Framework Agreement, general, for
the following procurement group
call for tenders 2019 - …

FRAMEWORK AGREEMENT

between

AMGROS I/S
Dampfærgevej 22
DK-2100 Copenhagen Ø
("Amgros")

and

.....
.....
.....
CVR no. (business reg. no.) .....
(The "Supplier")

for

the delivery of pharmaceuticals
in the period 1 April 2019 through 31 March 2020
(with the possibility of renewal)

[…]

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1. THE FRAMEWORK AGREEMENT

1.1 This framework agreement (the "Framework Agreement") gives Amgros the right, but not the obligation, to order pharmaceuticals from the Supplier on an ongoing basis, and the Supplier shall deliver pharmaceuticals in accordance with the terms and conditions of the Framework Agreement.

1.2 Purpose

The purpose of the Framework Agreement is to ensure the delivery of the pharmaceuticals listed in Appendix 1 to the hospital pharmacies run by the stakeholders of Amgros (referred to in the following as the "Hospital Pharmacies").

1.3 In respect of certain pharmaceuticals, the hospital pharmacy of the Capital Region *(Region Hovedstaden)* is furthermore entitled to make purchases for resale to the Faroe Islands and Greenland. The purchase and delivery thereof are subject to the provisions of the Framework Agreement, thus including delivery to the hospital pharmacy of the Capital Region, see clause 9.

1.4 Amgros resells the pharmaceuticals 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 pharmacy purchase price (in the following referred to by its Danish abbreviation "AIP")).

1.5 The Framework Agreement is non-exclusive. The Hospital Pharmacies are not obliged to use the Framework Agreement.

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

1.7 Amgros has drawn up *Guidelines for the day-to-day cooperation in connection with delivery of medicines to Amgros and the hospital pharmacies in Denmark.* The guidelines are available at Amgros' "Tenders Page", and the Supplier is required to be familiar with the guidelines as they include a description of the procedures regarding the cooperation between Amgros and the Supplier. In case of conflict between the guidelines and the Framework Agreement, the Framework Agreement shall prevail.

1.8 Option for delivery in the Pre-Agreement Period:

In the event that Amgros should wish to purchase the product in the period from signature of the Framework Agreement until the first day of the purchase period ("the Pre-Agreement Period"), Amgros shall be entitled to request in writing that the Supplier deliver the

product in the Pre-Agreement Period at the price stipulated in Appendix 1. Agreement on delivery shall be subject to the provisions of clause 1.10.

The option for delivery in the Pre-Agreement Period may only be exercised by Amgros where the pharmaceutical cannot be purchased under an agreement in force, e.g. due to a back order or if there is no agreement covering the pharmaceutical.

1.9 Option for delivery in the Post-Agreement Period:

In the event that Amgros should wish to purchase the product in the period from expiry/termination of the Framework Agreement and onwards ("the Post-Agreement Period"), Amgros shall be entitled to request in writing that the Supplier deliver the product in the Post-Agreement Period at the price stipulated in Appendix 1. Agreement on delivery shall be subject to the provisions of clause 1.10.

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

1.10 In the event of delivery 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 deliver the product by accepting (confirmation from the Supplier or the Supplier's wholesaler) the order, in which case the provisions of the Framework Agreement shall apply to the accepted order. Where the Supplier chooses to place a stock of the product with a wholesaler so that orders can be placed with the wholesaler, the Supplier must be aware that the wholesaler's acceptance of orders is deemed to be an acceptance on behalf of the Supplier to sell the product on the terms and conditions stipulated in the Framework Agreement, including at the price stipulated in the Framework Agreement.

2. PHARMACEUTICALS COVERED

2.1 The pharmaceuticals are specified in Appendix 1 by product name (trade name) and product number. Other product numbers shall only be covered by the Framework Agreement pursuant to the provisions of clause 3. The product name (trade name) of the pharmaceutical shall remain the same for the duration of the agreement, and all products offered under the same procurement number shall have the same product name (trade name), unless Amgros consents to a change, see clause 3.

2.2 Appendix 1 furthermore states Amgros' expected purchase under the Framework Agreement in the purchase period. This is merely a non-binding estimate made at the time of signature of the Framework Agreement; hence, the estimate shall not be binding on

Amgros and shall impose no purchasing obligation on Amgros. The estimate is based on the historical consumption. The actual purchase under the Framework Agreement may therefore vary considerably from the estimate, as the purchase of pharmaceuticals made by the Hospital Pharmacies is influenced by a number of factors, including a possible change of or new use of pharmaceuticals in the purchase period.

