiate the tenders submitted by the tenderers. The contracting authorities therefore requests the tenderers to submit their best offer. The contracting authority will thus comply with the procurement law framework for negotiation following, inter alia, from the Danish Public Procurement Act and the EU Public Procurement Directive.

Thus, no actual contract or price negotiations will be conducted and, therefore, the tenderers should ensure that their tenders are drawn up so as to allow a conclusion of the framework agreement without prior negotiations between the tenderer and the contracting authorities.

It is therefore important that the tenders are comprehensive and include all necessary information, including in particular all prices, and that they are accurate in every respect.

13. PUBLICATION OF PRICES – CONFIDENTIALITY

The contracting authorities will not of its own motion publish the tender prices received or the applicable prices under the agreement.

It should be noted that the contracting authorities are subject to rules on access to documents, and the contracting authorities are entitled and obliged to grant access to documents, including tenders received, to the extent stipulated by law.

This means that competitors, among others, may request access to the tenders submitted.

The contracting authorities are only entitled to exempt documents or information from disclosure to the extent provided for by law, including for the purposes of protecting information about the business affairs of others.

In respect of documents or information in the tender, the tenderer may request, and mark accordingly, that such documents or information be exempted from disclosure to the extent that the tenderer assesses on a case-by-case basis that the disclosure thereof is likely to entail an obvious risk - typically for reasons of competition - of causing damage to the business, in particular significant financial damage.

However, in any event, the contracting authorities will be entitled and obliged to grant disclosure of documents and information to the extent required by law, but the tenderer's request will be included in the Contracting Authorities' assessment of whether or not documents or information may be exempted.

14. TIME SCHEDULE FOR THE TENDER PROCESS

30 April 2019

12:00 noon Deadline for submission of tenders.

Early June

2019 Expected award of the contracts. Before the award of the contracts, the contracting authorities will obtain documentation for information provided in the ESPD from the successful tenderer(s), see "Instructions for the European Single Procurement Document (ESPD) and documentation regarding absence of exclusion grounds".

Mid June

2019 Expected conclusion of framework agreements.

The framework agreements cannot be entered into until the expiry of a standstill period. The standstill period commences on the day following the day when notice of the identity of the successful tenderer has been submitted to the tenderers and constitutes 10 days. If the standstill period expires on a Saturday, Sunday or holiday, the expiry of the deadline will be postponed to the next working day. The date of expiry of the standstill period will be stated in the notice to the tenderers regarding the result of the tender evaluation.

15 August 2019 Date of expiry of the period of validity of tenders, see paragraph 10.

1 February 2020 Deadline for publication at "medicinpriser.dk" (Denmark), "Farmalogg" (Norway) or "Lyfjaverðskrá" (Iceland, if part of the framework agreement), see clause 4.3 of the framework agreement.

1 April 2020 Commencement of purchase period, see clause 18 of the framework agreement.