Framework Agreement (I)

for procurement group

call for tenders 2020 – NF1.621.b

(Denmark, Norway and – as an option - Iceland)

JOINT NORDIC FRAMEWORK AGREEMENT

between

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

Landspítali, Eiríksgata 5, 101 Reykjavík, (“Landspítali”)

Sykehusinnkjøp HF, divisjon legemidler, Grev Wedels plass 7, 0151 Oslo (“Sykehusinnkjøp HF, divisjon legemidler”)

(collectively referred to as “the Contracting Authorities” or separately as “a Contracting Authority”)

and

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.....

.....

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

(The "Supplier")

for

the delivery of pharmaceuticals

in the period 1 February 2020 through 31 January 2021

(with the possibility of renewal)

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1. THE FRAMEWORK AGREEMENT

1.1 This framework agreement (the "Framework Agreement") has been concluded on the basis of a joint public procurement held by the Contracting Authorities (Amgros Sykehusinnkjop HF, divisjon legemidler and Landspítali) in accordance with the Danish Public Procurement Act (*Udbudsloven*).

1.2 The purpose of the Framework Agreement is to ensure the supply of the pharmaceuticals listed in Appendix 1 to the public hospitals and health authorities in the three countries; Denmark, Norway and Iceland (further specified as Customers in Appendix 7, 8 and 9). The Framework Agreement gives the Contracting Authorities and the Customers the right, but not the obligation, to purchase pharmaceuticals from the Supplier on an ongoing basis. The Supplier shall deliver pharmaceuticals in all three countries (Denmark, Norway and Iceland) in accordance with the terms and conditions of the Framework Agreement and the appendices, including the relevant national terms and conditions specified in Appendix 7, 8 and 9.

1.3 In Norway purchase of the pharmaceuticals is made through a wholesaler appointed by the Customers, see Appendix 7.

1.4 In Denmark certain pharmaceuticals is resold to the Faroe Island and Greenland, see Appendix 9.

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

1.5.1 The Framework 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 be in accordance with the terms and conditions stipulated in Appendix 5.

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 the appendices 7, 8 or 9, the appendices shall prevail. In case of conflict between the provisions of the Framework Agreement and the other appendices, the Framework Agreement shall prevail.

1.7 The Contracting Authorities in Denmark and Norway has drawn up guidelines for day-to-day cooperation, see Appendix 7 and 9.

1.8 Option for delivery in the Pre-Agreement Period:

In the event that a Contracting Authority or a Customer 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"), the Contracting Authority or the Customer shall be entitled to request in writing that the Supplier deliver the product in the

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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 a Contracting Authority or a Customer 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 a Contracting Authority or a Customer should wish to purchase the product in the period from expiry/termination of the Framework Agreement and onwards ("the Post-Agreement Period"), a Contracting Authority or a Customer 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 a Contracting Authority or a Customer 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 the order, in which case the provisions of the Framework Agreement shall apply to the accepted order. In Denmark, such orders can be accepted by the Supplier's wholesaler, see appendix 9.

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) for each country, unless the Contracting Authority in the country concerned consent to a change, see clause 3. It is not a requirement that the product name is the same for all three countries.

2.2 Appendix 1 furthermore states the expected purchase under the Framework Agreement in the purchase period for each of the countries. This is a non-binding estimate made at the time of signature of the Framework Agreement; hence, the estimate shall not be binding on the Contracting Authorities nor the Customers and shall impose no purchasing obligation on the contracting authorities nor the Customers. 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

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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 Customers' 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 deliver any orders placed. The Supplier may choose to deliver such products by accepting the order, in which case the provisions of the Framework Agreement shall apply to the accepted order. In Denmark, such orders can be accepted by the Supplier's wholesaler, see appendix 9. 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, the Contracting Authorities will forward an updated Appendix 1 when ready, however not later than 6 months before the purchase period.

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 the Contracting Authorities has given their 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. Changes to the Framework Agreement shall under all circumstances be in accordance with procurement law.