2.3 The Supplier is obliged to deliver the pharmaceuticals in accordance with all orders placed and thereby to meet the hospitals' continuing need for the pharmaceuticals, irrespective of whether it might significantly exceed the estimate made, see also clause 6.

2.4 If, however, Appendix 1 indicates that no purchases are expected (i.e. a "0" is stated), the Supplier shall not be obliged to satisfy any orders. The Supplier may choose to deliver such products by accepting (confirmation from the Supplier or the Supplier's wholesaler) the order, in which case the provisions of the Framework Agreement shall apply to the accepted order.

In the event that the expected purchase of the product in question has not been established at the time of signature of the Framework Agreement, no figure for the expected purchase of the product in question will be stated in Appendix 1 (the field will be empty). In such cases, Amgros will forward an updated Appendix 1 when ready [, however not later than [2] months after signature of the Framework Agreement].

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

3. OTHER PRODUCTS

3.1 Other products than those listed in Appendix 1 may be delivered under the Framework Agreement, see Appendix 6, provided that the terms and conditions stipulated are complied with, including that Amgros has given its specific written consent. New or changed products covered by the Framework Agreement pursuant to Appendix 6 will then be subject to the same terms and conditions as the products listed in Appendix 1.

4. REQUIREMENTS APPLICABLE TO THE PHARMACEUTICALS, ETC.

4.1 The Supplier shall in the period of the agreement have and maintain authorisation to produce, import or wholesale distribute pharmaceuticals within the EU/EEA, and the Supplier shall comply with all relevant legal and administrative provisions.

4.2 In the case of delivery of pharmaceuticals from stocks outside Denmark, the Supplier shall ensure that import control is carried out pursuant to the relevant rules applicable at any time (currently Executive Order no. 1358 of 18 December 2012 on production and import of pharmaceuticals and intermediates, and Executive Order no. 1359 of 18 December 2012 on distribution of pharmaceuticals) so as to ensure that this obligation will not rest with the Hospital Pharmacy.

4.3 The pharmaceutical shall be included in "Medicinpriser.dk" *(prices of medicines)* not later than 25 February 2019 in order to ensure delivery from the beginning of the purchase period and preparation of a possible change of products at the Hospital Pharmacies. A marketing authorisation applicable for Denmark shall be in place for the pharmaceuticals as from that date and throughout the entire purchase period, and the pharmaceuticals shall appear in the "Medicinpriser.dk" list of the Danish Medicines Agency *(Lægemiddelstyrelsen)*.

4.4 The pharmaceuticals shall be marked with a barcode in accordance with the requirements stated in Appendix 3. In addition, the requirements for the pharmaceuticals specified in Appendix 4 shall apply.

4.5 The Supplier shall have and maintain normal product liability insurance.

4.6 The residual shelf life of the pharmaceuticals on delivery shall not be less than 12 months. For pharmaceuticals 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. This provision shall not apply to pharmaceuticals whose shelf life pursuant to the summary of product characteristics is shorter than 24 months. For such pharmaceuticals, 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 pharmaceutical concerned.

4.7 In the event that the Supplier is only able to deliver pharmaceuticals with a shorter residual shelf life than as required in clause 4.6, the Supplier shall inform the Hospital Pharmacy thereof prior to delivery. If pharmaceuticals are delivered with a shorter residual shelf life than as stated in the requirement, the Supplier shall be obliged to take back the pharmaceuticals, in whole or in part, against reimbursement of the purchase sum and additional costs, if any, if the hospitals have not, through normal consumption, used the pharmaceuticals concerned before expiry of the shelf life. This shall apply regardless of whether the Hospital Pharmacy has pointed out, on receipt of the pharmaceuticals, the shorter residual shelf life or the right of return under the Framework Agreement. Furthermore, the right of return under the Framework Agreement shall apply regardless of whether the Hospital Pharmacy has reserved its right of return under the Framework Agreement in connection with any discussions with the Supplier regarding delivery of the pharmaceuticals.

4.8 Return of pharmaceuticals in accordance with clause 4.7 above may take place by use of PostNord to the Supplier's address as stated in the Framework Agreement, unless the Supplier on delivery of the pharmaceuticals informs that any return is to take place in another manner or to a different address. The Hospital Pharmacy's liability for any returned pharmaceuticals shall cease upon delivery of the pharmaceuticals to an independent carrier.

