Framework Agreement for

the following procurement group

tendering 202X – 1.x.a/1.x.b

FRAMEWORK AGREEMENT

between

AMGROS I/S

Dampfærgevej 22

DK-2100 Copenhagen Ø

("Amgros")

and

.....

.....

.....

CVR no. (business reg. no.) .....

(the "Supplier")

for

the supply of pharmaceuticals

Contents

List of appendices

1. DEFINITIONS

"Agreement" means this Framework Agreement.

"Period of Agreement" means the period from Amgros' signing of the Agreement until the end of the Agreement, including any extensions, see clause 8.

"AIP" means the purchase price of the pharmacies (referred to by its Danish abbreviation "AIP") as published on medicinpriser.dk.

"Amgros" means Amgros I/S, Dampfærgevej 22, DK-2200 Copenhagen Ø. Amgros is owned by the five Danish regions and carries out competitive tendering for pharmaceuticals etc. to cover the requirements of the hospitals in the five regions.

"Amgros' Supplier and Tendering Portal" means the portal at https:levportal.amgros.dk where the Supplier and other interested parties can find information about Amgros' calls for tenders, current agreements, etc.

"Purchase Period" means the period during which Amgros can purchase the Products from the Supplier as specified in clause 8.1.

"Post-Agreement Period" means the period from the day after the final day of the Purchase Period and for as long as purchases are made pursuant to the provisions of the Agreement on purchase in the Post-Agreement Period.

"Pre-Agreement Period" means the period from signature of the Agreement until the first day of the Purchase Period.

"Products" means the pharmaceuticals in the strengths, pharmaceutical forms and package sizes set out in Appendix 1 (with own product number) with any subsequent updates and changes, see the provisions of the Agreement in clause 24 (concerning Other products).

"Hospital Pharmacy" means the hospital pharmacy of each Danish region supplying pharmaceuticals to that particular region's hospitals, as well as, in the case of the Capital Region, to a certain extent the hospitals in the Faroe Islands and Greenland.

A: **COMMERCIAL TERMS**

2. ABOUT THE AGREEMENT / PRODUCTS INCLUDED

2.1 This Agreement is a framework agreement which gives Amgros the right, but not the obligation, to order the Products specified in Appendix 1 from the Supplier on an ongoing basis, and the Supplier shall deliver the Products in accordance with the terms and conditions of the Agreement.

2.2 This Agreement is non-exclusive. The Hospital Pharmacies are not obliged to use the Agreement. However, the Supplier is not entitled to enter into separate agreements with the Hospital Pharmacies or the individual hospitals about the purchase of Products during the Purchase Period of the Agreement. Amgros' purchase obligation under the Agreement is specified in clause 4.2.

2.3 The Products shall be included in the Danish Medicines Agency's list of medicine prices ("Medicinpriser.dk") not later than [DATE] in order to ensure supply from the beginning of the Purchase Period and preparation of any change of products by Amgros and the Hospital Pharmacies. The Products shall from this date and throughout the entire Purchase Period appear in the medicinpriser.dk list. After expiry of the Period of Agreement, the Products shall remain included in the medicinpriser.dk list until the Hospital Pharmacies' and Amgros' own stock of the Products is exhausted, but not more than nine months after expiry of the Period of Agreement. The status of Amgros' own stock can be seen on Amgros' Supplier and Tendering Portal.

2.4 The Agreement is entered into on the basis of a call for tenders where agreement may have been entered into with multiple suppliers under the individual procurement numbers. Purchasing shall take place in accordance with the terms and conditions stated in Appendix 5.

2.5 In addition, the Product requirements specified in Appendix 1Y shall apply.

3. SUPPLIER REQUIREMENTS

3.1 The Supplier shall have authorisation to produce, import or receive pharmaceuticals for wholesale distribution within the EU/EEA. The authorisation shall apply until the residual shelf lives of all the Products supplied have expired, irrespective of whether the expiry occurs after the Period of Agreement has ended. The Supplier shall submit a copy of its authorisation to Amgros via the menu "My company pages" (in Danish: "Mine firmasider") at Amgros' Supplier and Tendering Portal not later than the date specified in clause 2.3 for the Products' inclusion in the list at medicinpriser.dk. In case of updates of or changes to the authorisation, the Supplier shall ensure in the same way that Amgros has a copy of the applicable authorisation at all times.

4. EXPECTED PURCHASE

4.1 The Agreement is a framework agreement entered into for the purpose of ensuring the supply of pharmaceuticals to Amgros and the Hospital Pharmacies throughout the entire Purchase Period.

The Supplier is only obliged to supply Products to the Hospital Pharmacies and stocks specified in Appendix 1 under the Agreement, given that a framework agreement has been entered into with another supplier for the supply of the pharmaceuticals to the Hospital Pharmacies in the other regions. However, the Hospital Pharmacies in the other regions are entitled to purchase under the Agreement in the event that the primary supplier of the regions concerned are on back order or if the framework agreement with their primary supplier has ended. In such circumstances, the Supplier is not obliged to supply Products pursuant to orders received. The Supplier may choose to supply such Products by accepting (confirmation from the Supplier or the Supplier's wholesaler, distributor, or similar) the order, in which case the provisions of the Agreement shall apply to the accepted order, including the price that applies under the Agreement.

Where the Supplier chooses to place a stock of the Products with a wholesaler, distributor, or similar so that orders can be placed with the wholesaler, distributor, or similar, the Supplier must thus be aware that the acceptance of orders by the wholesaler, distributor, or similar is deemed to be an acceptance on behalf of the Supplier to sell the Products on the terms and conditions stipulated in the Agreement, including at the price that applies under the Agreement.

4.2 Amgros has in Appendix 1 stated the expected purchase of Products in the Purchase Period. This is merely a non-binding estimate made in connection with the conclusion of the Agreement; the estimate is therefore not binding on Amgros and imposes no purchase obligation on Amgros. The actual purchase under the Agreement may therefore vary significantly from the estimate, as Amgros' and the Hospital Pharmacies' requirement for the Products is influenced by a number of factors, including a possible change or new use of the Products or other pharmaceuticals in the Purchase Period, the level of disease in the population, or a change of the Danish stockpile size.

If the expected purchase of Products in Appendix 1 has not been determined at the time of signature of the Agreement, no figure will be indicated in Appendix 1 (the field will be blank) for the expected purchase of the Product in question. Amgros will forward an updated Appendix 1 when ready (however not later than two months after signature of the Agreement).

Appendix 1 indicates Amgros' expected purchase under the Agreement, part of which constitutes Amgros' purchase obligation. Amgros' purchase obligation in the Purchase Period constitutes 80 % of the informed estimate stated in Appendix 1 at the conclusion of the Agreement.

