

**ADVANCE PURCHASE AGREEMENT
("APA")
FOR
PANDEMIC INFLUENZA VACCINE**

This agreement is effective as of May 2, 2016 (the "Effective Date")

between

The Public Health Agency of Sweden, an agency with its principal address at
Folkhälsomyndigheten, Nobels väg 18, SE-171 82 Solna, Sweden (the "PHAS");

and

Seqirus UK Limited, a company incorporated in England with its registered office at 100 New
Bridge Street, London, UK, EC4V 6JA (company number 09614642) (the "Supplier"),

(each a "Party" and together, the "Parties").

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1. BACKGROUND

- 1.1. PHAS is a government agency accountable to the Government (Ministry of Health and Social Affairs). PHAS has a national responsibility for public health issues. It promotes good public health by building and disseminating knowledge to professionals involved in the public health, including infectious disease prevention.
- 1.2. PHAS has acquired the government assignment to ensure access to influenza vaccine treatment during a pandemic. The assignment aims to improve the Swedish preparedness against a future pandemic of influenza.
- 1.3. PHAS has carried out a public procurement procedure for the supply of vaccine in case of a possible influenza pandemic. Pursuant to this procedure, PHAS has accepted the tender offer made by the Supplier.
- 1.4. The Supplier and its Affiliates develop and manufacture vaccines and vaccine products, including various potential pandemic strains of influenza virus, and owns or exploits certain Intellectual Property.
- 1.5. As part of its fulfillment of its obligations under this APA the Supplier guarantees that throughout the duration of this APA it will be able to operate under the Marketing Authorisation for the purposes set forth herein.
- 1.6. PHAS wishes to reserve, and, in the event of an outbreak of pandemic influenza, PHAS wishes to purchase pandemic influenza vaccine from the Supplier, based on PHAS's estimated needs as provided for under the Reserved Volume, as set forth in detail under this APA.
- 1.7. Therefore, on the terms and conditions set out in this APA, the Supplier agrees to reserve production capacity for supply of pandemic influenza vaccine to PHAS, and supply and sell to PHAS the pandemic influenza vaccine in the event of a human influenza pandemic as communicated through a pandemic declaration.

2. DEFINITIONS

- "Advance Purchase Agreement/APA"** means this agreement, including its appendices.
- "Affiliate"** means in relation to the Supplier, any person that Controls, is Controlled by, or is under common Control with the Supplier, whereby "Control" means direct or indirect beneficial ownership of more than fifty percent (50%) (or such lesser percentage as is the maximum permitted level of foreign investment) of the share capital, stock, or other participating interest carrying the right to vote or to distribution of profits of a person, as the case may be, or otherwise the possession of the power to direct or cause the direction of the policies and management of such person.
- "All Reasonable Efforts"** means that the relevant Party shall make such efforts which, taking into regard the interests of both Parties, may not be deemed unreasonable.

"Best Evidence"	means the best available knowledge on the basis of existing best practices and established experience, to be used as best evidence in the absence of evidence-based practice regarding the Pandemic Vaccine, as established by experts at qualified clinics in Sweden unanimously through what is commonly referred to as a consensus panel, provided that such consensus panel (i) has been established in accordance with standard practice among Swedish authorities within the health care sector, (ii) has been established for the purpose of reviewing findings from day-to-day practice of Pandemic Vaccines in a Pandemic Period, (iii) consists of duly qualified experts for the purpose, and (iv) bases any recommendation on an independent assessment, an appropriate benefit/risk analysis and any other relevant factors.
"Business Day"	means a day during which banks are open for business in Stockholm.
"CHMP"	means the EMA's scientific committee in relation to medicines for human use (that is, the committee for medical products for human use).
"Competent Regulatory Authority"	means EMA and/or the European Commission and/or the Swedish Medical Products Agency and/or the corresponding authorities of an EEA member state, depending on the relevant regulatory procedure.
"Delivery Period"	means the time between the Firm Order placed by PHAS and delivery of the last shipment of product of Pandemic Vaccine under such order.
"Delivery Plan"	means the written time schedule for delivery of the Pandemic Vaccine to PHAS, which shall be within the time limits of first and last delivery as set forth in the Preliminary Delivery Plan, in accordance with article 8.3. The Delivery Plan shall include dates for delivery and the number of Doses for each delivery.
"Dose"	means a single dose of Pandemic Vaccine for a healthy adult as specified in the Specifications.
"Effective Date"	means the date listed on the first page of this APA.
"EMA"	means the European Medicines Agency.
"Firm Order"	has the meaning specified in article 8.1.2.
"Force Majeure"	means any circumstance outside of a Party's reasonable control, including but not limited to, war,

labour disputes, accidents, acts of terrorism, explosion, flood, earthquake, tornado, hurricane, fire, civil disorder, sabotage, riot, civil commotion or breakage or failure of machinery or apparatus.

