J O I N T N O R D I C T E N D E R S P E C I F I C A T I O N S

regarding

call for tenders for pharmaceuticals

(Amgros Tendering 2020 – 2.620.b)

L01BA01 Methotrexate

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1. THE CONTRACTING AUTHORITIES

Denmark and Norway have entered into a cooperation regarding the procurement of pharmaceuticals for use in all both 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 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 and Sykehusinnkjøp HF, divisjon legemidler can enter into framework agreements for delivery of the pharmaceuticals requested in the list of products.

A framework agreement will cover delivery of the pharmaceuticals in both countries.

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 – 2.620.b consist of these tender specifications with associated Annex 1 - 2:

Annex 1: Instructions for the European Single Procurement Document (ESPD) and documentation regarding absence of exclusion grounds
Annex 2: Evaluation method.

In addition, the tender documents consist of the following:

The Contract Notice, tender group 2020 – 2.620.b (issued on UBK afsendelsesdato)
Joint Nordic framework agreement, tender group 2020 – 2.620.b
List of products, tender group 2020 – 2.620.b
Appendix 7 and 9

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

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) and “Farmalogg” (Norway).

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

3.1 The list of products in general

In the list of products, the pharmaceutical 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.

This procurement group includes one lot number.

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:

> Concentrate, sterile means both "concentrate for infusion fluid, solution" and "concentrate for injection fluid, solution".

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

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.

Similarly, it is stated in paragraph 4.2.a how prices for several packages of the same pharmaceutical (i.e. the same pharmaceutical form and the same strength) under one procurement number must be determined when, in connection with several lines of the procurement number concerned, there is a requirement for different package sizes (indicated by several lines under the procurement number - and where the different packages are thus offered in different lines under the procurement number).

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.

The expected number of units stated is used where the contracting authorities, in order to compare prices under a lot number, calculates a weighted average price, see paragraph 5 below.

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.

3.7 Requirements for the pharmaceutical

The pharmaceutical is used for mixing at the hospital pharmacies/units, and the handling thereof involves working environment risks due to the nature of the pharmaceutical.

The pharmaceuticals must be delivered in vials, and it is an essential requirement that there is no, nor will be, overpressure in the vials, and that the caps of the vials remain tight after perforation with a needle.

In the evaluation of tenders, emphasis will be given to a number of factors of importance to the safety of the staff in the use of the pharmaceutical, including that the outer surface of the packaging is free of any residue from the pharmaceutical, and that both the primary and secondary packaging are generally of a quality and design that ensure the greatest possible safety to the staff in the use of the pharmaceutical, see sub-criterion 3 as further described in paragraph 5.

In the evaluation of tenders, emphasis will also be given to the physico-chemical stability of the pharmaceutical, see sub-criterion 2 as further described in paragraph 5. In connection with information about the supplier's own stability tests documenting a shelf-life of the ready-to-use solution that is longer than the shelf-life indicated in the summary of product characteristics, the stability data must be for the pharmaceutical in the packaging types used by the hospital pharmacies/units. These packaging types, which are purchased under a framework agreement previously put up for tender, are indicated in Appendix 4A. Upon

submission of tender, the suppliers may indicate the physico-chemical stability for ready-to-use solutions of the pharmaceutical in Appendix 4A, as further described in paragraph 4.5 below.

The supplier's information on the pharmaceuticals offered in relation to the above elements covered by the sub-criteria will - if the framework agreement is entered into - be considered a requirement for the pharmaceuticals covered by the framework agreement, and a change of these elements will therefore be considered a defect in the products delivered, see clause 4 of the framework agreement and Appendix 4.

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 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 to 4.5.

The tender and the documentation for the information submitted in the ESPD must be in Danish, Swedish, Norwegian or English. Similarly, the supplier's information about the pharmaceuticals offered in relation to the sub-criteria, see paragraph 4.5 and 5, must be in Danish, Swedish or 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 must provide the information requested in the tendering system about the products offered, including the price of the products offered.

Tenders for products under the 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 packages indicated by several lines under the lot number

For this procurement group, it is *not* a requirement that the price of different packages of the same pharmaceutical offered in different lines under the lot number is determined so that the price per unit is the same for these packages. This applies where the lot number covers several indicated packages of a pharmaceutical in the same pharmaceutical form and in the same strength (indicated by several lines under the lot number).