4.9 Upon return of pharmaceuticals, the Hospital Pharmacy will enclose a return slip with information on the pharmaceutical, 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 pharmaceuticals are returned due to the delivery of pharmaceuticals with short shelf life. The Hospital Pharmacy will at the same time inform Amgros of the returned products.

4.10 The Supplier shall not later than 8 days after receipt of the returned pharmaceuticals issue a credit note to Amgros.

5. INFORMATION ON THE PHARMARCEUTICALS, ETC.

5.1 At the request of Amgros, the Hospital Pharmacies or the hospitals, the Supplier shall provide further information on the pharmaceuticals, including, if required, documentation or information that is not publicly available, such as information on the application of the pharmaceuticals. Upon request, the Supplier shall in this context provide information on the quantitative or qualitative composition of the pharmaceuticals, including if pharmaceuticals are delivered from several different places of production.

5.2 The Supplier is furthermore obliged to provide Amgros with any additional information that may be relevant to the contractual relationship, including in this context as set out in clause 6.

6. SECURITY OF SUPPLY AND STOCK LEVEL

6.1 The Supplier is required to have a thorough knowledge of the trade, including knowledge of the fact that the hospitals' consumption of pharmaceuticals may fluctuate significantly throughout the entire purchase period, including that large fluctuations of orders must be expected both at the beginning and at the expiry of the Framework Agreement. It shall be the responsibility of the Supplier to ensure that, throughout the entire purchase period, such stock of each pharmaceutical is maintained as is appropriate in the circumstances taking into account the estimates informed by Amgros, the purchases made under the Framework Agreement and market trends in general.

6.2 At the beginning of the purchase period, an appropriate stock shall be understood to mean a quantity corresponding to at least 3 months' consumption based on the estimate for the purchase period informed at the conclusion of the Framework Agreement. In the course of the first month of the purchase period, the stock may only be reduced by the number of products actually purchased in the period, however an appropriate stock as described in clause 6.1 shall be maintained at all times. After the first month of the purchase period, an appropriate stock shall be maintained at all times as described in clause 6.1, but beyond that, there are no longer requirements for a specific stock level of a minimum size fixed in advance.

6.3 Throughout the entire purchase period, the Supplier shall at Amgros' request document that the above requirements for appropriate stock level are complied with at all times.

6.4 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 requirements for an appropriate stock will be complied with from the beginning of the purchase period.

6.5 In addition, Amgros shall be entitled to carry out audits at the Supplier in order to verify that the requirements for the size of the stock and its building up are complied with. If the Supplier has chosen to place its stock of the pharmaceutical with a wholesaler, the Supplier shall ensure that Amgros has a similar right to carry out such audits at the wholesaler. The right of Amgros to carry out audits shall apply from three months before the commencement of the purchase period and throughout the entire purchase period.

The Supplier's non-compliance with the above requirements regarding the size of the stock and build-up of stock may, as the case may be, constitute material breach of the Framework Agreement, see clause 12.5.1.

7. CORPORATE SOCIAL RESPONSIBILITY

7.1 Amgros expects that the Supplier has organised its business activities so that nature, climate and environment are protected and so that developments in society are sustainable and respect the human conditions of life and protect animals and vegetation.

7.2 The Supplier furthermore undertakes to act ethically and socially responsibly in the performance of the Framework Agreement.

8. ORDERING

8.1 The individual Hospital Pharmacies will place continuous orders with Amgros.

8.2 Amgros will then place continuous orders with the Supplier.

8.3 Ordering will take place electronically (or by fax).

8.4 The Supplier shall immediately confirm the order, if possible electronically or otherwise by fax to Amgros.

9. DELIVERY

9.1 Delivery shall take place not later than 3 working days after the Supplier's receipt of the order. "Working days" shall mean Mondays through Fridays, except for Danish public holidays, 5 June, 24 December and 31 December.

9.2 Delivery shall be DDP (Incoterms 2010) to the address stated by Amgros in the order (Hospital Pharmacy or related locations). A list of the places of delivery is available at the "Tenders Page" of Amgros, (https:levportal.amgros.dk). The list will be updated on a regular basis.