- “Good Manufacturing Practice (GMP)”** means good manufacturing practice in accordance with standards currently required by EU legislation and guidelines as amended from time to time, and any appropriate and agreed additional requirements by EMA or the Swedish Medical Products Agency.
- “Good Distribution Practice (GDP)”** means good distribution practice in accordance with standards currently required by EU legislation and guidelines as amended from time to time, and any appropriate and agreed additional requirements by EMA or the Swedish Medical Products Agency.
- “Good Pharmacovigilance Practice”** means good pharmacovigilance practices as drawn up by the European Medicines Agency pursuant to EU Directive 2001/83.
- “ILO and UN Core Conventions on labour rights”**
- Freedom of Association and Protection of the Right to Organise Convention, 1948 (No. 87),
- Right to Organise and Collective Bargaining Convention, 1949 (No. 98), Forced Labour Convention, 1930 (No. 29), Abolition of Forced Labour Convention, 1957 (No. 105), Minimum Age Convention, 1973 (No. 138), Worst Forms of Child Labour Convention, 1999 (No. 182), Equal Remuneration Convention, 1951 (No. 100), Discrimination (Employment and Occupation) Convention, 1958 (No. 111) and Art 32 of the UN Convention on the Rights of the Child.
- “Intellectual Property”** means any and all patents, supplementary protection certificates, utility models, designs, copyright, database rights, trademarks, property rights in biological or chemical materials, clinical data, bio-banks, knowhow, unpatented discoveries, technical information, procedures and applications related to Pandemic Vaccine and the right to apply any of the foregoing.
- “Marketing Authorisation”** means the marketing authorisation issued by EMA for the Pandemic Vaccine based on a Mock-up Approval.
- “Mock-up Approval”** means the CHMP’s approval in relation to the prototype vaccine under the so-called mock-up or pandemic preparedness authorisation procedure.

"Non-deliverable Pandemic Vaccine"	means Pandemic Vaccine that is received by PHAS that failed to comply with Swedish legal requirements or requirements under this APA at the time of delivery to PHAS, as well as Pandemic Vaccine being subject to recall, with the exception of Pandemic Vaccine that may not be used due to regulatory changes which occurs after shipment of the Pandemic Vaccine to PHAS.
"Order Period"	means the period of time in which PHAS must place all of its orders of Pandemic Vaccine, as specified in article 8.1.2.
"Pandemic Declaration"	means a pandemic declaration by the WHO, or any other official communication from WHO stating global outbreak of pandemic influenza, or where any of the Specific Pandemic Criteria is verified.
"Pandemic Facilities"	means the facilities used to perform the obligations of this APA, as described in Appendix 1.
"Pandemic Period"	means the time period from Pandemic Declaration until the start of the Post-pandemic Period.
"Pandemic Vaccine"	means the Supplier's future strain-matched pandemic influenza vaccine in prefilled syringes, as described in the Specifications.
"PHAS Production Percentage"	means the percentage of the Supplier's Total Weekly Production Capacity that will be allocated to PHAS throughout the Delivery Period.
"Post-pandemic Period"	means the time period following a Pandemic Period when influenza disease activity will have returned to levels normally seen for seasonal influenza worldwide or (i) WHO declares the Pandemic to be over, or (ii) otherwise officially communicates the end of the Pandemic, or (iii) where any of the Specific Post-pandemic Criteria is verified.
"Preliminary Delivery Plan"	means the written estimated time schedule for delivery of the Pandemic Vaccine to PHAS, which shall be within the time limits of first and last delivery as set forth in the Production Time Schedule, if applicable adjusted according to article 8.4 below. The Preliminary Delivery Plan shall include details of the estimated dates for delivery and the estimated number of Doses to be delivered each week.
"Preparedness Fee"	means the fee that PHAS shall pay to the Supplier for pandemic preparedness, in accordance with article 5 and Appendix 3 below.

"Production Switch"	means (i) the process of switching from the Supplier's seasonal influenza and pre-pandemic vaccine production at the Pandemic Facilities to production of the Pandemic Vaccine, and (ii), in the situation described in article 23, the process of switching from the Supplier's Pandemic Vaccine production to production of a pandemic vaccine from a different strain; as further described under article 7 below.
"Production Time Schedule"	means the written time schedule for production and delivery of the Pandemic Vaccine, and includes first and last delivery of the Pandemic Vaccine to PHAS, in accordance with article 5.2.
"Reduction Notice"	has the meaning defined in article 8.1.7.
"Reserved Volume"	means 8,900,000 (eight million and nine hundred thousand) Doses, which is the number of Doses reserved by PHAS, and which (subject to article 8.1.4) shall be reserved during the term of this APA) and is based on the assumption that two Doses are required per person.
"Specific Pandemic Criteria"	means: (i) the same virus has caused sustained community level outbreaks in two or more countries in different WHO regions as verified by WHO or national reference laboratories, and where severity is confirmed greater than or equal to United States CDC category 2; or (ii) there is an announcement by WHO of a positive recommendation on whether and when to move production to Pandemic Vaccine and the virus strain that should be used in the Pandemic Vaccine; or (iii) each and every government or governmental agency (as applicable) which has entered into an agreement similar to this APA with the Supplier agrees to declare a pandemic emergency.
"Specific Post-pandemic Criteria"	means: (i) termination of the Public Health Emergency of International Concern (PHEIC) previously issued by WHO; or (ii) modification or termination by WHO of temporary measures; or (iii) termination by the EU Commission of public health emergency under Article 12 of Decision 1082/2013/EU; or (iv) the pandemic virus strain has been included within normal seasonal influenza vaccine production.
"Specifications"	means the written specifications for the Pandemic Vaccine as set out in Appendix 2 and as updated or replaced in accordance with this APA and subject to any modifications, improvements or extensions necessary in order to comply with Variations or directives and/or instructions of WHO or the Competent Regulatory Authority.