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 number in question.

The offered price must apply for both countries. The price will be converted to the national currency for Denmark and Norway as described in the framework agreement, clause 10.

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)* and "Farmalogg" (Norway) 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.

c. Prices for framework agreement 1 and for other framework agreements

The supplier accepts on submission of tender that, on the basis of the tender, the supplier may be awarded a framework agreement in accordance with the terms and conditions of the tender documents, including conclusion of parallel framework agreements as described in paragraphs 6 and 7.

Hence, the supplier may not stipulate as a condition for the tender that the supplier be awarded a specific framework agreement.

However, the supplier may choose to submit prices (price 1) that will apply if the supplier is awarded framework agreement 1, and prices (price 2) if the supplier is awarded another framework agreement than framework agreement 1 (i.e. framework agreements 2, 3 4 etc.).

The rules outlined above for submission of prices under the lot number apply separately for the submission of price 1 and the submission of price 2, respectively. Reference is made to the guidelines in the procurement system concerning submission of different tender prices for the same product.

If the supplier submits tender with indication of a price, that price will be taken into account in the tender evaluation, both in relation to framework agreement 1 and in relation to other framework agreements, see paragraph 5.3.

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 authorisations for Denmark and Norway must be in place so that the pharmaceuticals have marketing authorisation and are indicated in the Danish Medicines Agency list at "medicinpriser.dk" and “Farmalogg” (Norway) 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”.

4.5 Information in relation to sub-criteria

As part of its tender, the tenderer must submit descriptions and material stating how the pharmaceuticals offered comply with the sub-criteria, see paragraph 5.

In relation to sub-criterion 2, the supplier must submit a current summary of product characteristics and may, in addition, submit Appendix 4A with information on the supplier's own stability tests documenting a shelf-life of the ready-to-use solution that is longer than the shelf-life indicated in the summary of product characteristics, see paragraph 5.

A "ready-to-use solution" means a prepared infusion fluid.

Appendix 4A is to be used for documentation of a shelf-life which is longer than the shelf-life set out in the summary of product characteristics. The pre-printed information in the appendix may not be changed. Appendix 4A must be dated and signed by the supplier's internal "Qualified Person" (pursuant to Article 49 of Directive 2001/83/EC) and must include the following information for at least one of the packaging types mentioned in Appendix 4A.

1) Active ingredient, pharmaceutical form, trade name, supplier name and any solvents for reconstitution of powder (e.g. sterile water or 0.9 % sodium chloride) enclosed with the product.

2) Whether light protection is necessary to achieve the shelf-life indicated.

3) Physico-chemical (p/c) stability for the ready-to-use solution.

4) The concentration range of the pharmaceutical in the ready-to-use solution within which the indicated p/c stability applies.

All the above information must be indicated for the purpose of the hospital pharmacies'/units' handling of the pharmaceutical following a potential conclusion of contract. However, only the information on the length of the shelf-life (days/nights, hours) will be included in the evaluation of the tender, see paragraph 5.

The hospital pharmacies will receive the filled in Appendix 4A if the supplier is awarded the framework agreement. The hospital pharmacies will be informed that Appendix 4A constitutes confidential information which is to be treated as such.

The supplier is obliged to submit a current summary of product characteristics, but is not obliged to also submit information of the supplier's own stability tests documenting a shelf-life that is longer than the shelf-life indicated in the summary of product characteristics. If the supplier does not submit information about the supplier's own stability tests, the shelf-life for ready-to-use solutions will only be evaluated on the basis of information from the summary of product characteristics.

In relation to sub-criterion 3, the supplier must submit documentation for the supplier's protection against residues of the pharmaceutical on the outer surface of the packaging, see paragraph 5.

The documentation must be dated and signed no further back in time than 6 months prior to the expiry of the tender deadline. The documentation must be signed by the "Qualified Person" (pursuant to Article 49 of directive 2001/83/EC) from the internal quality department.