4. REQUIREMENTS APPLICABLE TO THE SUPPLIER AND THE PHARMACEUTICALS

4.1 The Supplier shall in the period of the Agreement have and maintain an authorization to produce, import or wholesale distribute pharmaceuticals within the EU/EEA. The Supplier shall deliver pharmaceuticals which are produced, transported and stored in accordance with the GMP and the GDP guidelines. The Supplier shall comply with all further relevant legal and administrative provisions in the relevant country.

4.2 In the case of delivery of pharmaceuticals from stocks outside the country of delivery (Denmark, Norway or Iceland, as the case might be) the Supplier shall ensure that import control is carried out pursuant to the relevant rules applicable at any time in the relevant country in order to ensure that this obligation will not rest with the Customer. The import control can be carried out by a third party on behalf of the Supplier, e.g. a wholesaler, at the Supplier's expense.

4.3 The pharmaceutical shall be included in "Medicinpriser.dk" (Denmark), "Lyfjaverðskrá" (Iceland) and "Farmalogg" (Norway) no later than 1 December 2019 in order to ensure delivery from the beginning of the purchase period and preparation of a possible change

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of products at the customers. Marketing authorizations applicable for Denmark, Norway and Iceland shall be in place for the pharmaceuticals in sufficient time to ensure fulfilment of the requirement above and shall remain in force throughout the entire purchase period. The pharmaceuticals shall appear in the "Medicinpriser.dk" (Denmark), “Lyfjaverðskrá” (Iceland) and “Farmalogg” (Norway) throughout the entire purchase period. See appendix 7 and 9 for further information and requirements regarding Farmalogg and Medicinpriser.dk.

4.4 The pharmaceuticals shall be marked with a barcode in accordance with the relevant legal provisions in the country of delivery, see Appendix 3 (regulatory requirement). For pharmaceuticals delivered in Denmark, further bar code requirements apply, see Appendix 3 (Amgros’ requirements).

4.5 The Supplier shall have and maintain normal product liability insurance in the country of delivery. See appendix 7 regarding further requirements in Norway.

4.6 The residual shelf life of the pharmaceuticals on delivery shall not be less than 12 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. Se appendix 9 regarding residual shelf life for pharmaceuticals that are meant for resale to Greenland.

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 Customer 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 Customer have not, through normal consumption, used the pharmaceuticals concerned before expiry of the shelf life. This shall apply regardless of whether the Customer 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 Customer has reserved its right of return under the Framework Agreement in connection with any discussions with the Supplier regarding delivery of the pharmaceuticals. See Appendix 7, 8 and 9 for further national requirements regarding the return of pharmaceuticals.

5. INFORMATION ON THE PHARMARCEUTICALS AND COOPERATION

5.1 At the request of a Contracting Authority or the Customers, 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.

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

5.3 The Contracting Authority has the right to request meetings where representatives from the Contracting Authority, the Customer and the Supplier participate. The Supplier is responsible for making the necessary representatives attend the meeting. See appendix 7 regarding further requirements regarding such meetings in Norway.

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 Customers' 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 the Contracting Authorities, 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 2 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 the request of a Contracting Authority 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 the request of a Contracting Authority document that the stock is being built up, so that the above-mentioned requirements for an appropriate stock will be complied with from the beginning of the purchase period.

6.5 The Contracting Authorities 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 the Contracting Authorities has a similar right to carry out such audits at the wholesaler. The right of the Contracting Authorities to carry out audits shall apply from three months before the commencement of the purchase period and throughout the entire purchase period.

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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 The Contracting Authorities expects that the Supplier has organized 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.

7.3 See appendix 7 for specific Norwegian requirements.

8. ORDERING

8.1 See appendix 7, 8 and 9 for specific national requirements.

9. DELIVERY

9.1 Delivery terms, including delivery time and place is specified in appendices 7, 8 and 9.

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

9.3 The requirements stated in 9.4 - 9.8 shall only apply in Norway unless the Supplier and the Wholesaler agrees differently, see appendix 7.

9.4 A delivery shall be accompanied by a consignment note. The number of transport units and the storage conditions of the product shall be stated in the consignment note.