9.3 Delivery shall be in compliance with applicable law, including in accordance with the terms and conditions stated in the Supplier's marketing authorisation for the pharmaceutical concerned, including specific storage requirements.

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

10. PRICES

10.1 The price of each product number is stated in Appendix 1.

10.2 The prices shall be fixed for the entire duration of the Agreement, unless Amgros activates the price regulation mechanism and the Supplier chooses to submit a new, lower contract price, see clause 10.3.

10.2.1 If the pharmacy purchase price ("AIP") for the pharmaceutical concerned from the Supplier at any time in the purchase period is lower than the price stated in Appendix 1, Amgros shall be entitled to purchase the pharmaceutical in question from the Supplier at AIP price on the terms and conditions otherwise stated in the Framework 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.

The prices are stated in DKK inclusive of customs duties and other applicable taxes and duties except for VAT. In the event 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 burden of proof that an increase in taxes and duties has occurred, and that the taxes and duties are directly re-

lated to the products, and the net financial effect thereof, shall be on the Supplier. Similarly, the burden of proof that a decrease in taxes and duties has occurred, or that their cancellation is directly related to the products, and the net financial effect thereof, shall be on Amgros. The Supplier shall furthermore be obliged to inform Amgros of any downwards change of such taxes and duties.

10.3 Amgros may in the period of the Framework Agreement request the Supplier in writing to submit a new, lower price of the products covered by the Framework Agreement. The Supplier is not obliged to submit a new, lower price of the products covered by the Framework Agreement. The Supplier will be given at least 2 months' notice to submit a new, lower contract price. If the Supplier wishes to submit a new, lower contract price, such price shall be submitted in writing and received by Amgros not later than on the date stated in the notice in order for Amgros to accept the new price. The new, lower contract price will take effect from the effective date stated in the notice [and will at the same time be published at the "Tenders page"]. The new, lower contract price shall be binding for the rest of the period of the Framework Agreement or until Amgros once again activates the price regulation mechanism and the Supplier chooses to submit a new, lower contract price.

11. TERMS OF PAYMENT

11.1 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.

12. BREACH BY THE SUPPLIER

12.1 Back orders

12.1.1 If the Supplier fails to timely deliver a product ordered (or informs in advance that the product cannot be timely delivered), or if a product ordered is defective, the Supplier shall be deemed to be on back order.

12.1.1.1 If the pharmaceutical is not included in the list at Medicinpriser.dk at the time stated in clause 4.3, this shall also mean that the Supplier is deemed to be on back order in accordance with the provisions of this clause 12.1, and thereby entitle Amgros to make replacement purchases, etc., in accordance with the provisions of the Framework Agreement.

12.1.2 The Supplier shall immediately inform Amgros in writing if the Supplier is in a back order situation. The Supplier shall furthermore inform Amgros in writing as soon as the Supplier foresees, or should have foreseen, potential delivery problems and thereby a back order situation. If the pharmaceutical is not included in the list at Medicinpriser.dk at the time

stated in clause 4.3, this shall also mean that the Supplier is on back order and thereby entitle Amgros to make replacement purchases as described in this clause 12.

12.1.3 In the notification of back orders or expected back orders, the Supplier shall furthermore inform Amgros in writing of the cause of the back order and the expected duration of the back order period.

12.1.4 Unless Amgros and the Supplier expressly agree otherwise in writing, the Supplier shall be deemed to be on back order until the Supplier is once again able to deliver non-defective products and has built up an appropriate stock as described in clause 6 above. For the purposes of the practical handling and organisation of the purchases, the back order period shall not be deemed to be ended until 2 working days (24-hour days) after the Supplier has demonstrated to Amgros' satisfaction its ability to deliver and its stock capacity. For the duration of the back order period, Amgros shall be entitled to make replacement purchases as described in this clause 12 without being required, prior to each replacement purchase, to place an order with the Supplier for the products involved.

12.2 Non-delivery - replacement purchases

12.2.1 In the event of back orders, see clause 12.1, Amgros and/or the Hospital Pharmacies shall be entitled to immediately make purchases elsewhere of similar products. In the event of failure of timely delivery of a number of products ordered, Amgros and/or the Hospital Pharmacies shall thus be entitled to immediately make purchases elsewhere of the same number of similar products. In the event of the Supplier's failure in general to meet the Hospital Pharmacies' need for continuing deliveries (i.e. in a back order period as described in clause 12.1), Amgros and/or the Hospital Pharmacies shall be entitled to make the necessary purchase elsewhere of similar products in order to cover the hospital's need for pharmaceuticals, see also clause 12.2.2.