4.2.1 If Amgros expects the actual consumption to deviate significantly from the originally stated estimate in Appendix 1, Amgros may submit a revised estimate (a new appendix 1) to the Supplier. Submission of a revised Appendix 1 will have no impact on the scope of Amgros' purchase obligation.

4.2.2 Amgros' purchase obligation shall only apply if the Supplier not later than 30 days before the expiry of the Purchase Period, see clause 8.1, submits to Amgros a written notice stating that the remaining part of the purchase obligation quantity must be purchased by Amgros. If the Supplier fails to submit such notice, Amgros' purchase obligation shall cease to apply.

4.2.3 In the event of an extension of the Agreement, Amgros' purchase obligation for the extended period will be calculated proportionately. Amgros' purchase obligation for the extended purchase period is conditional on receipt, not later than 30 days before the expiry of the extended purchase period, of a written notice from the Supplier corresponding to the notice referred to in clause 4.2.2.

4.2.4 If Amgros makes replacement purchases pursuant to clause 19 of the Agreement, Amgros' purchase obligation will be reduced by the amount of the replacement purchases made. In case of repeated back order periods amounting to at least 56 calendar days, Amgros' purchase obligation will cease to apply.

4.3 The Supplier is obliged to deliver the Products in accordance with all orders placed and thereby to meet the hospitals' and Amgros' continuous Product requirements, irrespective of whether it significantly exceeds the estimate informed, see also clause 13.

4.4 If, however, Appendix 1 does not indicate an estimated purchase (i.e. a "0" is stated), the Supplier will not be obliged to satisfy orders. The Supplier may choose to deliver such Products by accepting (confirmation from the Supplier or the Supplier's wholesaler, distributor or similar) the order, in which case the provisions of the Agreement shall apply to the accepted order.

Where the Supplier chooses to place a stock of the Products with a wholesaler, distributor or similar so that orders can be placed with the wholesaler, distributor or similar, the Supplier must thus be aware that the acceptance of orders of the wholesaler, distributor or similar is deemed to be an acceptance on behalf of the Supplier to sell the Products on the terms and conditions stipulated in the Agreement, including at the price that applies under the Agreement.

4.5 The maximum value is stated in Appendix 1. If the Agreement includes sub-agreements (tender numbers), the maximum value for each sub-agreement will be stated in Appendix 1. The maximum value equals the maximum purchase on the Agreement (the individual sub-agreement). However, the Danish Public procurement Act's provision on amendments to contract, entitles Amgros to

place orders on the Agreement (sub-agreement) above the value mentioned in Appendix 1. The Supplier is in any case obliged to comply with such orders, unless otherwise stated in clause 4.4 above.

5. MINIMUM STOCK

5.1 At the beginning of the Purchase Period, the Supplier shall have a minimum stock of the Products corresponding to at least three months' consumption based on the estimate for the Purchase Period stated in Appendix 1 at the conclusion of the Agreement, see clause 4. Additional stock requirements are set out in clause 13.

5.2 In the course of the first month of the Purchase Period, the stock may only be reduced by the number of Products purchased in the period, and the Supplier shall maintain an appropriate stock as described in clause 13.1. After the first month of the Purchase Period, the Supplier shall continue to maintain an appropriate stock as described in clause 13.1, but beyond that, there are no longer requirements for a specific stock level of a minimum size fixed in advance.

6. RESIDUAL SHELF LIFE

6.1 The residual shelf life of the Products on delivery shall not be less than 12 months. For Products where the order indicates that they are meant for resale to Greenland, the residual shelf life on delivery shall not be less than 18 months. These two provisions shall not apply to Products whose shelf life pursuant to the summary of product characteristics is shorter than 24 months. For such Products, the residual shelf life on delivery shall not be less than half of the shelf life stated in the summary of product characteristics for the Product concerned. Additional provisions concerning delivery and possible return of Products that do not meet the residual shelf life requirements are set out in clause 17.

7. PRICES

7.1 The price of each Product is stated in Appendix 1. Amgros will resell the Products to the Hospital Pharmacies at a price corresponding to the purchase price paid by Amgros plus a specific percentage rate (however not exceeding a price corresponding to the AIP). In certain cases, Amgros will purchase the Products for its own stock, see clause 15.

7.2 The prices shall be fixed for the entire Period of Agreement, unless Amgros activates the price regulation mechanism, and the Supplier chooses to quote a new, lower contract price, see clause 7.5.

7.3 If the AIP for the Product concerned is lower during the Purchase Period than the price stated in Appendix 1, Amgros will be entitled to purchase the Product in question from the Supplier at the AIP price on the terms and conditions otherwise stated in the Agreement. Such price changes shall apply to orders received by the Supplier the day after the Danish Medicines Agency's publication of a changed AIP.

7.4 The prices are stated in DKK inclusive of customs duties and other applicable taxes and duties except for VAT. In case of adjustment of applicable Danish taxes and duties directly related to the Products, the prices shall be adjusted by the net financial effect thereof to ensure an unchanged situation for the Supplier. The Supplier has the burden of proving that an increase in taxes and duties has occurred, that they are directly related to the Products, and the net financial effect thereof. Similarly, Amgros has the burden of proving that a decrease in or cancellation of taxes and duties is directly related to the Products, and the net financial effect thereof. The Supplier is obliged to inform Amgros of any downwards change of such taxes and duties.

7.5 Amgros may in the Period of Agreement request the Supplier in writing to quote a new, lower contract price for the Products. The Supplier is not obliged to quote such new, lower contract price. The Supplier will be given at least two months' notice to quote a new, lower contract price. If the Supplier wishes to quote a new, lower contract price, any acceptance of such price by Amgros will require that it is submitted in writing and received by Amgros not later than on the date stated in the notice. The new, lower contract price will apply from the effective date stated in the notice and will at the same time be published on Amgros' Supplier and Tendering Portal. The new, lower contract price shall be binding for the rest of the Period of Agreement or until Amgros again activates the price regulation mechanism and the Supplier chooses to quote a new, lower contract price.

7.6 Amgros does not consider prices under the Agreements entered into to be confidential, and by submitting its tender the Supplier shall be deemed to have given its consent to Amgros' publication of the contract prices on Amgros' Supplier and Tendering Portal at the beginning of the Purchase Period. This also means that Amgros will not exclude applicable contract prices pursuant to the Agreement from access to documents after publication of the prices.

8. DURATION AND TERMINATION OF AGREEMENT

8.1 This Agreement shall become effective when Amgros has accepted the Supplier's offer, e.g. by submission of a copy of the Agreement duly signed by Amgros. The Agreement shall thereafter apply for the period XX.XX.202X through XX.XX.202X.

8.2 Extension of Agreement

8.2.1 Amgros is entitled to extend the Agreement up to [x] times for each Product on unchanged terms and conditions by up to one year at the time, provided that Amgros notifies the Supplier of the extension not later than [xx days/months] before expiry of the Purchase Period.