9.5 The individual pharmaceuticals / orders shall be clearly identifiable in the consignment. In deliveries with several batch numbers of the same pharmaceutical, the batch numbers must be clearly separated.

9.6 The delivery must be secured for transport to the extent necessary in the form of outer packaging so as to avoid physical harm to the delivery.

9.7 Carton labels must be positioned so that they are visible in the consignment, e.g. on a pallet.

9.8 If several batch numbers of the same pharmaceutical are delivered on a pallet, the batch number holding the most units must be placed at the bottom.

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10. PRICES

10.1 The price of each product number is stated in Appendix 1 in EUR. The prices in EUR shall be fixed for the entire duration of the Agreement, however, see clause 10.2, 10.4.

10.2 Once a year, the first time on 15 January 2020, the Supplier shall convert the prices in Appendix 1 to DKK and NOK with an exchange rate calculated as an average rate based on the exchange rates applicable for the period 1 October to 31 December the preceding year as published by the national bank of the relevant country (the Danish National Bank and Norges Bank). The converted prices shall be fixed for one year and used for invoicing for purchases made in the period 1 February to 31 January, see clause 11.1. The converted prices shall be forwarded by the Supplier to the Contracting Parties by means of an updated Appendix 1 including both the original price in EUR as well as the converted prices in both DKK and NOK as per 1 February the year concerned.

10.3 If the official Pharmacy purchase price in one of the countries (the "AIP" as defined below) for the pharmaceutical concerned from the Supplier, at any time in the purchase period, is lower than the applicable converted prices, see clause 10.2, the Contracting Authorities or the Customers shall be entitled to purchase the pharmaceutical in question from the Supplier at AIP price (whichever is lowest) 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 publication of a changed AIP. By AIP is meant "Apotekernes Indkøbspris (AIP)" published at "Medicinpriser.dk" (Denmark), "apotekenes maksimale innkjøpspris, ekskl. MVA (merverdiavgift)" published by the Norwegian Medicines Agency, "Oversikt over maksimalpriser" (Norway) and "Innkaupsverð apóteka" published at "Lyfjaverðskrá" (Iceland).

10.4 The prices in Appendix 1 are stated in EUR inclusive of customs duties and other applicable taxes and duties except for VAT. In the event of adjustment of applicable Danish, Norwegian and/or Icelandic 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 related 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 the Contracting Authorities. The Supplier shall furthermore be obliged to inform the Contracting Authorities of any downwards change of such taxes and duties.

11. TERMS OF PAYMENT

11.1 In Denmark and Norway, the pharmaceuticals shall be invoiced in the currency of the country of delivery (in DKK for Denmark and NOK for Norway), see clause 10.2. See appendices 7 and 9 for specific national requirements regarding terms of payment.

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11.2 In Iceland, the pharmaceuticals shall be invoiced in EURO (the price is stated in appendix 1). See appendix 8 for the specific national requirements regarding terms of payment.

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. If the pharmaceutical is not included in the list at "Medicinpriser.dk" (Denmark), "Lyfjaverðskrá" (Iceland) or "Farmalogg" (Norway) 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 the Contracting Authority or Customer concerned to make replacement purchases, etc., in accordance with the provisions of the Framework Agreement.

12.1.2 The Supplier shall immediately inform the Contracting Authority and/or Customer concerned in writing if the Supplier is in a back order situation. The Supplier shall furthermore inform the Contracting Authority and/or Customer concerned in writing as soon as the Supplier foresees, or should have foreseen, potential delivery problems and thereby a back order situation.

12.1.3 In the notification of back orders or expected back orders, the Supplier shall furthermore inform the Contracting Authority and/or Customer concerned in writing of the cause of the back order and the expected duration of the back order period.

12.1.4 Unless the Contracting Authority 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 organization 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 the satisfaction of the Contracting Authority concerned its ability to deliver and its stock capacity. For the duration of the back order period, the Contracting Authority and/or Customer concerned 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, the Contracting Authority and/or Customer concerned shall be entitled to immediately make purchases elsewhere of similar

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products. In the event of failure of timely delivery of a number of products ordered, the Contracting Authority and/or Customer concerned 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 Customers' need for continuing deliveries (i.e. in a back order period as described in clause 12.1), the Contracting Authority and/or Customer concerned shall be entitled to make the necessary purchase elsewhere of similar products in order to cover the Customer's need for pharmaceuticals, see also clause 12.2.2.