12.2.2 The Hospital Pharmacies and/or Amgros shall be entitled to immediately make purchases elsewhere of the number of products deemed necessary for reasons of security of supply, including the necessary stock level of the pharmaceutical concerned. The Hospital Pharmacy and/or Amgros shall thereby have the opportunity of ordering a larger number of products than comprised by the back order if it is deemed necessary by Amgros and/or the Hospital Pharmacy, e.g. where, due to exceptional circumstances, it is necessary to purchase a certain minimum amount to ensure supply in the back order period, e.g. in connection with purchase of non-registered pharmaceuticals. Replacement purchases may be made until the date of expiry of the back order period, see clause 12.1.4.

12.2.3 In the event of non-delivery, the Hospital Pharmacy shall have a significantly extended right to purchase products that are more expensive than the cheapest in the market if justified by patient safety and/or cost-related considerations in connection with a change

of products. If, for example, it concerns a pharmaceutical where Amgros or the Hospital Pharmacy estimates that repeated changes of product numbers are not appropriate for patient safety reasons, pharmaceuticals may be purchased from the pharmaceuticals supplier who can document the best ability to deliver, notwithstanding that the pharmaceuticals supplier concerned may not be the cheapest in the market. The assessment will include considerations such as the Supplier's expected resumption of delivery (as notified by the Supplier), the estimated consumption in the back order period, the nature and application of the pharmaceutical, the extent of any previous back order periods in the purchase period, and whether it is deemed necessary that the same pharmaceuticals supplier is able to fully cover the entire need for the pharmaceutical in one or several hospitals. In the event of back orders at the beginning of the purchase period, the Hospital Pharmacy shall in general and with due consideration of the above guidelines be entitled to continue the use of a previously used pharmaceutical in order to avoid a change of product.

12.2.4 Amgros and the Hospital Pharmacies shall have an extended right to arrange for replacement purchases themselves, including a right not to purchase the cheapest available alternative in accordance with the provisions of this clause 12. Amgros shall be entitled to only purchase products listed with a price at "Medicinpriser.dk"; hence, Amgros shall not be obliged to examine the possibility of purchasing replacement goods not listed with a price at "Medicinpriser.dk".

12.2.5 In connection with back orders notified by the Supplier with at least 6 weeks' notice, the Supplier may suggest a replacement solution. Amgros will then consider whether to accept the solution. The Supplier's suggested solution shall be submitted to Amgros not later than four weeks before the first day of the back order period.

12.2.6 The Supplier shall compensate Amgros' and/or the Hospital Pharmacy's additional costs of purchasing similar products elsewhere.

The Supplier shall cover all additional costs of Amgros and the buying Hospital Pharmacy in connection with the purchases referred to in this clause 12 from other pharmaceuticals suppliers, including Amgros' and the Hospital Pharmacies' documented administration costs in connection with the handling of replacement purchases, and any additional costs that the wholesaler may charge in connection with such purchases (e.g. in connection with purchase of non-registered pharmaceuticals), irrespective of whether the products purchased might be fully consumed in the back order period.

12.2.7 With the exceptions following from the above provisions in this clause 12, the general rules of Danish law regarding mitigation of loss shall apply.

12.2.8 The Supplier shall not be obliged to pay compensation in the event of failure to meet orders for pharmaceuticals not covered by the delivery obligation, see clause 2.4.

12.3 Defects

12.3.1 The above mentioned provisions of clause 12.2 regarding replacement purchases shall also apply if the products supplied by the Supplier are defective, unless the Supplier before the expiry of the delivery deadline of 3 working days, see clause 9, is able to replace the product. "Working days" shall mean Mondays through Fridays, except for Danish public holidays, 5 June, 24 December and 31 December.

12.3.2 In the event of the Supplier's non-compliance with requirements concerning bar codes and import control, see clause 4, Amgros and the Hospital Pharmacies themselves shall furthermore be entitled to carry out the remedy required at the Supplier's expense.

12.4 Withdrawals

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

12.4.2 Replacement purchases in the event of a withdrawal may take place in accordance with the provisions of clause 12.2. For the purposes of the practical handling and organisation of the purchases, the back order period shall not be deemed to have ended until 2 working days (24-hour days) after the Supplier has demonstrated to Amgros' satisfaction its ability of supply and build-up of stock.