"Temporary Authorisation"	means an authorisation issued by the Swedish Medical Products Agency under Chapter 4, Section 10, second paragraph, of the Swedish Act on Medical Products (Sw. <i>Läkemedelslagen</i> (2015:315)), as amended from time to time, or any other similar agreement by the Swedish Medical Products Agency legally allowing the Supplier to put the Pandemic Vaccine on the market in Sweden without a full and up-to-date Marketing Authorisation.
"Total Weekly Production Capacity"	means the Supplier's total, weekly bulk Pandemic Vaccine production at its Pandemic Facilities.
"Total Purchase Price"	means the price to be paid by PHAS for the Pandemic Vaccine as ordered under article 8 below, adjusted for any cancellations or reductions in accordance with article 13.
"Variations"	means such variations to the Marketing Authorisation for the Pandemic Vaccine as may be required by Commission Regulation (EC) No 1234/2008 as amended from time to time.
"WHO"	means the World Health Organization.

3. SUPPLY OF PANDEMIC VACCINE

- 3.1. The Supplier shall (i) reserve production capacity for supply of the Reserved Volume of the Pandemic Vaccine to PHAS, and (ii) offer to supply and to sell to PHAS the Pandemic Vaccine in accordance with PHAS' orders, both (i) and (ii) subject to the terms and the conditions set forth in this APA.

4. COMPLIANCE

- 4.1. The Supplier shall ensure that the Pandemic Vaccine is manufactured, controlled and delivered, and that agreed documentation is submitted, in accordance with the Specifications, Good Manufacturing Practice, Good Distribution Practice, Good Pharmacovigilance Practice and all applicable legal requirements of Sweden, and in accordance with the approval of the Competent Regulatory Authority.

The Supplier shall ensure that 1) the ILO and UN Core Conventions on labour rights, 2) the national laws regulating labour rights and working environment of the production country, 3) the UN Universal Declaration of Human Rights, and 4) the national and international environmental laws are respected during the manufacturing process of the Pandemic Vaccine. The Supplier shall safeguard that these provisions (1-4) are adhered to where Pandemic Vaccine is manufactured.

- 4.2. If any breach of the above article 4.1 is discovered, the Supplier shall notify PHAS, and shall submit a description of the measures the Supplier will apply to remedy such breach.

5. SUPPLY PREPAREDNESS

- 5.1. During the term of this APA, including any Post-pandemic Periods, but excluding the Delivery Period, the Supplier shall reserve production capacity for supply exclusively to PHAS for the Reserved Volume, with an estimated delivery time for full delivery from Production Switch in accordance with the Production Time Schedule and article 7 below. During the Delivery Period, the obligation in the preceding sentence shall apply to the PHAS Production Percentage.

- 5.2. The Production Time Schedule is set forth in this article 5.2:

- 5.2.1. The first delivery shall be made by the later of (a) [REDACTED] weeks following seed virus receipt by the Supplier and (b) the earlier of [REDACTED] weeks following receipt by the Supplier of all reagents necessary for the manufacturing of the Pandemic Vaccine and the decision to use an alternative release methodology for such manufacturing. Subject to article 12.5, the total delivery to PHAS is expected to be completed [REDACTED] weeks after the first delivery.
- 5.2.2. Delivery timings are estimated based on the average output of the Supplier's actual experienced outputs (bulk yield) for pandemic strain (H1N1pnd09) using the same production methods as for the Pandemic Vaccine.
- 5.2.3. Delivery timings are independent of regulatory approval status. If a Marketing Authorisation or approval of Variations is not yet available at the time the Pandemic Vaccine is otherwise available for delivery, shipment may be made by the Supplier under quarantine in accordance with article 15.3.

- 5.3.** PHAS shall pay annually to the Supplier a Preparedness Fee in accordance with Appendix 3. The Preparedness Fee will be suspended during an actual Pandemic Period by being reduced in relation to the number of days during the calendar year concerned which is a Pandemic Period. The Preparedness Fee for the first calendar year during the term of this APA shall be reduced in relation to the number of days during which this APA is not in force and shall be paid within thirty (30) days of the Effective Date.
- 5.4.** The Preparedness Fee shall cover all expenses that are necessary in order to maintain readiness for the manufacturing of Pandemic Vaccine reserved for supply to PHAS under article 5.1 above, including but not limited to expenses related to the readiness of manufacturing sites, maintaining a relevant Marketing Authorisation, upholding GMP facility requirements, risk assessments, including evaluation of strains, technical variations, transportation arrangements, satisfactory investments in equipment and facilities maintenance, safety updates, readiness for potential clinical trial requirements, and maintaining staff capabilities and competence. The Preparedness Fee shall constitute the Supplier's only compensation for maintaining supply preparedness under article 5.1 above.
- 5.5.** The Supplier shall ensure and maintain the required preparedness throughout the term of this APA, and shall not make any changes to the Pandemic Facilities that may have any adverse impact on the supply preparedness, production and supply of Pandemic Vaccine in accordance with this APA without the prior written consent from PHAS. The Supplier shall refrain from committing itself to produce Pandemic Vaccine pertaining to more than 100 % of its estimated Total Weekly Production Capacity.
- 6. INSPECTIONS, AUDITS AND REPORTS**
- 6.1.** Subject to PHAS' prior written notice of no less than six (6) weeks, PHAS shall have the right to inspect or audit the Pandemic Facilities, either as an inspection at the Pandemic Facilities during normal working hours on any Business Day, or as a document audit, as chosen by PHAS, against the requirements specified in this APA. Each party shall bear its own costs related to such inspections.
- 6.2.** Each year during the term of this APA, the Supplier shall report in writing to PHAS its fulfilment of the requirements specified in this APA, including reports on clinical trials and safety data reports and any other data as reasonably requested by PHAS. Unless otherwise agreed in writing, the first report shall be submitted to PHAS on June 30, 2016, and thereafter submitted the same date each year.
- 6.3.** During the term of this APA, the Supplier shall on a quarterly basis report in writing the main aspects on how the supply preparedness under article 5 above will be maintained for the following three (3) months. The first report shall be submitted four (4) weeks following the Effective Date. Following submission of such report, PHAS may request a meeting between the parties, to be held face-to-face or by telephone, videolink or other appropriate means as agreed by the Parties, in order to further assess and discuss the pandemic preparedness. PHAS' request shall be submitted to the Supplier at least three (3) weeks prior to the requested date. The place for face-to-face meetings shall be decided by PHAS. Each party shall bear its own costs related to such meetings.
- 7. PRODUCTION SWITCH PROCESS, START OF PRODUCTION OF PANDEMIC VACCINE**