The supplier must furthermore submit descriptions and photo material of the product displaying the design and quality of the primary packaging and the secondary packaging, respectively, as well as descriptions of the suitability of the packaging in offering the greatest possible safety to staff when used, see paragraph 5.

It is the tenderer's responsibility to ensure that the tenderer's descriptions in relation to the sub-criteria are adequate and suitable as the basis for evaluating the tender in accordance with the specific contents of the sub-criterion in question.

The tenderer is requested to attach the above documents to the tender upon submission of tender in Amgros' electronic tendering system in accordance with the guidelines.

If a tenderer should fail to provide, in whole or in part, the information mentioned in this paragraph 4.5 the contracting authorities will be entitled to either reject the tender as non-compliant, to remedy or disregard the error/defect if provided for under the procurement rules, see also paragraph 8 below, or, if possible, to give adverse effect to the defect in the evaluation of the sub-criterion in question, see paragraph 5 below.

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

5.1 Award criterion

The contracting authorities will enter into a framework agreement with multiple suppliers, see paragraph 6. The framework agreement will be entered into with the suppliers having submitted the most economically advantageous tender evaluated in accordance with the award criterion "best price-quality ratio"..

In this connection, the contracting authorities will apply the following sub-criteria and sub-sub-criteria:

1. Price - weighting 35 %

The price will be evaluated on the basis of the tender price per unit.

The price offered per package will thus be converted by the contracting authorities 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.

The supplier must submit tender for the pharmaceutical in different packages under the lot number (indicated by two lines under the lot number) and the lowest price will be calculated as the weighted average

lowest price per unit. The weighted average price is calculated on the basis of the indicated expected consumption of the different packages. The supplier of the weighted average lowest price per unit is deemed to have submitted the lowest price.

As stated in paragraph 4.2.a, it is a requirement that the price of multiple products in the same line under the lot number is determined so that the price per unit is the same for these products. If the offered prices per product 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.

2. Shelf-life - weighting 35 %

In the evaluation of the sub-criterion "Shelf-life", weight will be attached, in order of priority, to the Shelf-life of ready-to-use solutions and the shelf-life of opened vials and reconstituted solution as further described in the following:

- Shelf-life for ready-to-use solutions

Documentation of the longest possible shelf-life for ready-to-use solutions assessed on the basis of either the information in the summary of product characteristics or the information mentioned in paragraph 4.5 above about the supplier's own stability tests documenting a shelf-life that is longer than the shelf-life stated in the summary of product characteristics.

In this connection, weight is given to the longest possible shelf-life in terms of physico-chemical stability. Long shelf-life when stored at room temperature is preferred to shelf-life at refrigerated temperature.

A maximum number of points will be awarded to a shelf-life of 28 days or more. Hence, additional points will not be awarded to a shelf-life beyond 28 days.

If the supplier does not submit information about the supplier's own stability tests as set out in paragraph 4.5, the shelf-life for ready-to-use solutions will only be evaluated on the basis of information from the summary of product characteristics.

- Shelf-life for opened vials and reconstituted solutions

Documentation of the longest possible shelf-life for opened vials and reconstituted solutions assessed on the basis of information from the summary of product characteristics.

In this connection, weight is given to the longest possible shelf-life in terms of physico-chemical stability.

3 Working environment - quality and cleanness of packaging - weighting 30 %

In the evaluation of the sub-criteria weight will be attached to the following elements with equal weight:

- Documentation and quality of decontamination process, process control and/or final inspection.
- Documentation and quality of validation of decontamination process, quantitative tests of residues on outer surface.
- Breakage resistant vials or vials of material with extra protection which protects during transport and when dropped and which minimises the risk of spread of the pharmaceutical if the vial is broken. The vials must furthermore be manageable for the staff.

5.2 The evaluation method

If one or more suppliers have exercised the option set out in paragraph 4.2 of submitting different prices for framework agreement 1 (price 1) and for other framework agreements (price 2), the tender evaluation will be carried out in two rounds (evaluation with different tender prices).

In the first evaluation round, all tenders will be evaluated in accordance with the award criteria set out in paragraph 5.1 and the suppliers' price 1 will be applied in the evaluation of the "price" criterion. Framework agreement 1 will be awarded on the basis of this evaluation.