12.5 General

12.5.1 The general rules of Danish law shall apply as regards breach, including the right of termination for material breach, see for example clause 12.5.2.

12.5.2 Suspension or withdrawal of the Supplier's authorisations, see clause 4.1, shall be considered material breach entitling Amgros to immediately terminate the Framework Agreement for cause.

12.5.3 The Supplier’s product liability shall be subject to the general rules of Danish law.

12.6 Force Majeure

12.6.1 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 of their obligations under the Framework Agreement.

12.6.2 Examples of force majeure events are war, riots, nationwide disturbances, import or export bans, 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.

12.6.3 Force majeure shall not be deemed to be, for example, withdrawal of a pharmaceutical, shutdown of one or several production facilities or other forms of limited production failures, failure to obtain required approvals and licences, etc. (both relative to internal quality controls at the Supplier and relative to legal requirements, etc.), failures in the Supplier's supply chain, 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.

12.6.4 A subcontractor's circumstances shall only be considered force majeure if the subcontractor is met with an obstacle covered by the above paragraphs in this clause 12.6 which the Supplier should not have avoided or overcome.

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

12.6.6 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.

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

13. AMGROS

13.1 In the event that Amgros is in breach of its payment obligations under the Framework 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 Framework 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 Framework Agreement unless Amgros has fulfilled its payment obligations before the expiry of the time-limit.

13.2 As for Amgros' claimant's default, including the claimant's default of the Hospital Pharmacies, the general rules of Danish law shall apply.

14. CONTACT PERSONS

14.1 Appendix 2 states the day-to-day contact person of each Party and the contract manager of each Party, including their telephone/fax numbers and e-mail addresses. Appendix 2 furthermore states the details of the distributors of the pharmaceuticals.

15. CONFIDENTIALITY

15.1 The Parties shall observe confidentiality to the usual extent regarding matters that are not generally known.

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

15.3 Amgros does not consider prices under the Framework 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 current prices under the agreement if Amgros should choose to do so. This furthermore means that Amgros will not exclude the current prices under the Framework Agreement from access to documents after publication of the prices.

15.4 The Supplier shall be entitled to include Amgros in its list of references, but the Supplier shall not otherwise use the name of Amgros for marketing purposes.

15.5 After consultation with the Supplier, Amgros shall decide whether and, if so, in what way, to announce the conclusion of the Framework Agreement. However, Amgros will give notice of the award of the contract in accordance with the procurement rules.

16. ASSIGNMENT

16.1 Amgros shall be entitled to assign its rights and obligations under the Framework Agreement to another public institution or an institution owned by the public sector or essentially financed by public funds.

16.2 The Supplier shall not assign its rights and obligations under the Framework Agreement to any third party without the written consent of Amgros.

17. APPLICABLE LAW AND VENUE

17.1 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.

17.2 Venue shall be the City Court of Copenhagen.

18. DURATION AND TERMINATION

18.1 The Framework Agreement shall become effective when Amgros has accepted the Supplier's offer, e.g. by submission of a copy of the Framework Agreement duly signed by Amgros (the period from the Framework Agreement's entry into force until its expiry is referred to in the Framework Agreement as "the period of the agreement"). The Framework Agreement shall thereafter apply to purchases in the period 1 April 2019 through 31 March 2020 (this period - together with a possible renewal period - is in the Framework Agreement referred to as "the purchase period").

18.2 Renewal

Amgros shall be entitled to extend the Framework Agreement for each pharmaceutical on unchanged terms by up to 1 year, provided that Amgros notifies the Supplier thereof not later than [meddelelsesdato option].

Amgros shall be entitled to extend the Framework Agreement [x] times for each pharmaceutical on unchanged terms and conditions by up to 1 year at the time, provided that Amgros notifies the Supplier thereof not later than [xx days/months] before the expiry of the Framework Agreement.

18.3 In the event that Amgros has given notification of enhanced requirements for bar codes in the renewal period, see Appendix 3, the Supplier shall be entitled to refuse to renew the Framework Agreement, provided that the Supplier informs Amgros thereof in writing not later 1 month after the Supplier has received Amgros' notification of renewal.