- 7.1. Unless otherwise agreed in writing, and provided that the Supplier has not switched the manufacturing production from its seasonal influenza vaccine and/or pre-pandemic vaccine to production of the Pandemic Vaccine at the Pandemic Facilities at an earlier stage at the Supplier's discretion, the Supplier is obliged to make the Production Switch without undue delay after Pandemic Declaration or availability of seed virus strain suitable for the Supplier's production of Pandemic Vaccine, whichever is the latest.
- 7.2. After completion of the Production Switch, the Supplier shall use All Reasonable Efforts to start manufacturing the Pandemic Vaccine without undue delay. The Supplier is not obliged to commence actual production of Pandemic Vaccine especially for PHAS until a Firm Order has been placed by PHAS.
- 7.3. The Supplier shall use All Reasonable Efforts to manufacture the Pandemic Vaccine without undue delay and within the time limits set forth in the Production Time Schedule including any later adjustments of the time limits in accordance with article 8 and article 12.5 below.

8. ORDERS, TIME SCHEDULES, PHAS PRODUCTION PERCENTAGE

8.1. Orders

- 8.1.1 PHAS shall place any order for Pandemic Vaccine in writing, quantifying the number of Doses, in accordance with the provisions of article 8.1.2 to 8.1.9 inclusive. As set forth in the definition of Pandemic Vaccine, all Doses shall be in prefilled syringes, subject to the following.

8.1.1.1 Should at the scheduled delivery time the full number of Doses in prefilled syringes ordered by PHAS not be available for Supplier to deliver, then the Supplier shall without unreasonable delay inform PHAS thereof and PHAS shall have the option to accept the missing number of Doses of Pandemic Vaccines to be delivered in multi-dose vials in a sufficient number to replace those Doses ordered in prefilled syringes. Should PHAS not accept such option then Supplier shall deliver the Pandemic Vaccine in prefilled syringes in accordance with a Delivery Plan adjusted to reflect the Supplier's expected ability to deliver such prefilled syringes to PHAS.

8.1.1.2 At the written request of PHAS to Supplier, an equivalent number of Doses originally ordered by PHAS in prefilled syringes will instead be supplied to PHAS in multi-dose vials should such equivalent number of Doses be available for allocation to PHAS by the Supplier in multi-dose vials with the same or an approximately similar delivery schedule and with the appropriate packaging and labeling.

- 8.1.2. PHAS Option to Order the Pandemic Vaccine:

If PHAS decides to order Pandemic Vaccine in accordance with this article 8.1, it may determine the number of Doses to be delivered, provided that the first Firm Order placed shall be for at least [REDACTED] Doses of the Reserved Volume and the aggregate of all orders placed may not exceed the Reserved Volume. PHAS shall be deemed to have validly placed an order for the Pandemic Vaccine if such order has been placed by PHAS and received by the Supplier's order department during the time period from the day of the Pandemic Declaration to midnight (Swedish time) of the [REDACTED] calendar day following the Pandemic Declaration (the "Order Period"). An order only becomes binding: (i) upon expiry of the Order Period, or (ii) if PHAS prior to expiry of the Order Period declares the order as binding in writing ("Firm Order"). Any obligation of the Supplier to supply Pandemic Vaccine to PHAS shall only become effective and due upon an order becoming a Firm Order. Such a Firm Order may only be increased or reduced in accordance with this article 8 and article 13 below.

Within the Order Period and without any compensation to the Supplier, PHAS may revoke entirely, increase or reduce its order within its Reserved Volume, providing such order is not a Firm Order.

The Supplier shall inform PHAS from time to time of the contact details of its order department for purposes of placing orders.

8.1.3. Non-Binding Orders:

For the avoidance of doubt no order (i) issued before or after the Order Period, or (ii) to the extent it exceeds, alone or in aggregate with all other orders hereunder, a quantity greater than the Reserved Volume; will be binding on the Supplier. If the first order placed by PHAS is for a quantity lower than [REDACTED] Doses it will not be binding on the Supplier. With respect to such an order placed by PHAS or any such order as mentioned under (i) or (ii) above, the Supplier shall consider these but shall be under no obligation whatsoever to accept any such order.