8.2.2 The Supplier may refuse to extend the Agreement, provided that the Supplier submits written notice of its refusal to Amgros not later than eight months before the expiry of the Purchase Period.

8.3 Option for supply in the Pre-Agreement Period:

In the event that Amgros should wish to purchase one or more Products in the Pre-Agreement Period, Amgros shall be entitled to request the Supplier in writing to supply the Product(s) in question in the Pre-Agreement Period at the price stated in Appendix 1. Agreement for the supply shall be pursuant to the provisions of clause 8.5.

The option for supply in the Pre-Agreement Period may only be exercised by Amgros in one or both of the following situations:

a) where the purchase takes place as part of stockpiling (of Amgros' own stock) of the Products before commencement of the Purchase Period. The Products are not re-sold to the Hospital Pharmacies before the commencement of the Purchase Period; or

b) where the Products cannot be purchased under an agreement in force, e.g., due to a back order situation or if there is no agreement covering the Products. The Products may be consumed by the Hospital Pharmacies in the same way as if they were purchased during the Purchase Period.

Where Amgros has entered into a purchase agreement with the Supplier based on (a) above, Amgros shall contact the Supplier again if it becomes relevant for Amgros to use the opportunity of reselling the Products to the Hospital Pharmacies before the Purchase Period commences due to the circumstances set out in b) above.

8.4 Option for supply in the Post-Agreement Period:

In the event that Amgros should wish to purchase one or more Products in the Post-Agreement Period, Amgros shall be entitled to request the Supplier in writing to supply the Product(s) in question in the Post-Agreement Period at the price stated in Appendix 1. Agreement for the supply shall be pursuant to the provisions of clause 8.5.

The option for supply in the Post-Agreement Period may only be exercised by Amgros if the pharmaceuticals cannot be purchased under an agreement in force, e.g. due to a back order situation or if there is no agreement covering the pharmaceuticals. The Post-Agreement Period shall not exceed one year.

8.5 In the case of supply in the Pre-Agreement Period or the Post-Agreement Period, the Supplier shall not be obliged to deliver the Product pursuant to orders received. The Supplier may choose to supply the Product by accepting (confirmation from the Supplier or the Supplier's wholesaler, distributor or similar) the order, in which case the provisions of the Agreement shall apply to the accepted order. Where the Supplier chooses to place a stock of the Products with a wholesaler, distributor or similar so that orders can be placed with the wholesaler, distributor or similar, the Supplier must thus be aware that acceptance of orders by the wholesaler, distributor or similar is deemed to be an acceptance on behalf of the Supplier to sell the Products on the terms and conditions stipulated in the Agreement, including at the price that applies under the Agreement.

8.6 Termination

8.6.1 The Supplier is not entitled to terminate the Agreement during the Period of Agreement, nor in any extension period.

8.6.2 For each Product, Amgros is entitled to terminate the Agreement (i.e. possibly as a partial termination of the Agreement applicable to certain Products) at three months' notice in the event that substantial changes in the market or substantial changes in the treatment principles should occur for a specific Product or within the therapy area concerned. Substantial changes may be, for example, the marketing of new products within the therapy area concerned, expiry of patent, substantial price changes in the market or other substantial changes of the market and competition situation for the Product concerned or within the therapy area in question.

8.6.3 Amgros is furthermore entitled to terminate the Agreement (i.e. possibly as a partial termination of the Agreement applicable to certain Products) at three months' notice if the price in Appendix 1 corresponds to the Supplier's AIP for the Product concerned.

8.6.4 If the Danish Complaints Board for Public Procurement *(Klagenævnet for Udbud)* or a court of law should decide that the Agreement is ineffective *(in Danish: "uden virkning")*, or that the award decision is to be annulled, Amgros will be entitled to terminate the Agreement to expire in accordance with the decision and at a notice that is appropriate in the circumstances. Amgros' purchase obligation will cease to apply in connection with such termination.

8.6.5 If the Danish Complaints Board for Public Procurement or a court of law should decide that one of Amgros' other agreements is ineffective, or that the award decision concerning one of Amgros' other agreements is to be annulled, Amgros will be entitled to also terminate the Agreement, in whole or in part, (at a notice that is appropriate in the circumstances). This shall only apply if the other agreement in question and the Agreement concern the same therapy area, and the connection between the use of the Products and the other products within the therapy area is such that termination of all agreements concerning all these products and the Products for the purpose of re-tendering is assessed, on a case-by-case basis, to be expedient. Amgros' purchase obligation will cease to apply in connection with such termination.

8.6.6 In addition to clauses 8.6.2 to 8.6.5 above, Amgros may terminate the Agreement in accordance with section 185(1) of the Danish Public Procurement Act *(udbudsloven)* at a notice that is appropriate in the circumstances. Amgros' purchase obligation will cease to apply in connection with such termination.

8.6.7 If 1) the decision to award the Agreement is annulled or the Agreement is declared ineffective and an order to terminate is issued, and 2) there is the required basis of liability, and 3) the Supplier has suffered a loss, the Supplier may be entitled to damages or other form of compensation, including, for example, for costs of complying with the additional terms and conditions or requirements passed on by Amgros in the notice of termination. Indirect losses, however, shall not be compensated, and damages shall be limited to the Supplier's direct loss based on the turnover that the Supplier might achieve in a three-month period, calculated as an average on the basis of the estimate informed by Amgros for the Purchase Period.

8.6.8 However, the Supplier will not be entitled to damages and will have no claim against Amgros if the Supplier at the time of conclusion of the Agreement knew or should have known the factual and/or legal circumstances causing the award decision to be annulled or the Agreement to be declared ineffective, or if Amgros terminates the Agreement in accordance with clause 185(1) of the Danish Public Procurement Act.

9. LIMITATION OF LIABILITY

9.1 Notwithstanding clauses 18 and 19 below, if Amgros makes replacement purchases of a product from another supplier in a back order period, the Supplier will not be liable in damages for the part of the compensation per unit that exceeds twice the price per unit stated for the Product in Appendix 1 of the Agreement. This means, for example, that if the price per unit X in Appendix 1 is stated to be DKK 80, and the price of the replacement product purchased by Amgros is DKK 300 per

unit, the Supplier shall only compensate DKK 80 x 2 = DKK 160 per unit, regardless of the fact that Amgros has paid an extra price of DKK 220 per unit.

B: LOGISTIC CONTRACT TERMS - TERMS AND CONDITIONS OF TRADE AND DELIVERY

10. INTRODUCTION

10.1 Section B defines the logistic terms between Amgros and the Supplier concerning ordering, delivery and payment of the Products covered by the Agreement, special conditions concerning supply to Amgros' stock, the information to be provided to Amgros' purchasing system prior to the beginning of the Period of Agreement, and the marking, delivery and invoicing requirements.

