

TENDER SPECIFICATIONS

regarding

call for tenders for pharmaceuticals

(Amgros Tendering 2019 - 1.x.a)

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Table of contents

1.	THE CONTRACTING AUTHORITY	3
2.	THE CALL FOR TENDERS	3
2.1	General call for tenders	3
2.2	Tender documents.....	3
2.3	The pharmaceuticals put up for tender	4
2.4	The period of the framework agreement.....	5
2.5	Options	5
2.6	Price regulation mechanism in the period of the framework agreement	5
3.	LIST OF PRODUCTS, INCLUDING REQUIREMENTS FOR THE PRODUCTS PUT UP FOR TENDER	6
3.1	The list of products in general.....	6
3.2	Pharmaceutical form	7
3.3	Strength	7
3.4	Packages	8
3.5	Units.....	10
3.6	Expected consumption	10
3.7	Requirements for the pharmaceutical.....	11
4.	CONTENT OF THE TENDERS	11
4.1	Submission of tenders	11
4.2	Indication of price for the products offered.....	11
4.3	Information about marketing authorisation	14
4.4	The European Single Procurement Document and documentation regarding absence of exclusion grounds.....	15
5.	THE CONTRACTING AUTHORITY'S EVALUATION OF TENDERS IN ACCORDANCE WITH THE AWARD CRITERION	15
6.	SELECTION OF MULTIPLE TENDERS	16
7.	PURCHASE UNDER ONE FRAMEWORK AGREEMENT WITH MULTIPLE SUPPLIERS.....	16
8.	FRAMEWORK AGREEMENT - RESERVATIONS AND VARIANTS - FORMAL REQUIREMENTS.....	17
9.	AMBIGUITIES.....	17
10.	PERIOD OF VALIDITY OF TENDERS	18
11.	PROCESSING OF TENDERS, ETC.....	18
12.	NEGOTIATIONS	19
13.	PUBLICATION OF PRICES - CONFIDENTIALITY	19
14.	TIME SCHEDULE FOR THE TENDER PROCESS	20

1. THE CONTRACTING AUTHORITY

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2. THE CALL FOR TENDERS

2.1 General call for tenders

This call for tenders is conducted as an open procedure.

Tenders for the pharmaceuticals are invited so that Amgros can enter into framework agreements for delivery of pharmaceuticals to the hospital pharmacies of Amgros' stakeholders (the regions).

Amgros organises its calls for tenders for the purpose of entering into framework agreements that are assessed to be able to cover the requirements of the hospital pharmacies for pharmaceuticals, taking into account the characteristics and application of each pharmaceutical.

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

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, Amgros will endeavour 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 2019 - 1.x.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 2019 - 1.x.a (issued on ...).

Framework agreement (General call for tenders 2019 - 1.x.a).

List of products 2019 – 1.x.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 pharmaceuticals put up for tender

The pharmaceuticals put up for tender are primarily - but not exclusively - used for the treatment of These therapeutic areas have been considered by a committee set up by the Danish Council for the use of Expensive Hospital Medicines (Rådet for Anvendelse af Dyr Sygehusmedicin (RADS)) and/or the Danish Medicines Council (Medicinrådet). Treatment guidelines, etc., are available at either www.rads.dk or www.medicinraadet.dk.

Some of the pharmaceuticals put up for tender are covered by the mentioned treatment guidelines.

The various pharmaceuticals are put up for tender in separate lots for the purpose of concluding framework agreements on the delivery of these pharmaceuticals. Framework agreements will be entered into separately for each procurement number, see paragraphs 3.1 and 5.

In relation to the call for tender, the pharmaceuticals are thus put up for tender separately and independently of the other pharmaceuticals.

The use of some of the pharmaceuticals within the therapeutic areas mentioned above is explained in the treatment guidelines. The treatment guidelines thus contain information stating how the pharmaceuticals covered by the framework agreements entered into by Amgros are intended to be used within the scope of the guidelines. The treatment guidelines may contain treatment cascades for different types of treatments where the pharmaceuticals put up for tender may be included as possible treatments. The position of the individual pharmaceutical in the treatment cascade is decided by RADS/the Danish Medicines Council on the basis of an assessment of the pharmaceutical.