18.4 Where bar codes are changed, Amgros' renewal request may be conditional upon renewal of multiple framework agreements, e.g. where agreements have been entered into with multiple suppliers regarding a specific framework agreement under a particular lot or multiple framework agreements within a particular therapy area. Final notification regarding renewal of the Framework Agreement will then take place by notification to the Supplier not later than 10 working days after expiry of the Suppliers' time-limit for refusing a renewal of the Framework Agreement.

18.5 The Supplier shall not be entitled to terminate the Framework Agreement during the period of the agreement, including in a possible renewal period.

18.6 For each pharmaceutical, Amgros shall be entitled to terminate the Framework Agreement (i.e. possibly as a partial termination of the Framework Agreement applicable to certain pharmaceuticals) at 3 months' notice in the event that substantial changes in the market or substantial changes in the treatment principles should occur for a specific pharmaceutical or within the therapy area concerned. Substantial changes may be, for example, 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 pharmaceutical in question or within the therapy area in question.

18.7 Amgros' possible termination of the Framework Agreement due to substantial changes within the therapy area in question may thus take place if, in the circumstances, there is such connection between the use of multiple pharmaceuticals within the therapy area that termination of Framework Agreements regarding all these pharmaceuticals for the purposes of re-tender is assessed, on a case-by-case basis, to comply the most with fundamental procurement law principles.

18.7.1 Amgros shall furthermore be entitled to terminate the Framework Agreement (i.e. possibly as a partial termination of the Framework Agreement applicable to certain pharmaceuticals) at 3 months' notice if the price in Appendix 1 corresponds to the Supplier's AIP for the pharmaceutical concerned.

18.8 If the Danish Complaints Board for Public Procurement *(Klagenævnet for Udbud)* or a court of law should decide that the Framework Agreement is ineffective *(in Danish: "uden virkning")*, or that the award decision is to be annulled, Amgros shall be entitled to terminate the Framework Agreement for expiry in accordance with the decision and at a notice that is appropriate in the circumstances.

18.9 If the Danish Complaints Board for Public Procurement or a court of law should decide that one of Amgros' other framework agreements is ineffective, or that the award decision concerning one of Amgros' other framework agreements is to be annulled, Amgros shall be entitled to also terminate the Framework Agreement, in whole or in part (at a notice that is appropriate in the circumstances). This shall only apply if the other framework agreement in question and the Framework Agreement concern the same therapy area, and the connection between the use of the pharmaceuticals within the therapy area is such that termination of all framework agreements regarding all these pharmaceuticals in order to re-tender is assessed, on a case-by-case basis, to comply the most with fundamental procurement law principles.

18.10 In addition to clauses 18.6 and 18.9 above, Amgros may terminate the Framework Agreement in accordance with section 185 of the Danish Procurement Act *(udbudsloven)*.

18.11 If the required basis of liability exists, and the Supplier has suffered a loss, the Supplier shall be entitled to claim damages or other form of compensation as a result of the decision to award the Framework Agreement being annulled or the Framework Agreement being declared ineffective and an order to terminate being issued, including for example any costs of complying with the additional terms and conditions or requirements transferred by Amgros in the notice of termination. Indirect losses, however, shall not be compensated and damages shall be limited to a maximum of 3 months' turnover for the Supplier during the purchase period calculated as an average on the basis of the estimate informed by Amgros for the purchase period.

18.12 If the Supplier, at the time of conclusion of the agreement, had or should have had knowledge of the actual and/or legal circumstances causing the cancellation of the award of the Framework Agreement or causing the Framework Agreement to be declared ineffective, or if Amgros terminates the Framework Agreement pursuant to section 185 of the Danish Procurement Act, the Supplier shall have no claim for damages or other form of compensation against Amgros, including, for example, the costs of complying with additional terms and conditions or requirements transferred by Amgros in the notice of termination.

19. SIGNATURES

Date:

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

2019 - Procurement group

Appendix 1A Specification of pharmaceutical forms

To be completed on final conclusion of agreement

2019 - Procurement group

Appendix 3 Bar code requirements

A. Bar code requirements 2018 and 2019

For agreements entered into on the basis of Amgros' tenders 2018 and 2019, the following bar code requirements for pharmaceuticals delivered from 1 April 2018 through 31 March 2020 shall apply.

Similar bar code requirements shall apply to pharmaceuticals delivered under the general terms and conditions for de minimis procurement from 1 April 2018 through 31 March 2020.