An additional evaluation round will then be carried out for the purpose of awarding the other framework agreements. The tenders from the remaining tenderers will be evaluated in accordance with the award criteria set out in paragraph 5.1, and the suppliers' price 2 will be applied in the evaluation of the "price" criterion (or price 1 if the supplier in question has chosen to submit only one price). Framework agreements 2, 3, 4, etc., will be awarded on the basis of this evaluation.

The evaluation method is described in more detail in Annex 2 of the Tender Specifications.

6. SELECTION OF MULTIPLE TENDERS

As stated in paragraph 5, the contracting authorities will enter into a framework agreement with up to 5 suppliers (i.e. agreements with several different suppliers regarding the delivery of the pharmaceutical under the lot number) in order to ensure patient safety as stated below.

A large part of the patients use a product which, according to the patient's individual circumstances, ensure the patient the best possible treatment.

Documentation of the shelf life of the pharmaceutical in a specific type of packaging may have an impact on whether or not patients can receive treatment in their own homes. Likewise, it may require a specific concentration range of the pharmaceutical to use the mentioned specific packaging for treatment of the patient in the patient's own home. For patient safety considerations, the hospitals must be offered the opportunity of buying the pharmaceutical with documentation of the shelf life in the necessary concentration ranges and in the selected type of packaging, such as, for example, infusion containers or portable infusion pumps.

A part of the preparation of cytostatics takes place in a robot. The robot eliminates strain from repetitive work among the staff. The design and material of the packaging of the pharmaceutical may cause technical problems. For production reasons, the hospital pharmacies must be offered the opportunity of purchasing the pharmaceutical in a packaging where the technical challenges of the pharmaceutical's packaging have been reduced.

The contracting authorities will use the parallel framework agreements to ensure patient safety and to take into account the technical issues.

The framework agreement with multiple suppliers will be entered into with the aim, furthermore, of ensuring reliability of supply. Where a supplier is unable to supply under the framework agreement, the pharmaceutical may thus be purchased from any of the other suppliers with whom a framework agreement has been entered into, pursuant to the terms and conditions of the framework agreement, including at the price that applies under the framework agreement.

The order of priority will be such that framework agreement 1 will be entered into with the supplier offering the most economically advantageous tender, framework agreement 2 with the supplier offering the second most economically advantageous tender, etc.

7. PURCHASE UNDER ONE FRAMEWORK AGREEMENT WITH MULTIPLE SUPPLIERS

When using the framework agreements, the hospitals must in principle choose the pharmaceutical evaluated to be the most economically advantageous tender (framework agreement 1).

Derogations from this principle may be made in the following circumstances:

1. Patients where, due to the patient's diagnosis, the most efficient treatment is not the pharmaceutical covered by framework agreement 1 as this has not been authorised for the necessary indications.
2. In hospital units where specific portable infusion pumps or syringes are used for patients receiving treatment in their own homes and where the supplier is not able to document shelf life in the specific portable infusion pumps or syringes or at the concentration range required for the pump or syringe, but where a supplier of the pharmaceutical under another framework agreement is able to do so.
3. Technical challenges in connection with the use of the pharmaceutical in a robot due to the design and material of the packaging are reduced when using a pharmaceutical covered by a different framework agreement than framework agreement 1.
4. Covering purchase in the event of another supplier's failure to supply the pharmaceutical, see paragraph 6.

If several of the other framework agreements entered into comply with the considerations justifying a purchase under a different framework agreement than framework agreement 1, the hospitals must use the highest ranking framework agreement.

The terms and conditions of the framework agreement entered into - including price - apply to all deliveries to the contracting authorities and/or the customers, also when these purchases are made in exceptional cases where other specific medical and patient safety related circumstances apply.

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.

For this procurement group with award criterion best price-quality ratio information of the price of the pharmaceutical will be given to the other tenderers as part of the grounds for the award of the contract. Hence, the price cannot be exempted from access to documents.

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 contract. Before the award of the contract, 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 agreement. The framework agreement 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) or “Farmalogg” (Norway), see clause 4.3 of the framework agreement.
1 April 2020	Commencement of purchase period, see clause 18 of the framework agreement.