12.2.2 The Contracting Authority and/or Customer concerned 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 Contracting Authority and/or Customer concerned shall thereby have the opportunity of ordering a larger number of products than comprised by the back order if it is deemed necessary by the Contracting Authority and/or Customer concerned, 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 clause12.1.4.

12.2.3 In the event of non-delivery, the Contracting Authority and/or Customer concerned 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 the Contracting Authority and/or Customer concerned 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 chosen 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 Customer 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 The Contracting Authority and/or Customer concerned 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. The

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Contracting Authority and/or the Customer shall be entitled to only purchase products listed with a price at the relevant national register of pharmaceuticals, ("Medicinpriser.dk" in Denmark, "Farmalogg" in Norway and "Lyfjaverðskrá" (Iceland)). Hence, the Contracting Authority and/or the Customer shall not be obliged to examine the possibility of purchasing replacement goods not listed with a price at the relevant register.

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. The Contracting Authority and/or Customer concerned will then consider whether to accept the solution. The Supplier's suggested solution shall be submitted to the Contracting Authority and/or Customer concerned not later than four weeks before the first day of the backorder period.

12.2.6 The Supplier shall compensate the Contracting Authority and/or the Customer concerned their additional costs of purchasing similar products elsewhere.

The Supplier shall cover all additional costs of the Contracting Authority and/ or the Customer concerned in connection with the purchases referred to in this clause 12 from other pharmaceuticals suppliers, including documented administration costs in connection with the handling of replacement purchases, and any additional costs that these suppliers 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, see clause 9.1, is able to replace the product.

12.3.2 In the event of the Supplier's non-compliance with requirements concerning bar codes and import control, see clause 4, the Contracting Authority and/or the Customer concerned shall furthermore be entitled to carry out the remedy required at the Supplier's expense. In Norway such remedy might also be carried by the Wholesaler.

12.4 Withdrawals

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12.4.1 In the event that the Supplier and/or the relevant national 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 organization 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 Contracting Authority in questions' 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. Breach against one country is deemed to be a breach against all countries. Repeated or substantial breach in one or more of the countries can entail a material breach of the entire Framework Agreement, causing potential termination of the Agreement as a whole. Notwithstanding the provision above, breaches of the provisions regarding corporate social responsibilities applicable for Norway will only cause potential termination of the Agreement for Norway, see Appendix 7, clause 7.3.

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

12.5.3 The Supplier's product liability shall be subject to the general rules of the country of delivery.

12.6 Force Majeure

12.6.1 Both a Contracting Authority 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.

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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 licenses, 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 the Contracting Authorities 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.

12.7 Notifications

12.7.1 Any information and/or notifications to be given by the Supplier under this clause 12, shall be given both to the parties mentioned in the specific clauses as well as to other institutions and/or third parties mentioned in Appendices 7, 8 and 9, if any.

12.8 Right of return

12.8.1 The Supplier shall accept returns of delivered pharmaceuticals and credit the invoiced price of the returned pharmaceuticals in the following situations:

- Pharmaceuticals with a shorter residual shelf life than required, see clause 4.7
- Defective pharmaceuticals see clause 12.3
- Withdrawals see clause 12.4, and
- Any other situation where the Contracting Authority and/ or the Customer concerned is entitled under the Framework Agreement to return the pharmaceuticals.

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12.8.2 Return of pharmaceuticals shall be made in accordance with the procedure set out regarding return of pharmaceuticals in accordance with clause 4.7 and Appendix 7, 8 and 9.

13. BREACH BY THE CONTRACTING AUTHORITIES

13.1 The Supplier shall be entitled to terminate the Framework Agreement with effect for the future if the Supplier has sent written notice to one of the Contracting Authorities stating, firstly, that the Contracting Authority, in a specified manner, is in breach of its obligations, secondly, that such breach will result in termination of the Framework Agreement unless the Contracting Authority has fulfilled its obligations before the expiry of the time-limit.