The treatment guidelines will form the basis of recommendations for pharmaceuticals with indication of specific pharmaceuticals. In treatment guidelines with several pharmaceuticals ranking equally therapeutically, the prices of the pharmaceuticals will have an effect on which of the pharmaceuticals ranking equally will be recommended as the first choice.

If during the period of the agreement new contract prices are obtained through the price regulation mechanism, see paragraph 2.6, for the products covered, this may result in changes in the relevant recommendation(s) for pharmaceuticals.

The framework agreements are put up for tender for the purpose of covering the hospital pharmacies' needs for the pharmaceuticals specified in the product list, and procurement of the pharmaceuticals under the framework agreement may both be for treatment of the indications mentioned above and for the possible treatment of other indications. It should be noted in this connection that the treatment guidelines, etc., for the indications mentioned above do not necessarily cover most of the consumption of the pharmaceuticals put up for tender.

The treatment guidelines mentioned may be updated during the term of the framework agreement, which may result in a change in the recommendation for pharmaceuticals and impact on the consumption of the pharmaceuticals put up for tender.

2.4 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.

2.5 Options

Options for the pharmaceuticals covered by the call for tenders will be indicated in the product list.

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 authorisation for Denmark is in place and the pharmaceutical is included in the list at "medicinpriser.dk".

2.6 Price regulation mechanism in the period of the framework agreement

Amgros may in the period of the framework agreement request that the supplier submit a new, lower price of the products covered by the framework agreement, see for more detail clause 10.3 of the framework

agreement. The supplier is not obliged to submit a new, lower price of the products covered by the framework agreement.

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

In the list of products, the pharmaceuticals put up for tender (under each procurement 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 procurement numbers, a pharmaceutical may be further specified by requiring specific ingredients or pharmaceutical formulation.

A procurement number may comprise the active ingredient in different forms, e.g. different pharmaceutical forms/strengths/packages (indicated by multiple lines under the relevant procurement 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 procurement number in question. This means that the supplier's tender must include at least one product per line under a procurement number. Depending on the layout of the list of products, a tender may include several products in the same line under a procurement 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 procurement 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, Amgros 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 procurement number, such products must have the same product name (trade name).

Where the product list is designed so that there are multiple lines under the same procurement number, the requirement for the same product name (trade name) applies to the products offered in all the lines under the procurement number, so that only products with one product name (trade name) are offered under the procurement 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 Amgros defines the pharmaceutical forms as follows:

Capsules means both hard and soft capsules.

Prolonged-release capsules means both hard and soft prolonged-release capsules.

Tablets means film-coated, coated and ordinary tablets.

Oral fluid means oral emulsion, solution and suspension.

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".

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

Powder for injection fluid means both "powder for injection fluid, solution" and "powder for injection fluid, suspension".

Powder for infusion fluid means "powder for infusion fluid, solution".

3.3 Strength

a. No requirement as to a specific strength

Where under a procurement number no specific strength is required, the supplier must offer the pharmaceutical in customary strengths. Customary strengths mean strengths that are customary in the trade of the pharmaceutical in question.

Where no strength requirement is stated, Amgros would prefer that the supplier offers several strengths, but that is not a mandatory requirement.

Where the supplier chooses under a procurement number to submit tender for several strengths in the same line under the procurement number concerned, specific requirements apply for setting prices for such different products, see paragraph 4.2.a below.

For all procurement numbers of this procurement group, the strength requirements are stipulated in the list of products, see below.

b. Strength indicated as a range

Strength is indicated in the list of products with the total quantity of the active ingredient in the container in question.

If the strength for a pharmaceutical under a procurement number is indicated as a range, the supplier must submit tender for the pharmaceutical in at least one strength within the range stated.

Where strength is indicated as a range, Amgros would prefer that the supplier offers several strengths within the range, but that is not a mandatory requirement.