8.1.4. Volume Release:

Upon expiry of the Order Period, the Supplier' obligations hereunder to reserve on behalf of PHAS the capacity required to manufacture the Reserved Volume, and PHAS' obligation to pay the Preparedness Fee, shall be suspended until commencement of a subsequent Post-Pandemic Period. For the avoidance of doubt, PHAS acknowledges that the Supplier may offer and supply any Doses within the Reserved Volume which are not Firm Orders, or any Doses (relating to a Firm Order) which have been cancelled by PHAS and where no request has been made by PHAS to donate such doses to WHO as described in article 13.3, to any third party whatsoever at its sole discretion.

8.1.5. Increase due to change in the number of doses required for immunisation:

In accordance with what is stated in article 8.1.3, the Supplier shall not be obligated to accept any order that exceeds the Reserved Volume. Without prejudice to such overall limitation, the Supplier shall take any order from the PHAS in excess of the Reserved Volume into consideration should the Competent Regulatory Authority advise PHAS that the Supplier's efficacy data requires an increased number of Doses of the Pandemic Vaccine per patient in place of the number of Doses per patient recommended at the time of the Firm Order. The Supplier will balance any such excess order against the availability at the time of Pandemic Vaccine with the Supplier, its manufacturing capacity of the Pandemic Vaccine, Supplier's commitments to supply the Pandemic Vaccine to other customers and any other relevant factors and review whether there is potential for delivering such excess number, or part of it, of Doses to PHAS, but, for the avoidance of doubt, with no obligation to deliver any order which, alone or in aggregate with all other orders hereunder, exceeds the Reserved Volume and no such delivery would be subject to delivery timelines otherwise set forth under this APA.

8.1.6. Reduction due to change in number of doses required for immunisation:

PHAS shall be entitled to reduce a Firm Order by serving written notice on the Supplier if the Competent Regulatory Authority advises PHAS that the Supplier's data supports the efficacy of a reduced number of Doses of the Pandemic Vaccine per patient in place of the number of Doses per patient recommended at the time of the Firm Order. Any such reduction in the volume shall be no greater than the number of Doses rendered unnecessary due to the implementation of the new dosage regime going forward and such reduction notwithstanding PHAS will still have to order at least [REDACTED] Doses in aggregate.

Any such reduction in the volume pursuant to this article 8.1.6 shall be prorated across the remaining Doses specified in the Delivery Plan and thereby the percentage of the weekly

production allocated to Sweden and the PHAS Production Percentage shall be reduced going forward accordingly.

Payments due are [REDACTED] of the purchase price for Doses ordered but not delivered and not scheduled for delivery during the five week period following the cancellation notification date. For the avoidance of doubt, [REDACTED] of the purchase price would be due for all other Doses.

8.1.7 Reduction due to adverse reactions:

PHAS shall be entitled to reduce a Firm Order by serving written notice on the Supplier ("**Reduction Notice**") if, in connection with the use of the Pandemic Vaccine, there are independent reports of adverse reactions to the Pandemic Vaccine other than such adverse reactions as specifically described in the Summary of the Product Characteristics and (i) the number of reports suggest that the adverse effect is either common (affecting >1/100 vaccinated) or at least uncommon (affecting >1/1000 vaccinated) and (ii) such adverse reactions are established through Best Evidence as adverse reactions to the Pandemic Vaccine with a serious effect on human health.

Any such reduction in the ordered volume shall be no greater than the number of Doses rendered unnecessary due to the change in the recommendation or the Marketing Authorisation going forward.

Any such reduction in the volume pursuant to this article 8.1.7 shall be prorated across the remaining Doses specified in the Delivery Plan and thereby the PHAS Production Percentage shall be reduced going forward accordingly.

Should the Competent Regulatory Authority at the same time as the communication to PHAS of such Best Evidence as mentioned above in this article 8.1.7, or thereafter, confirm such Best Evidence in the population concerned, then payments due are [REDACTED] of the purchase price for Doses ordered but not delivered and not scheduled for delivery during the five week period following the date of the Reduction Notice. For the avoidance of doubt, [REDACTED] of the purchase price would be due for all other Doses, including for all Doses after the Reduction Notice unless the Competent Regulatory Authority confirms the Best Evidence concerned.

8.1.8 Cancellations for reasons other than those covered above in this article 8.1 of Doses ordered under a Firm Order are permitted, provided, however, that the full purchase price would be due and payable.

8.1.9 Consecutive cancellation events are permitted under the terms set out above.

8.2 The Supplier shall confirm each Firm Order in writing within five (5) Business Days of the day it becomes a Firm Order.

8.3 The Supplier shall submit a Preliminary Delivery Plan to PHAS no later than eight (8) weeks after Pandemic Declaration provided that a Firm Order has been placed by PHAS. The time limits of the Preliminary Delivery Plan shall be in accordance with the time limits of the Production Time Schedule (first and last delivery date) provided that the following presumptions are met:

- 1) calibrated reagents are received within four (4) weeks after Pandemic Declaration;

- 2) the production output corresponds with the average output of the Supplier's actual experienced outputs (bulk yield) for pandemic strain (H1N1pnd09) by use of the same production methods as for the ordered vaccine;
- 3) Competent Regulatory Authorities do not require any clinical tests, in addition to the tests already required in the strain variation guidelines; and
- 4) the amount of antigen required for each Dose as determined by clinical study does not exceed 7.5 microgrammes.