10.2 Amgros has drawn up a Guideline for the practical day-to-day cooperation in connection with the supply of medicine to Amgros and the Hospital Pharmacies in Denmark. The guideline is available on Amgros' Supplier and Tendering Portal, and the Supplier is required to be familiar with the guideline as it includes a description of the procedures for the cooperation between Amgros and the Supplier. In case of conflict between the guideline and the Agreement, the Agreement shall prevail.

11. LOGISTICAL CONDITIONS

11.1 The Supplier shall on an ongoing basis work towards optimising its logistical conditions so that Amgros is ensured the greatest possible security of supply.

11.2 The Supplier shall support the internal logistics of Amgros and the Hospital Pharmacies, including by submitting, on request, all the information necessary for the potential use of stock robots with respect to the dimensions (width, height and depth) and weight of the Products. On request, the Supplier shall inform Amgros and the Hospital Pharmacies of the packaging of the Products on delivery, including the number of packages in a shrink wrap, a parcel and on a pallet. All information shall be submitted electronically by the Supplier in the format requested by Amgros and the Hospital Pharmacies.

12. CONTACT PERSONS

12.1 Appendix 4 states the day-to-day contact person of each Party and the contact person of the contract manager of each Party, including their telephone numbers and e-mail addresses. In Appendix 4, the Supplier has furthermore provided information about the Supplier's distributor(s), wholesaler(s) or other entity/entities responsible for transporting the Products.

13. SECURITY OF SUPPLY AND STOCK LEVEL

13.1 The Supplier is required to have a thorough knowledge of the trade, including knowledge of the fact that the hospitals' consumption of pharmaceuticals and thereby the Products may fluctuate significantly throughout the entire Purchase Period, including that large fluctuations of orders must be expected, both at the beginning and at the end of the Agreement. It is the Supplier's responsibility to ensure that, throughout the entire Purchase Period, a stock is maintained of each Product that is appropriate in the circumstances, taking into account the estimates informed by Amgros, the purchases made under the Agreement and market trends in general.

13.2 At the beginning of the Purchase Period, the Supplier is obliged to have a minimum stock if so stated in clause 5.1.

13.3 Throughout the entire Purchase Period, the Supplier shall at Amgros' request document that the above stock requirements are complied with at all times.

13.4 From three months before and until the beginning of the Purchase Period, the Supplier shall at Amgros' request document that the stock is being built up, so that the above stock requirements and, if applicable, a minimum stock, see clause 5.1, are complied with from the beginning of the Purchase Period.

13.5 In addition, Amgros is entitled to carry out audits at the Supplier in order to verify that the stock size and build-up requirements are complied with. If the Supplier has decided to place its stock of Products with a wholesaler, distributor or other entity responsible for the transportation of the Products, the Supplier shall ensure that Amgros has an equivalent right to carry out such audits at the wholesaler, distributor or the other entity responsible for the transportation of the Products. Amgros' right to carry out audits shall apply from three months before the beginning of the Purchase Period and throughout the entire Purchase Period.

13.6 The Supplier's non-compliance with the above stock size and build-up requirements may, as the case may be, constitute a material breach of the Agreement, see clause 27.3.

14. ORDERING/PLACING OF ORDERS

14.1 The ordering of Products will be as follows:

- The individual Hospital Pharmacies place orders with Amgros on an ongoing basis.

- Amgros then places orders with the Supplier on an ongoing basis. Where orders are placed for Products to Amgros' own stock, this will be stated in the order.

- The Supplier shall immediately confirm the order to Amgros.

14.2 Placing of orders, order confirmation and invoicing, including credit notes etc., in connection with the purchase of Products under the Agreement shall take place electronically.

15. TERMS OF DELIVERY

15.1 Delivery shall take place not later than three working days after the Supplier's receipt of the order. Delivery to Amgros' own stock, however, shall take place not later than 10 working days after the Supplier's receipt of the order, unless another date has been agreed with Amgros in writing in connection with the specific order. "Working days" shall mean Mondays through Fridays, except for Danish public holidays, 5 June, 24 December and 31 December.

15.2 Delivery shall be DDP (Incoterms 2020) to the address stated by Amgros in the order (Hospital Pharmacy, related locations or Amgros' own stock) in Denmark. A list of the places of delivery is available on Amgros' Supplier and Tendering Portal under the menu "Delivery/Withdrawals - Current places of delivery (in Danish: "Levering/Tilbagekaldelser - Aktuelle leveringssteder"). The list is updated on an ongoing basis.

15.3 To ensure security of supply for selected products, Amgros may purchase selected products for Amgros' own stock. Amgros will re-sell those products to the Hospital Pharmacies, see clause 7.1, and purchase new products for its own stock. In such cases, the Supplier will deliver the Products directly to Amgros. Amgros will as a general rule maintain a stock of a specific quantity of Products. However, there may be cases where Amgros wishes to reduce the quantity or entirely cease maintaining a Product on stock. If so, the Supplier will receive a revised estimate, see clause 4.2.

15.4 Delivery shall be in compliance with applicable law, including in accordance with the terms and conditions stated in the marketing authorisation for the Product concerned, including specific storage requirements. Delivery of Products will not be deemed to have taken place until receipt of a voucher or delivery note, satisfying the statutory requirements, for the Product concerned.

15.5 The Products shall be marked with a barcode in accordance with the requirements stated in Appendix 2. If there is no barcode marking, Amgros and the Hospital Pharmacies will be entitled to remedy the matter at the Supplier's expense.

15.6 In respect of certain pharmaceuticals, the hospital pharmacy of the Capital Region (Region Hovedstaden) is entitled to make purchases for resale to the Faroe Islands and Greenland. The purchase and delivery thereof shall be pursuant to the provisions of the Agreement, including that delivery shall take place to the hospital pharmacy of the Capital Region, see clauses 15.2 and 15.2.

15.7 On delivery, the delivery note shall carry Amgros' order number as a reference.

16. INCOMING CONTROL AND RECEIPT OF PRODUCTS

16.1 In connection with supply of Products that have not been stored in a stock in Denmark immediately before delivery to the Hospital Pharmacy, the Supplier shall ensure that national incoming control is carried out pursuant to the relevant rules applicable at any time (currently Statutory Order no. 1358 of 18 December 2012 on production and import of pharmaceuticals and intermediates, and Statutory Order no. 1541 of 18 December 2019 on distribution of pharmaceuticals) so as to ensure that this obligation will not rest with the Hospital Pharmacy or Amgros. If, on delivery, a documented national incoming control is not stated on the delivery note or voucher for the Products, the delivered products will be considered as defective. This is remedied by Amgros or the Hospital Pharmacy carrying out a national incoming control. A penalty will be imposed on the Supplier of DKK 5,000 per batch number per delivery for such management and for coverage of Amgros' and the Hospital Pharmacy's additional costs.