Where the supplier chooses under a procurement number to submit tender for the pharmaceutical in several strengths within the range indicated (i.e. several products in the same line under a procurement number), specific requirements apply for setting prices for such different products, see paragraph 4.2.a below.

The list of products of this procurement group does not contain procurement numbers with strength indicated as a range.

c. Requirement for specific strength

Strength is indicated in the list of products with the total quantity of the active ingredient in the container in question.

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

The list of products of this procurement group does not contain procurement numbers with specific strength requirements, see above.

3.4 Packages

a. No requirement as to a specific package size

Where under a procurement 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, Amgros would prefer that the supplier offers several package sizes, but that is not a mandatory requirement.

For all procurement numbers in this procurement group, the package size requirements are stipulated in the list of products, see below.

b. Package sizes indicated as a range

If the package size under a procurement 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, Amgros would prefer that the supplier offers several packages within the range, but that is not a mandatory requirement.

The list of products of this procurement group does not contain procurement numbers with package sizes indicated as a range.

c. 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.

The list of products regarding this procurement group does not contain procurement numbers with specific package size requirements, see above.

d. Several different packages under one procurement number

Where, pursuant to the above guidelines, the supplier chooses under a procurement 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 procurement 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 procurement number in the list of products, a unit is specified by Amgros. The unit may correspond to DDD (Defined Daily Dose specified by WHO) or another unit specified by Amgros.

The unit is used by Amgros for comparison of prices offered under a procurement number, see paragraph 5 below. The unit stated in the list of products is used for allowing products under the same procurement 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, Amgros has under "quantity per unit" indicated the expected ... consumption of the pharmaceuticals put up for tender ... on the basis of

The expected number of units stated per... is used where Amgros, in order to compare prices under a procurement 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, Amgros will, after consultation with the hospital pharmacies, 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. Amgros 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 Amgros, on entering into the framework agreement, has 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...

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 procurement 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 4.3 to 4.4.

The tender must be in Danish, Swedish or Norwegian. However, the marketing authorisation, see paragraph 4.3, and the documentation for the information submitted in the ESPD, see paragraph 4.4, may be in 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 (procurement 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 procurement 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 DKK and as stated below.

a. A tender comprising multiple products under one procurement number

Depending on the layout of the list of products, a tender must - or may - comprise multiple products under one product 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 procurement number and may, if appropriate, include multiple products in the same line under the procurement number.

If in one tender under one procurement 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 procurement number must have the same product name (trade name), see paragraph 3.1.

Several strengths indicated by several lines under a procurement number

Where a procurement number covers a pharmaceutical in several indicated strengths (indicated by several lines under the procurement number in question), it is not a requirement that the supplier's prices for the different strengths are determined so that the price per unit is the same for the pharmaceutical in the different strengths.

Several strengths in the same line under a procurement number

Where no requirement for a specific strength is indicated under a procurement number and the supplier chooses to submit tender for several different strengths (i.e. several products in the same line under the procurement number in question), see paragraph 3.3.a, it is a requirement that the price for these different strengths is determined so that the price per unit is the same for these strengths.

Where strength is indicated as a range under a procurement number and the supplier chooses to submit tender for several different strengths within this interval, (i.e. several products in the same line under the procurement number in question), see paragraph 3.3.b, it is a requirement that the price for these different strengths within the range indicated is determined so that the price per unit is the same for these different strengths.

Several packages indicated by several lines under a procurement number

Where a requirement is indicated for tenders for several different packages of a pharmaceutical in one specific pharmaceutical form and in one specific strength (indicated by several lines under the procurement number in question), it is a requirement that the price per package is determined so that the price per unit is the same for these different packages.

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

Several different packages in the same line under a procurement number

Where the supplier under a procurement 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 procurement number in question, see the instructions in this respect in paragraphs 3.4.a, b and c), 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 procurement 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 Amgros 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 procurement number. This also applies where a tender under a procurement number covers several different packages of a pharmaceutical in the same pharmaceutical form and in the same strength for which there is a requirement, in the case of several lines under the procurement number concerned, for different packages of the pharmaceutical.