- 8.4** In the event that the Supplier is unable to meet the delivery dates in the Production Time Schedule due to failure of any of the presumptions above, or any other event outside the Supplier's reasonable control, the Supplier shall use All Reasonable Efforts to notify PHAS without undue delay. Subject to the Supplier's notification, the timelines of the Preliminary Delivery Plan will be extended accordingly. If the Supplier in such an event is unable to provide the Preliminary Delivery Plan within eight (8) weeks after Pandemic Declaration, the Preliminary Delivery Plan shall be submitted as soon as possible and without undue delay.
- 8.5** No later than three (3) weeks prior to the first delivery date according to the Preliminary Delivery Plan, the Supplier shall submit the Delivery Plan to PHAS in writing. PHAS may place additional orders after the end of the Order Period within its Reserved Volume on the terms and conditions of this APA, provided however that the Supplier has uncommitted Pandemic Vaccine available within its estimated Total Weekly Production Capacity, in which case the Supplier shall confirm the order without undue delay (following which it shall be deemed to be a "Firm Order") and update the Delivery Plan.
- 8.6** The PHAS Production Percentage shall be calculated at the end of the Order Period by dividing one [REDACTED] of the ordered volume under Firm Orders of Pandemic Vaccine by the Total Weekly Production Capacity of the Supplier at the Pandemic Facilities multiplied by one hundred (100).
- 8.7** The PHAS Production Percentage, as stated in the Preliminary Delivery Plan, shall, unless otherwise agreed, be firm throughout the Delivery Period. The foregoing sentence is subject to the provisions of article 8.3 and article 13.2.

9 SHIPPING AND DELIVERY

- 9.1** The Supplier shall ship and deliver the Pandemic Vaccine in accordance with the GDP guidelines as ordered by PHAS, [REDACTED] to the address in Sweden as chosen by PHAS as set out in Appendix 4, which address may be changed by the Parties' mutual written agreement.
- 9.2** The Supplier shall deliver the Pandemic Vaccine to PHAS within the time limits set forth by the Supplier in the Delivery Plan with any later adjustments in writing in accordance with this APA.
- 9.3** With each Pandemic Vaccine shipment, the Supplier shall provide the documentation and temperature monitoring devices as are necessary for PHAS' control against the requirements of this APA. This includes the Certificate of Analysis (CoA), EU batch release certificate and a copy of the "official control authority batch release" from the Swedish Medical Products Agency for the batch(es) included in the shipment, unless PHAS approves otherwise in writing and provided that such documents have not been submitted earlier.

- 9.4** On receiving the Pandemic Vaccine shipment, PHAS shall perform a visual inspection of the transport packaging, and any temperature indicators which may be inspected without unpacking the consignment (i.e. on the outside of the transport packaging or in the vehicle). PHAS shall at the time of delivery notify the Supplier in writing of any apparent loss or damage to the carrier, and may refuse to accept Non-deliverable Pandemic Vaccine, as further set out in article 14 below.
- 9.5** Within seven (7) Business Days, PHAS shall notify the Supplier in writing about deviations concerning temperature logged by the monitoring devices included in the transport boxes and quantum discrepancies between what has been delivered and the order. PHAS may refuse to accept Non-deliverable Pandemic Vaccine, as further set out in article 14 below.
- 9.6** PHAS shall have ten (10) Business Days from the date of receipt of the Pandemic Vaccine shipment and the documentation to inspect the Pandemic Vaccine against the requirements of this APA. PHAS may refuse to accept Non-deliverable Pandemic Vaccine, as further set out in article 14 below, and any notice of rejection must be given in writing and received by the Supplier within the same 10-day period, or the shipment will be deemed to have been accepted.

10 RISK OF LOSS, TITLE ETC

- 10.1** Risk of loss and title to the Pandemic Vaccine shall be transferred to PHAS upon receipt by PHAS of each shipment at the agreed place of delivery, in accordance with article 9.1 above, without prejudice to PHAS' right to refuse acceptance of the Pandemic Vaccine in accordance with articles 9.4, 9.5 and 9.6 above.
- 10.2** Upon PHAS' written request after delivery, the Supplier shall provide all necessary information, labels or product inserts of Pandemic Vaccine that may be required by a Competent Regulatory Authority.

11 PRICES AND PAYMENT

- 11.1** PHAS shall pay for the Pandemic Vaccine in accordance with Appendix 3. The prices are listed exclusive of value added tax.
- 11.2** All prices shall be quoted and all payments under this APA shall be made in Swedish Krona (SEK) with payment terms of thirty (30) calendar days upon receipt of invoice from the Supplier.
- 11.3** The Supplier shall invoice PHAS upon shipment according to article 9.1, i.e. upon each delivery of the Pandemic Vaccine as ordered by PHAS to the address in Sweden as chosen by PHAS and set out in Appendix 4 (or as changed by the Parties' mutual written agreement).
- 11.4** If a Party is late in making any payments under this APA, such Party shall pay interest according to Section 6 of the Swedish act on interest (*Sw. Räntelagen (1975:635)*).