17. RETURN OF PRODUCTS

17.1 The residual shelf life requirement is set out in clause 6.

17.2 In the event that the Supplier is only able to deliver Products with a shorter residual shelf life than required in clause 6.1, the Supplier shall inform Amgros and the Hospital Pharmacy thereof prior to delivery. If Products are delivered with a shorter residual shelf life than required, the Supplier will at any time be obliged to take back the Products, in whole or in part, against reimbursement of the purchase sum and additional costs, if any. This shall apply regardless of whether Amgros or the Hospital Pharmacy has pointed out, on receipt of the Products, the shorter residual shelf life or the right of return under the Agreement. Furthermore, the right of return under the Agreement shall apply regardless of whether Amgros or the Hospital Pharmacy has reserved the right of return under the Agreement in connection with any discussions with the Supplier regarding delivery of the Products.

17.3 Return of Products in accordance with clause 17.2 may take place using PostNord or other carrier chosen by Amgros to the Supplier's address as stated in the Agreement, unless the Supplier on delivery of the Products informs that any return is to take place in another manner or to a different

address. The Hospital Pharmacy's and Amgros' liability for any returned Products shall cease upon delivery of the Products to an independent carrier.

17.4 Upon return of Products, the Hospital Pharmacy or Amgros will enclose a return slip with information on the Product, package size, batch number, shelf life and quantity, as well as the name of the Hospital Pharmacy and contact person, including contact details. The Hospital Pharmacy will furthermore state on the return slip that the Products are returned due to the delivery of Products with short shelf life. The Hospital Pharmacy will at the same time inform Amgros of the returned products.

17.5 The Supplier shall not later than eight working days after receipt of the returned Products issue a credit note to Amgros.

18. PARTIAL DELIVERY AND BACK ORDERS

18.1 The Supplier shall be deemed to be on back order in the following situations:

- If a Product ordered is not delivered on time and in the quantity ordered.
- If the Supplier informs in advance that the quantity of the Product ordered cannot be delivered on time.
- If a Product delivered is defective, and the Supplier is unable to deliver a new Product without defects within three working days.
- If the Products have not been included in the list at medicinpriser.dk at the time stated in clause 2.3.
- If the Products are not at medicinpriser.dk at the time stated in clause 2.3, Amgros will be entitled to assume that the Supplier will be on back order for three months and to make replacement purchases accordingly.

18.2 The Supplier shall furthermore inform Amgros in writing via the menu "My company pages" on Amgros' Supplier and Tendering Portal as soon as the Supplier foresees, or should have foreseen, potential delivery problems and thereby a back order situation. The notice shall include the cause of the back order situation and the expected duration thereof. If the notice does not include information about the expected duration of the back order situation and such information has not been submitted to Amgros not later than five working days after the back order situation occurred,

Amgros will assume that the Supplier is on back order for three months, and the Supplier will be liable to compensate the replacement purchases made in this connection.

18.3 Unless Amgros and the Supplier expressly agree otherwise in writing, the Supplier shall be deemed to be on back order until the Supplier is able to fulfil the orders in full and has built up an appropriate stock as described in clause 13 above. However, the back order period shall not be deemed to have ended until two working days (24-hour days) after the Supplier has demonstrated to Amgros' satisfaction its supply and stock capacity.

18.4 For the duration of the back order period, Amgros shall be entitled to make replacement purchases as described in clause 19 without being required, prior to each replacement purchase, to place an order with the Supplier for the Products in question.

19. REPLACEMENT PURCHASES

19.1 In the event of back orders, see clause 18, Amgros and/or the Hospital Pharmacies shall be entitled to immediately make the required purchases of equivalent products elsewhere for the purpose of covering the hospitals' requirement for the Products.

19.2 The Hospital Pharmacy and/or Amgros shall be entitled to order a larger number of products than comprised by the back order if it is deemed necessary by Amgros and/or the Hospital Pharmacy, for example where, due to exceptional circumstances, it is necessary to purchase a certain minimum amount to ensure supply in the back order period, for example in connection with the purchase of non-registered pharmaceuticals. Replacement purchases may be made until the date of expiry of the back order period, see clause 18.

19.3 In back order situations, the Hospital Pharmacy shall have a significantly extended right to purchase products that are more expensive than the cheapest in the market where justified by patient safety, security of supply and/or cost-related considerations, such as change of products. If, for example, it concerns a product where Amgros or the Hospital Pharmacy estimates that repeated changes of product numbers are not prudent for patient safety reasons, pharmaceuticals may be purchased from the supplier who can document the best ability to deliver, notwithstanding that the supplier concerned may not be the cheapest in the market. The assessment will include considerations such as the Supplier's notice of when supplies are expected to be resumed, the estimated consumption in the back order period, the nature and application of the Product, the extent and solution of any previous back order periods in the Purchase Period, and whether it is deemed necessary that the same supplier be able to fully cover the entire requirement for the product on back order in one or several hospitals. In case of back orders at the beginning of the Purchase Period, the Hospital

Pharmacy will in general and with due consideration of the above guidelines be entitled to continue the use of a previously used product in order to avoid a change of product.

19.4 Amgros is entitled to only purchase products listed with a price at medicinpriser.dk; hence, Amgros is not obliged to examine the possibility of purchasing replacement goods not listed with a price at medicinpriser.dk.

19.5 Where the Supplier notifies an expected back order situation at a notice of at least six weeks, the Supplier may propose a solution for replacement purchases if the Supplier has submitted its proposed solution to Amgros not later than four weeks before the first day of the back order period. Amgros may decide at its own discretion whether to accept the Supplier's suggested solution.

19.6 The Supplier shall compensate Amgros' and/or the Hospital Pharmacy's additional costs of purchasing replacement products elsewhere. The Supplier is in this connection obliged to cover any documented additional costs incurred by Amgros and the buying Hospital Pharmacy, such as the costs of a wholesaler in connection with the purchase of non-registered pharmaceuticals.

19.7 Amgros is furthermore entitled to demand a proportionate price reduction for defective Products and/or to set off amounts against the Supplier, including set-offs against claims in other contractual relationships between the Supplier and Amgros.

19.8 With the exceptions following from the above provisions, the general rules of Danish law regarding set-off and mitigation of loss shall apply.

19.9 The Supplier is not obliged to pay compensation in case of failure to meet orders for Products not covered by the delivery obligation, see clauses 4.4 and 8.5.

20. WITHDRAWALS

20.1 In the event that the Supplier and/or the Danish Medicines Agency withdraws a Product, in whole or in part, the Supplier shall be deemed to have failed to deliver the Product concerned (back order), unless the Supplier immediately (i.e. before the end of the same day) delivers packages of the Product that are not subject to the withdrawal, and the quantities of which fully correspond to the Products withdrawn.