If the supplier should erroneously indicate prices for such different products without the required conformity between the converted prices per unit for the products, Amgros 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 DKK excl. VAT for each of the products offered under the procurement number in question.

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*) or similar. The price offered must not be dependent on or based on offers of other services, nor must the prices offered under different procurement numbers be interdependent.

4.3 Information about marketing authorisation

It is not required that a marketing authorisation for the pharmaceutical offered is in place at the time of submission of tender, but final marketing authorisation for Denmark must be in place not later than the date stipulated in paragraph 14.

Where a product number allocated by Dansk Lægemiddel Information A/S (*Danish Pharmaceutical Information*) is indicated for the product offered at the time of submission of tender, and the product concerned at the time of submission of tender is included in the Danish Medicines Agency's list at "medicinpriser.dk", this will be documentary evidence of the pharmaceutical having marketing authorisation.

If the product concerned at the time of submission of tender is not included in the list at "medicinpriser.dk", there will be no documentation of marketing authorisation, and the supplier must then submit a copy of valid marketing authorisation to Amgros as soon as it is in place so that it is received by Amgros not later than the date stipulated in paragraph 14.

If Amgros has not received a copy of valid marketing authorisation on the date stipulated in paragraph 14 at the latest, Amgros will be entitled to consider the tender non-compliant. If the tender is considered non-compliant, the framework agreement will be entered into with the supplier offering the pharmaceutical at the lowest price and with a marketing authorisation in place.

It is furthermore a requirement that the pharmaceutical is included in the Danish Medicines Agency's list at "medicinpriser.dk" not later than on the date stipulated in clause 4 of the framework agreement, see also paragraph 14.

Final marketing authorisation for Denmark for the pharmaceutical offered must be available not later than by expiry of the deadline for submission of tender, see paragraph 14.

On submission of tender, the supplier must document that the pharmaceutical has a marketing authorisation. Where a product number allocated by Dansk Lægemiddel Information A/S (*Danish Pharmaceutical Information*) is indicated for the product offered at the time of submission of tender, and the product concerned at the time of submission of tender is included in the Danish Medicines Agency's list at "medicinpriser.dk", this will be documentary evidence of the pharmaceutical having marketing authorisation. If the product concerned at the time of submission of tender is not included in the list at "medicinpriser.dk", the supplier must submit a copy of valid marketing authorisation to Amgros so that it is received by Amgros before expiry of the deadline for submission of tenders.

If Amgros has not received information about the marketing authorisation as stated in the provisions above before expiry of the deadline for submission of tenders, Amgros will be entitled to consider the tender non-compliant. If the tender is considered non-compliant, the framework agreement will be entered into with the supplier offering the pharmaceutical at the lowest price and with a marketing authorisation in place.

It is furthermore a requirement that the pharmaceutical is included in the Danish Medicines Agency's list at "medicinpriser.dk" not later than on the date stipulated in clause 4 of the framework agreement, see also paragraph 14.

It is not required that a marketing authorisation for the pharmaceuticals offered is in place at the time of submission of tender, but final marketing authorisation for Denmark must be in place so that the pharmaceuticals have marketing authorisation and are indicated in the Danish Medicines Agency list at "medicinpriser.dk" not later than the date stated in clause 4 of the framework agreement, see also paragraph 14.

If the Supplier fails to comply with the requirement regarding admission to the list at "medicinpriser.dk" 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" drawn up by Amgros and 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 Amgros 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 procurement number, Amgros 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 by Amgros 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 procurement number in question.

Where the supplier must submit tender for a pharmaceutical in several different forms under a procurement number, for example different pharmaceutical forms or strengths (indicated by several lines under the procurement number concerned), 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 forms. The Supplier of the weighted average lowest price per unit is deemed to have submitted the lowest price.

Where the supplier must submit tender under a procurement number for a pharmaceutical in several different package sizes indicated by several lines under a procurement number, it is a requirement, however, that the price of these different package sizes is determined so that the price per unit is the same for the package sizes, see paragraph 4.2.a, and the tenders are in such cases compared directly on the basis of the calculated unit price (price per unit).