13.2 See Appendices 7, 8 and 9 for further national requirements and responsibilities.

14. CONTACT PERSONS

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

14.2 Appendices 7, 8 and 9 states the day-to-day contact person of each Contracting Authority and the contract manager of each Contracting Authority, including their telephone numbers and e-mail addresses.

15. CONFIDENTIALITY

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

15.2 However, the Contracting Authorities are subject to rules on access to documents and 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 The Supplier shall be entitled to include the Contracting Authorities in its list of references, but the Supplier shall not otherwise use the name of the Contracting Authorities for marketing purposes.

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

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16. ASSIGNMENT

16.1 The Contracting Authorities 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 the contracting authorities.

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 the Contracting Authorities has accepted the Supplier's offer, e.g. by submission of a copy of the Framework Agreement duly signed by the Contracting Authorities (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 February 2020 through 31 January 2021. This period - together with a possible renewal period - is in the Framework Agreement referred to as "the purchase period".

18.2 The Contracting Authorities shall be entitled to extend the Framework Agreement 2 times for each pharmaceutical on unchanged terms and conditions by 6 months at the time, provided that the Contracting Authorities notifies the Supplier thereof not later than 6 months before the expiry of the Framework Agreement.

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

18.4 Where bar codes are changed, the contracting authorities'' 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

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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 The Contracting Authorities 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 AIP for the pharmaceuticals concerned, see clause 10.3.

18.7 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, the Contracting Authorities 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.

18.8 If the Danish Complaints Board for Public Procurement or a court of law should decide that one of the Contracting Authorities other framework agreements is ineffective, or that the award decision concerning one of the Contracting Authorities other framework agreements is to be annulled, the Contracting Authorities 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.

18.9 In addition to clause 18.7 above, the Contracting Authorities may terminate the Framework Agreement in accordance with clause 185 of the Danish Procurement Act *(udbudsloven)*.

18.10 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 the Contracting Authorities 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 the Contracting Authorities for the purchase period.

18.11 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

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award of the Framework Agreement, or causing the Framework Agreement to be declared ineffective, or if the Contracting Authorities terminates the Framework Agreement pursuant to clause 185 of the Danish Procurement Act, the Supplier shall have no claim for damages or other form of compensation against the contracting authorities, including, for example, the costs of complying with additional terms and conditions or requirements transferred by the Contracting Authorities in the notice of termination.

19. SIGNATURES

Date:

For and on behalf of the Amgros:

_____

Jon Bjergfelt

Head of Sourcing

Date:

For and on behalf of the Supplier:

[The Supplier has accepted the Framework Agreement upon submission of tender in the procurement process]

Date:

For and on behalf of the Landspítali:

_____

Date:

For and on behalf of the Sykehusinnkjøp HF, divisjon legemidler

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Appendix 1A Specification of pharmaceutical forms

To be completed on final conclusion of agreement.

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Appendix 3 Bar code requirements

For agreements entered into on the basis of Joint Nordic procurements, the following bar code requirements for delivered pharmaceuticals shall apply.

Secondary packaging – regulatory requirements[1]

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 – Amgros' requirements (for Denmark only)

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

[1] Section on" Secondary packaging" is only a service information to Supplier. The Contracting Authorities assumes no responsibility for errors or omissions in the contents on the information. The Supplier is still responsible for complying with all regulatory requirements for the Pharmaceuticals.

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- 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

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

To be completed on final conclusion of agreement based on the tender conditions paragraph 6 and 7.

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Appendix 6 Other pharmaceuticals

General

A change concerning pharmaceuticals (as specified in Appendix 1) shall require the prior written consent of the Contracting Authorities.

The Contracting Authorities are not obliged to give their consent.

According to a case-by-case assessment and with due consideration of the procurement rules, the Contracting Authorities 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 the Contracting Authorities 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

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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, see Appendix 1A.

Additional other products

In addition to the instances of other strengths or package sizes than those mentioned above, the Contracting Authorities 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.

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