20.2 Replacement purchases in the event of a withdrawal may take place in accordance with the provisions of clause 19. For the purposes of the practical handling and organisation of the purchases, the back order period shall not be deemed to have ended until two working days (24-

hour days) after the Supplier has demonstrated to Amgros' satisfaction its supply and stock capacity.

21. TERMS OF PAYMENT

21.1 Amgros' payments shall be due 30 days after the date when the Supplier has submitted a satisfactory invoice. The invoice shall include Amgros' order number and the time of delivery. Invoicing shall take place electronically by using EAN number 5798000016729.

21.2 If the Supplier does not invoice from a business registered in Denmark, and the Supplier therefore submits invoices without stating Danish VAT, the Supplier shall ensure that Amgros receives sufficient information for Amgros' Intrastat reporting, such as tariff codes, as well as weight and volume of the Products purchased.

21.3 Denmark has implemented the EU Directive on electronic invoicing in public procurement (2014/55/EU) into Danish law by Act no. 1593 of 18 December 2018, and the implementation will have an impact on the provisions of the Agreement on ordering, delivery and invoicing. Since all orders necessary for the practical implementation of the Act have not been drawn up and/or published at the time of call for tenders for this Agreement, the Supplier shall be particularly aware that the provisions of the Agreement (in particular those pertaining to invoicing) may be subject to updates in the Period of Agreement in order to comply with applicable law.

C: GENERAL TERMS

22. PRODUCTS INCLUDED

The Products are specified in Appendix 1 by product name (trade name) and product number. The Framework Agreement only covers other product numbers in accordance with the provisions of clause 24. The name (trade name) of the Products shall remain the same for the duration of the Period of Agreement, unless Amgros consents to a change.

23. PRODUCT INFORMATION ETC.

23.1 At the request of Amgros, the Hospital Pharmacies or the hospitals, the Supplier shall provide further information on the Products, including, if required, documentation or information that is not publicly available, such as information on the application of the Products, production-related data etc. Upon request, the Supplier shall in this context provide information on the quantitative

or qualitative composition of the Products, including where Products are delivered from several different production sites.

23.2 The Supplier is furthermore obliged to provide Amgros with any additional information that may be relevant to the contractual relationship.

24. OTHER PRODUCTS

24.1 Other products than the Products may be delivered under the Agreement, provided that the terms and conditions stipulated in Appendix 3 are complied with. New or changed products covered by the Agreement in accordance with Appendix 3 will then be subject to the same terms and conditions as the Products listed in Appendix 1.

24.2 The new products that are allowed included, see Appendix 3, shall have the same product name (trade name) as the other Products under the product number in question, unless Amgros accepts otherwise.

25. RELATIONSHIP BETWEEN THE AGREEMENT AND APPENDICES

25.1 The Agreement includes a number of appendices that are considered an integral part of the Agreement. In case of conflict between the provisions of the Agreement and its appendices, the Agreement shall prevail.

26. INSURANCE

26.1 The Supplier's product liability shall be in accordance with the general rules of Danish law. The Supplier shall have and maintain normal product liability insurance.

27. LEGAL COMPLIANCE

27.1 The Supplier shall comply with all relevant legal and administrative provisions.

27.2 The Products delivered shall for the duration of the residual shelf life period be included in the list at medicinpriser.dk and comply with all applicable laws and guidelines. This provision shall remain in force after the end of the Agreement, which means that Amgros is entitled to return the Products at the Supplier's expense and risk and claim reimbursement of payment for the duration of the residual shelf life period if the Products no longer appear on medicinpriser.dk, and/or if the marketing authorisations required for the hospital pharmacies' use of the Products, see clause 2.3, no longer apply.

27.3 Unless expressly derogated from in the Agreement, the general rules of Danish law shall apply as regards breach, including the right of termination in case of material breach.

27.4 Suspension or withdrawal of the Supplier's authorisations and/or the marketing authorisations required for the hospital pharmacies' use of the Products, see clauses 3.1 and 3.1, shall be considered material breach entitling Amgros to immediately terminate the Agreement for cause.

27.5 The Supplier shall be obliged to ensure that the performance of the Agreement at all times does not entail a violation of sanctions, export control laws and regulations, embargoes or similar. The Supplier shall, throughout the duration of the Agreement, be obliged to notify Amgros immediately in writing in the event of any changes in the ownership of the Supplier or any sub-supplier, changes in the control of the Supplier/sub-supplier and any other matter relevant to ensure compliance with sanctions, export control rules, embargoes or similar. It will be considered a material breach under clause 27.3, and thereby constitute Amgros' right to terminate the Agreement, if the performance of the Agreement will entail a violation of sanctions, export control rules, embargoes or similar. This also applies in case of, but shall not be limited to, changes in the ownership of the Supplier, changes in the control of the Supplier etc., which entail that the performance of the Agreement will lead to such a violation, and equivalent changes in the ownership of sub-suppliers, changes in the control of the sub-supplier etc.

28. THIRD PARTY RIGHTS

28.1 The Supplier warrants and represents that the Products delivered by the Supplier, the purchase and resale of the Products to the Hospital Pharmacies in accordance with the provisions of the Agreement, and the hospitals' use of the Products in accordance with the summary of product characteristics for the Products concerned will not infringe any third party rights (such as patent rights).

28.2 In case of doubt as to whether delivery, purchase, resale and/or use of the Products in Denmark, the Faroe Islands and/or Greenland will infringe any third party rights, Amgros will be entitled to require that the Supplier provides a written explanation within a reasonable deadline notified by Amgros in writing of at least two working days. Uncertainty as to whether third party rights will be infringed may arise, for example, if a manufacturer of pharmaceuticals informs Amgros that the manufacturer considers a Product covered by the Agreement to infringe the manufacturer's patent rights or if Amgros becomes aware of an infringement case concerning the Product in Denmark or abroad.

28.3 If, after having received the Supplier's explanation, Amgros is not sufficiently reassured that delivery, purchase, resale and/or use of the relevant Product in Denmark, the Faroe Islands and/or

Greenland may take place without risking an infringement of third party rights, Amgros and the Hospital Pharmacies shall be entitled to immediately cease all purchase of the Product, including to cancel existing orders and return any Products delivered by the Supplier with packaging still unbroken.

28.4 If a third party issues legal proceedings, including brings a lawsuit, seeks interim relief by a restraining injunction, or raises a claim for damages against Amgros, the Hospital Pharmacies or the hospitals due to an alleged infringement of third party rights, the Supplier shall indemnify Amgros, the Hospital Pharmacies and/or the hospitals for all claims and expenditure incurred, including legal costs, in this connection.

28.5 Upon having become aware of a potential infringement of any third party rights, the Supplier shall immediately inform Amgros thereof in writing and cooperate with Amgros on the handling of the case.