As stated in paragraph 4.2.a, it is in certain instances a requirement that the price of multiple products under the same procurement 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, Amgros will be entitled to purchase the products in question on the basis of the lowest converted price per unit.

If under a procurement 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 procurement 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 procurement numbers in this procurement group.

8. FRAMEWORK AGREEMENT - RESERVATIONS AND VARIANTS - FORMAL REQUIREMENTS

Amgros 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, Amgros 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, Amgros will be entitled to obtain additional information, including a missing ESPD.

9. AMBIGUITIES

The tenderer may clarify any ambiguities at the information meeting or by request for further information on the tender specifications (written questions), see paragraph 14.

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

Minutes of the information meeting will be published in Amgros' tendering system.

Similarly, written questions and the related answers will be published in the tendering system in anonymised form under the procurement group in question.

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 Danish, Swedish, Norwegian or English in the tendering system under the procurement group to which the question pertains. Questions will be answered in Danish.

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

Amgro 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.

Amgro is not obliged to return the tender to the tenderer.

Amgro 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 procurement numbers. On a case-by-case assessment, the tender process may be cancelled, inter alia, if Amgro 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.

If, in particular, Amgro only receives tender from one supplier, the level of the prices offered compared to the AIP price of the supplier concerned will be included in the evaluation of whether competition has been sufficiently effective. Furthermore, the assessment of sufficient and effective competition may depend on a specific assessment of the level of the prices offered compared with the AIP prices from other suppliers.

There may, as the case may be, be such a link in the use of different pharmaceuticals under several different procurement numbers that Amgro, on a case-by-case assessment, may choose to cancel several procurement numbers within the same therapy area if certain procurement numbers need to be cancelled. The cancellation of a procurement 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 Amgros, including if Amgros may have to cancel the tender process or procurement 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 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 Amgros.

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

Amgros does not consider applicable prices under the agreement to be confidential. By submitting its tender, the tenderer consents to Amgros' possible publication, at Amgros' discretion, after the tender process is completed, of the prices applicable under the framework agreements entered into on the basis of the call for tenders.

It should be noted that Amgros is subject to rules on access to documents, and Amgros is 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.

Amgros is 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.

The above consent implies that Amgros does not exempt applicable prices under the agreement from access to documents after Amgros' publication thereof.

In respect of other documents or information in the tender, the supplier may request, and mark accordingly, that such other 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 inflicting damage on the business, in particular significant financial damage.

However, in any event, Amgros will be entitled and obliged to grant disclosure of other documents and information to the extent required by law, but the tenderer's request will be included in Amgros' assessment of whether or not to exempt documents or information.

14. TIME SCHEDULE FOR THE TENDER PROCESS

16 May 2018

10:00-16:00 Information meeting at CfL (Center for Ledelse). Time and place may be changed.

Max. 2 persons per tenderer. Sign-up (with names and titles of participants) must be on or before 8 May 2018 at amgros@amgros.dk.

... Questions, see paragraph 9, received before the expiry of this deadline will be answered in any event.

Questions received after this deadline will also be answered, unless the nature of the question renders it unduly burdensome to answer not later than 6 days before the expiry of the deadline for submission of tenders.

Questions received later than 6 days before the expiry of the deadline for submission of tenders will not be answered.

...

12:00 noon Deadline for submission of tenders.

28 September 2018

12:00 noon Deadline for providing marketing authorisation, see paragraph 4.3.

October

2018	Expected award of the contract. Before the award of the contract, Amgros 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".
November	
2018	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 on electronic submission of the notice and 15 days on submission by letter. 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 Amgros' notice to the tenderers regarding the result of the tender evaluation.
31 January 2019	Date of expiry of the period of validity of tenders, see paragraph 10.
25 February 2019	Deadline for publication at "medicinpriser.dk", see paragraph 4.3 and clause 4 of the framework agreement.
1 April 2019	Commencement of purchase period, see clause 18 of the framework agreement.