Secondary packaging

For pharmaceuticals produced on or before 8 February 2019, it is a requirement that the secondary packaging is marked with either EAN 13- bar code or 2D (GS1 DataMatrix) bar code containing as a minimum an identification key.

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

For all pharmaceuticals for oral use, all pharmaceuticals for external use as well as all pharmaceuticals for injection and for infusion, it is a requirement that the primary packaging is marked with a bar code. However, this requirement shall not apply to tablets or capsules in blister sheets or other similar packaging in which tablets/capsules are single-dosed individually.

The bar code must either be an EAN 13 bar code or 2D (GS1 DataMatrix) bar code and must as a minimum contain an identification key.

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

Pharmaceuticals for infusion means:

- Infusion fluid
- Concentrate for infusion fluid
- Powder for infusion fluid

B. Renewal of framework agreements - bar code requirements 2020

Framework agreements entered into on the basis of Amgros tender 2019 may be extended for 2020. In a possible renewal period, the bar code requirements will correspond to the requirements stipulated for the 2020 tender.

At present, the requirements are expected to be as stated below.

C. Bar code requirements tender 2020

Secondary packaging

For pharmaceuticals produced on or before 8 February 2019, it is a requirement that the secondary packaging is marked with either EAN 13- bar code or 2D (GS1 DataMatrix) bar code containing as a minimum an identification key.

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

For all pharmaceuticals for oral use, all pharmaceuticals for external use as well as all pharmaceuticals for injection and for infusion, it is a requirement that the primary packaging is

marked with a bar code. However, this requirement shall not apply to tablets or capsules in blister sheets or other similar packaging in which tablets/capsules are single-dosed individually.

The bar code must either be an EAN 13 bar code or 2D (GS1 DataMatrix) bar code and must as a minimum contain an identification key.

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

Pharmaceuticals for infusion means:

- Infusion fluid
- Concentrate for infusion fluid
- Powder for infusion fluid

However, Amgros reserves the right within the procurement law framework to change the bar code requirements applicable in the renewal period (2020) if the final bar code requirement for tender 2020 is changed as compared to expectations at present.

If so, the Supplier will receive a notice of change of bar code requirements as stated in connection with the provisions regarding Amgros' notice of renewal of the Framework Agreement, see clause 18 of the Framework Agreement.

1 April 2018

2019 - Procurement group

Appendix 4 Requirements regarding the pharmaceuticals

To be completed on final conclusion of agreement

2019 - Procurement group

Appendix 6 Other pharmaceuticals

General

A change concerning pharmaceuticals (as 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 procurement rules, Amgros may consent to the inclusion in the Framework 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 Framework Agreement.

Consent may only be granted for other products if they comply with the requirements stipulated for the pharmaceutical put up for tender, including the specifications regarding the pharmaceutical form, strength and package size that appeared 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 pharmaceutical 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 stated in Appendix 1 for the pharmaceutical in question.

[This price per unit will be stated in Appendix 1 by Amgros on the basis of the Supplier's tender for the pharmaceutical in question in the public procurement, see paragraph 3.5 of the tender specifications].

Other strengths or other package sizes

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

For pharmaceuticals where the list of products in the tender process stated a range of package sizes of the pharmaceutical in question, the Supplier may in the period of the agreement offer other package sizes within the range indicated of the pharmaceutical concerned (i.e. the pharmaceutical in the same pharmaceutical form and same concentration).

For pharmaceuticals where the list of products in the tender process did not state a requirement for a specific strength of the pharmaceutical in question, the Supplier may in the period of the agreement offer other strengths of the pharmaceutical concerned (i.e. the pharmaceutical in the same pharmaceutical form and in the package sizes that may be indicated).

For pharmaceuticals where the list of products in the tender process did not state a requirement for a specific package size of the pharmaceutical in question, the Supplier may in the period of the agreement offer other package sizes of the pharmaceutical concerned (i.e. the pharmaceutical in the same pharmaceutical form and same concentration).

The same pharmaceutical form means the pharmaceutical form of the pharmaceutical specified in the product list under the procurement number in question, see clause 3.2 of the tender specifications, cf. Appendix 1A.

Additional other products

In addition to the instances of other strengths or package sizes than those mentioned above, Amgros may grant its consent to the Framework 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 pharmaceutical of at least the same quality or better. Hence, consent may be granted for a new product of a pharmaceutical 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 significant change, including whether consent may imply a risk of competition being distorted.