12 DELAYED DELIVERY OR NON-DELIVERY

- 12.1** If the Supplier becomes aware, or ought to have been aware, that it will be unable to produce or deliver the Pandemic Vaccine as ordered by PHAS in accordance with the Delivery Plan, the Supplier shall notify PHAS in writing without undue delay. If the Supplier fails to give such

notification, the Supplier shall cover all expenses incurred by PHAS as a consequence of the late notification, regardless of the reason for the delayed delivery.

- 12.2** If the total volume of Pandemic Vaccine ordered under article 8 has not been delivered within the last delivery date in accordance with the Delivery Plan, the Supplier shall be obliged to pay liquidated damages of █ percent (█) per week of the purchase price for the Doses that are delayed until such damages have reached █ percent (█) of the Total Purchase Price of such Doses.
- 12.3** If the Supplier has been obliged to pay liquidated damages for █ weeks or more in accordance with article 12.2 above, or if it is apparent that the Supplier will be unable to deliver parts of the ordered Pandemic Vaccine within the same time period, PHAS may at its sole discretion decide whether PHAS will accept or cancel whole or parts of any later delivery of Pandemic Vaccine.
- 12.4** A cancellation by PHAS in accordance with article 12.3 shall not under any circumstance be subject to any fees or additional payments by PHAS.
- 12.5** Without prejudice to article 22, the Supplier's delay due to an event of Force Majeure, to the extent such event affects the Supplier's ability to manufacture or deliver the Pandemic Vaccine, shall not be considered a delay under this APA. The last delivery date as estimated in the Delivery Plan shall be postponed accordingly.

13 CANCELLATION AND DONATIONS

- 13.1** PHAS may cancel a Firm Order on the conditions set out in article 8.
- 13.2** In case of cancellation, the Supplier shall implement the cancellation into the Delivery Plan according to article 8.
- 13.3** In order to provide an equitable geographical distribution of Pandemic Vaccine, any Doses cancelled under this article 13 that PHAS is obliged to pay full purchase price for, may at PHAS' request be offered to be donated to the WHO provided that satisfactory arrangements regarding regulatory, legal, indemnification, pharmacovigilance and quality aspects can be secured with WHO, and provided that any such arrangements concern no less than █ Doses to be so donated. The Supplier shall not have any liability for any failure to agree such terms with WHO and in the event terms cannot be agreed with WHO, PHAS shall continue to be responsible for paying the purchase price for any such Doses which could not be delivered to WHO, subject to any rights of cancellation PHAS may have pursuant to this APA. Should any Doses be reallocated to WHO in accordance with this article 13.3, the purchase price of such Doses as well as any additional cost associated with the reallocation shall in all events be borne by PHAS. PHAS may exercise this option in respect of Firm Orders at any time upon written notice to the Supplier.

14 NON-DELIVERABLE PANDEMIC VACCINE

- 14.1** Non-deliverable Pandemic Vaccine may be destroyed by PHAS unless the Supplier has collected such Pandemic Vaccine within 14 calendar days of having been informed by PHAS that such Pandemic Vaccine will be destroyed after said deadline.

- 14.2** The Supplier shall reimburse PHAS for all reasonable expenses related to Non-deliverable Pandemic Vaccine including but not limited to the costs of such Pandemic Vaccine (provided any payments have been made), transportation costs to or from PHAS' customers, costs related to recall, costs related to destruction or return of such Pandemic Vaccine and man-hours at PHAS.

PHAS is to receive all reimbursements due hereunder within 3 months after PHAS has put forward its claim, failing which PHAS shall be paid interest on any monies outstanding at the current rate of interest payable to them, until such time as an actual payment is made.

- 14.3** The Supplier shall use All Reasonable Efforts to replace Non-deliverable Pandemic Vaccine within reasonable time limits unless otherwise requested by PHAS in writing. If the Supplier fails to use All Reasonable Efforts to replace the Pandemic Vaccine within a reasonable time limit, PHAS may cancel the delayed Pandemic Vaccine without any cost for PHAS. Such Non-deliverable Pandemic Vaccine, that has not been replaced by the Supplier and that has not been cancelled by PHAS under this article 14 within the last delivery date as set forth in the Delivery Plan, shall be subject to the provisions of articles 12.2 to 12.5 (inclusive) above.