29. CONFIDENTIALITY

29.1 The Parties shall observe usual confidentiality regarding matters that are not in the public domain.

29.2 However, Amgros is subject to rules on access to documents, and Amgros shall be entitled and obliged to grant access to the Agreement and other documents and correspondence regarding the contractual relations to the extent stipulated by law.

29.3 If it is stated in clause 7.6 that Amgros does not publish the prices on Amgros' Supplier and Tendering Portal, Amgros will endeavour to exclude the contents of the Agreement with reference to the provisions of the Danish Access to Documents Act *(offentlighedsloven)* regarding trade secrets. If Amgros is requested to provide access to the Agreement, Amgros may inform the Supplier thereof if Amgros finds it necessary in order for Amgros to proceed with the request for access. At Amgros' request, the Supplier shall assist Amgros in the drafting of responses to the request. Irrespective of the above, however, Amgros will give notice of the award of the contract in accordance with the public procurement rules.

29.4 The Supplier may not without Amgros' prior consent publish information on the conclusion of the Agreement. The Supplier is entitled to include Amgros in its list of references, but the Supplier shall not otherwise use Amgros, the Hospital Pharmacies or the hospitals for marketing purposes.

29.5 On conclusion of the Agreement, the Supplier consents to Amgros' resale of information about the Hospital Pharmacies' consumption of the Products to third parties.

30. ASSIGNMENT

30.1 Amgros is entitled to assign its rights and obligations under the Agreement to another public institution or an institution owned by the public sector or essentially financed by public funds.

30.2 The Supplier shall not assign its rights and obligations under the Agreement to any third party without the prior written consent of Amgros. If the Supplier, as a result of a business transfer or restructuring, in whole or in part, wishes to assign its rights and obligations to a third party, including an affiliated company, the Supplier shall follow the instructions on assignment of agreements published on Amgros' Supplier and Tendering Portal under the menu "Help and support - Guidances".

31. CORPORATE SOCIAL RESPONSIBILITY

31.1 The Supplier shall perform its obligations while respecting the environment and climate and shall assume corporate social responsibility by complying with national laws and agreements and respecting international guidelines, conventions and agreements on human rights, labour rights, environment and anti-corruption, etc., as set out in:

- OECD's Guiding Principles for multinational companies (2011) (link: https://www.oecd.org/daf/inv/mne/48004323.pdf) as amended and updated; and
- The UN Guiding Principles on Business and Human Rights (2011) (link:https://www.ohchr.org/Documents/Publications/GuidingPrinciplesBusinessHREN.pdf)

31.2 In order to ensure compliance with the above clause 31.1, the Supplier shall have in place a due diligence process for the supply chain. This means that the Supplier shall identify, prevent, mitigate and remedy actual and potential adverse impacts on human rights, the environment and anti-corruption in connection with its own activities and those of affiliated companies. With respect to its own subcontractors, including the subcontractors of affiliated companies, the Supplier shall seek to prevent or remedy such impacts and take the necessary measures to stop or prevent the impact.

Amgros shall be entitled at any time to request that the Supplier provide documentation for such due diligence process. Not later than four weeks after Amgros' request, the Supplier shall report in writing how the Supplier complies with the due diligence process and the related obligations. Amgros shall be entitled to share the information with the Regions and other public procurement organisations in Norway, Sweden, Finland, and Iceland if such other public procurement organisations also have an agreement with the Supplier. If requested by the Supplier, Amgros will inform the recipients of the information that the Supplier considers the information confidential.

31.3 The Supplier warrants that the Products are provided in accordance with the guidelines set out in clauses 31.1 and 32.2. If there is reasonable indication that the guidelines have not been complied in connection with the Agreement, Amgros may require the Supplier to explain its compliance with the guidelines, including how the Supplier ensures that the guidelines are complied with by its own subcontractors, and that the Supplier explain how it will ensure that current impacts on human rights and the environment in the supply chain are effectively handled in accordance with the guidelines. Amgros reserves the right to require a follow-up of the report by, for example, requiring, if necessary, that action plans be prepared or investigations by third parties be conducted, and that the Supplier actively contributes to such follow-up.

If the Supplier does not want or cannot explain to Amgros' satisfaction that the guidelines have been complied with within a reasonable time-limit determined by Amgros, Amgros reserves the right to consider it a material breach, entitling, but not obliging, Amgros to terminate the Agreement pursuant to clause 27.3.

31.4 In the performance of the Agreement, the Supplier shall consistently include environmental management as described in ISO 14001 or equivalent. In this connection, the Supplier shall make efforts to improve the environmental performance by actively contributing to improvement of the environment, technology and economy in the performance of the Agreement, including by, inter alia, reducing consumption of energy and materials to the extent possible. The Supplier shall at all times refrain from using unnecessary packaging. Finally, as part of the environmental performance, Amgros wants the Supplier to address environmental and working environment issues in the life cycle of the products.

In this connection, the Supplier shall be able to document its efforts in writing.

32. FORCE MAJEURE

32.1 Both Amgros and the Supplier shall be entitled to claim force majeure in accordance with the general rules of Danish law as a justification for non-compliance with their obligations under the Agreement.

32.2 Examples of force majeure events are war, riots, nationwide disturbances, import ban to Denmark, export ban from the Product's country of origin, natural disasters, disruption of energy supply, large-scale fires, widespread labour disputes (general strikes and corresponding lockout) and other extraordinary events of a similar exceptional nature and of vital significance which the Supplier did not or should not have taken into consideration and which prevent the Supplier's compliance with its obligations.

32.3 Force majeure shall not be deemed to be, for example, withdrawal of a Product or other products, shutdown of one or several production facilities or other forms of limited production failures, failure to obtain the necessary authorisations and licences etc. (both as regards internal quality controls at the Supplier and as regards legal requirements etc.), extended administrative procedures, failures in the Supplier's supply chain, infringement cases in relation to third party rights, see clause 28, and other events of a similar nature which the Supplier should have taken into account or which do not prevent the Supplier's compliance with its obligations.

32.4 A subcontractor's circumstances shall only be considered force majeure if the subcontractor is met with an obstacle covered by the above examples in this clause 32 which the Supplier should not have avoided or overcome.

32.5 In the event of force majeure, each party shall bear the losses incurred by that party as a result of the force majeure event.

32.6 Force majeure shall be claimed only for the number of days the force majeure situation exists and only after written notification thereof to the other party without undue delay and not later than five working days.

32.7 If the force majeure situation has not ceased to exist before the expiry of 30 days, both Amgros and the Supplier shall be entitled to terminate the Agreement in writing with immediate effect, and neither party shall have a claim against the other party as a result of the termination.

33. AMGROS' OBLIGATION TO PAY

33.1 If Amgros is in breach of its payment obligations under the Agreement, the Supplier shall be entitled to interest pursuant to the provisions of the Danish Interest Act *(renteloven)*. In addition, the Supplier shall be entitled to terminate the Agreement with effect for the future if the Supplier has sent written notice to Amgros stating, firstly, that Amgros, in a specified manner, is in breach of its payment obligations, secondly, that failure to make payment within 30 days will result in termination of the Agreement, unless Amgros has fulfilled its payment obligations before the expiry of the time-limit.

34. APPLICABLE LAW AND VENUE

34.1 The contractual relationship shall be subject to Danish law (except the private international law rules of Danish law) and the Danish courts of law. CISG (Contracts for the International Sale of Goods), however, shall not apply.

34.2 Venue shall be the City Court of Copenhagen.

35. SIGNATURES

Date:

For and on behalf of Amgros:	For and on behalf of the Supplier:
_____ Head of Sourcing	*[The Supplier has accepted the Agreement upon submission of tender in the procurement process]*

202X – 1.x.a/1.x.b

Appendix 1X Specification of pharmaceutical forms

The requirements regarding specific pharmaceutical forms 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".

202X – 1.x.a/1.x.b

Appendix 1Y Additional requirements concerning the Products

202X – 1.x.a/1.x.b

Appendix 2 Bar code requirements

Secondary packaging - regulatory requirements[1]

For pharmaceuticals produced on or after 9 February 2019, it is a requirement that the secondary packaging is marked with 2D (GS1 DataMatrix) bar code containing GTIN, expiry date, batch/lot number and serial number.

Primary packaging - Amgros' requirements

Amgros requires a barcode on the primary packaging for all medicines for oral use, external use as well as injection and infusion.

The barcode must either be an EAN 13 barcode or a 2D (GS1 DataMatrix) barcode and must as a minimum contain an NTIN or a GTIN.

Pharmaceuticals for oral use means:

- Tablets or capsules
- Oral fluids and drops

Pharmaceuticals for external use means:

- Ointments, creams, or gel
- Cutaneous liquids

Pharmaceuticals for injection means:

- Injection fluid
- Injection fluid concentrate
- Powder for injection
- Injection fluid in pre-filled syringe

Pharmaceuticals for infusion means:

- Infusion fluid
- Infusion fluid concentrate
- Powder for infusion fluid

The following medicines are exempt from the requirement for a barcode on the primary packaging:

- Tablets or capsules in blister sheets or other similar packaging in which tablets/capsules are single dosed individually.
- Pre-filled single-dose containers (e.g., pre-filled pens/syringes) that are intended for use for one dose/patient and where multipacks of the drug in question do not exist.

1 January 2023

[1]The paragraph "Secondary packaging - regulatory requirements" is only provided as courtesy information for the Supplier and does not provide an exhaustive list of the regulatory requirements, nor, therefore, any exemptions from or modifications of the law. Amgros is therefore not responsible for any errors or omissions in the text. The Supplier remains responsible for compliance with the law in the area.

202X – 1.x.a/1.x.b

Appendix 3 Other Products

General

A change concerning the Products (as the Products are specified in Appendix 1) shall require the prior written consent of Amgros.

Amgros is not obliged to give its consent.

According to a case-by-case assessment and with due consideration of the public procurement rules, Amgros may consent to the inclusion under the Agreement of other products than those indicated in Appendix 1, so that procurement of these other products takes place on the terms and conditions of the Agreement.

Consent may only be granted for other products if they comply with the requirements stipulated for the pharmaceuticals put up for tender, including the specifications regarding the pharmaceutical form, strength and package size stated in the list of products of the pharmaceutical put up for tender, see for details below.

After consent has been granted, other products may be included as a replacement of a Product covered by Appendix 1 or as a supplement thereof.

It is a condition that the price of other products is fixed on the basis of the price per unit offered by the Supplier and stated in Appendix 1 for the Product in question.

Other strengths or other package sizes

For pharmaceuticals where the list of products in connection with the tender procedure stated a range of the strength of the pharmaceutical in question, the Supplier may in the Period of Agreement offer other strengths within the range indicated of the pharmaceutical concerned (i.e. in the same pharmaceutical form and in any package sizes that may be indicated).

For pharmaceuticals where the list of products in connection with the tender procedure stated a range of package sizes of the pharmaceutical in question, the Supplier may in the Period of Agreement offer other package sizes within the range indicated of the pharmaceutical concerned (i.e. of the pharmaceutical in the same pharmaceutical form and same strength).

For pharmaceuticals where the list of products in connection with the tender procedure did not state a requirement for a specific strength of the pharmaceutical in question, the Supplier may in the Period of

Agreement offer other strengths of the pharmaceutical concerned (i.e. of the pharmaceutical in the same pharmaceutical form and in the package sizes that may be indicated).

For pharmaceuticals where the list of products in connection with the tender procedure did not state a requirement for a specific package size of the pharmaceutical in question, the Supplier may in the Period of Agreement offer other package sizes of the pharmaceutical concerned (i.e. of the pharmaceutical in the same pharmaceutical form and same strength).

The same pharmaceutical form means the pharmaceutical form of the pharmaceutical specified in the product list under the procurement number in question, see Appendix 1X.

Additional other products

In addition to the cases of other strengths or package sizes mentioned above, Amgros may grant its consent to the Agreement comprising additional other products, provided that such additional other products comply with the specifications of the pharmaceutical put up for tender that was included in the list of products, and provided that it concerns a product of at least the same quality or better. Consent may thus be granted for a new product of a Product covered by Appendix 1 of the same strength and the same package size, but which in relation to, for example, device or similar is a newer and improved product.

In such cases, consent will depend on a specific assessment, taking into account whether it is a change of a fundamental element, including whether consent may imply a risk of competition being distorted.

202X – 1.x.b (only)

Appendix 5 Terms and conditions for purchase under one framework agreement with multiple suppliers

The Agreement is entered into on the basis of a call for tenders where agreement may have been entered into with multiple suppliers under the individual procurement numbers.

Under each procurement number, the order of priority of the agreements is 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.

When using Amgros' framework agreements, the hospitals must in general choose the pharmaceutical (under the procurement number concerned) evaluated to be the most economically advantageous tender (framework agreement 1).

Derogations from this basic rule may be made in the following circumstances:

1. Patients treated with another pharmaceutical and where continuance of the patient's treatment with the pharmaceutical used until now is assessed to be required for patient safety considerations.
2. Patient safety considerations warrant that another pharmaceutical should be chosen on the basis of a specific assessment of the effect and side effects of the pharmaceutical in relation to the patient.
3. The pharmaceutical is not approved for the treatment relevant to the patient.

…

X. Replacement purchase in the event of another supplier's failure to supply the pharmaceutical.

If several of the other framework agreements entered into under the procurement number concerned 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 Agreement entered into - including price - apply to all deliveries made via Amgros' Purchase System, also when these purchases are made in exceptional cases where other specific medical and patient safety related circumstances apply.