15 DELIVERY OF PANDEMIC VACCINE WITHOUT REGULAR AUTHORISATIONS

- 15.1** After the Production Switch, and subject to PHAS' written request, the Supplier may accept to deliver Pandemic Vaccine to PHAS in accordance with a Temporary Authorisation, regardless of a possible absence of a Marketing Authorisation for the Pandemic Vaccine, or a possible absence of approval of necessary Variations by the Competent Regulatory Authority, provided however that such supply is not in conflict with any applicable laws or regulations the Supplier is subject to.
- 15.2** To the extent that the Supplier is not fully covered by the Pharmaceutical Insurance scheme referred to under article 20 (meaning that such insurance scheme does not make actual payments in full, or does not release the Supplier, for any reason) for losses, costs or damages that the Supplier may be held liable for under the Swedish Torts Act (Sw. skadeståndslagen (1972:207)) and the Swedish Product Liability Act (Sw. produktansvarslagen (1992:18)), and without prejudice to article 19.3, PHAS shall indemnify and hold harmless the Supplier against any liability, damages, penalties, fines, costs, expenses and other losses suffered or incurred by the Supplier resulting from or arising out of claims by the Competent Regulatory Authority, other authorities of Sweden and/or other third parties to the extent such claims, liability, damages, penalties, fines, costs, losses and/or expenses relate to the Supplier supplying the Pandemic Vaccine to PHAS either without Marketing Authorisation or without approval of necessary Variations in accordance with article 15.1.
- 15.3** If the Supplier rejects a request by PHAS in accordance with article 15.1 above, in the case of absence of Marketing Authorisation or approval of Variations, the Supplier may, upon PHAS' written request and without prejudice to article 19.1 below, accept to deliver the Pandemic Vaccine to a storage facility under PHAS' control. The Pandemic Vaccine will be under quarantine and will not be released by PHAS until the Marketing Authorisation or Variation is issued. Any additional, reasonable expenses the Supplier accrues as a result of such delivery (e.g. transportation, administration) shall be borne by PHAS.
- 15.4** Furthermore, the Supplier may, upon PHAS' written request and without prejudice to article 19.1 below, accept to deliver Pandemic Vaccine to a storage facility under PHAS' control prior to issuance of EU batch release certificate or the "official control authority batch release" from

the Medical Products Agency. Such Pandemic Vaccine will be under quarantine, and will not be released by PHAS, until such batch releases are issued. Any additional, reasonable expenses the Supplier accrues as a result of such delivery (e.g. transportation, administration) shall be borne by PHAS.

- 15.5** The Supplier shall upon receiving PHAS' written request in accordance with articles 15.1, 15.3 or 15.4 above, diligently assess the request based on a patient risk/benefit approach. The Parties shall in good faith agree on the specific details such deliveries shall be subject to.

16 SUBCONTRACTORS

The Supplier may appoint subcontractors to carry out its obligations under this APA, provided that (i) the Supplier shall be solely responsible for such subcontractors' compliance with the provisions of this APA, and (ii) should the Supplier at any time appoint a subcontractor as responsible for transportation of the Pandemic Vaccine to the address set forth in article 9.1, other than subcontractors that are appointed on the Effective Date, the Supplier shall promptly notify PHAS in writing about such subcontractor.

17 INFORMATION AND SUPPORT

- 17.1** The Supplier shall without undue delay loyally inform PHAS in writing about changes regarding the Marketing Authorisation for the Pandemic Vaccine and other matters that PHAS has a legitimate interest in having knowledge about.
- 17.2** Specifically, the Supplier shall without undue delay notify PHAS in writing if the Supplier becomes aware or should reasonably have become aware of a clustering of actual or suspected serious adverse events in connection with the Pandemic Vaccine. For the avoidance of doubt, this article 17.2 shall apply without prejudice to any other obligation under Swedish law or decisions or guidelines from a Competent Regulatory Authority to notify of adverse events that the Supplier is subject to for the Pandemic Vaccine.
- 17.3** The Supplier shall email any information under article 17.2 to Salumeh Bastami (salumeh.bastami@folkhalsomyndigheten.se).
- 17.4** The obligations of this article 17, as well as any obligations to provide technical support under Appendix 5, shall rest with the Supplier for the total shelf life of the Pandemic Vaccine supplied to PHAS.

18 INTELLECTUAL PROPERTY RIGHTS

PHAS recognizes the Supplier's and/or any third party's right, title and interest in and to all Intellectual Property.

19 WARRANTIES, INDEMNITIES AND LIMITATION OF LIABILITY


- 19.1** The Supplier warrants that:

- 19.1.5** The Pandemic Vaccine will, at the time of delivery, comply with the standards and specifications in the Marketing Authorisation for the Pandemic Vaccine. If delivery is made

under article 15.1 above, the Pandemic Vaccine will, at the time of delivery, comply with the standards and specifications in the Temporary Authorisation.

- 19.1.6 The Pandemic Vaccine is manufactured, controlled and delivered, and that agreed documentation is submitted, in accordance with the Specifications, Good Manufacturing Practice, Good Distribution Practice, Good Pharmacovigilance Practices and all applicable legal requirements under the Swedish Act on Medicinal Products (Sw. *Läkemedelslagen (2015:315)*), and in accordance with the approval of the Competent Regulatory Authority.
- 19.1.7 It has the necessary facilities, equipment, know-how, procedures and personnel to perform its obligations in compliance with this APA.
- 19.1.8 It will not during the term of this APA enter into any agreement under which the Supplier owes any obligation to a third party that would be in conflict with the Supplier's obligations under this APA.
- 19.2 The Supplier shall indemnify and hold PHAS harmless from all losses, costs and damages that the Supplier may be held liable for under the Swedish Torts Act (Sw. *skadeståndslagen (1972:207)*) and the Swedish Product Liability Act (Sw. *produktansvarslagen (1992:18)*), to the extent that such losses are fully covered by the Pharmaceutical Insurance scheme referred to under Article 20 below (meaning that such insurance scheme makes actual payments in full and the Supplier is released).
- 19.3 Furthermore, the Supplier shall indemnify and hold PHAS harmless from all losses, costs and damages caused by the Pandemic Vaccine not being manufactured in accordance with GMP or with the Specifications, or transportation not being organised in accordance with GDP prior to delivery to PHAS.
- 19.4 Moreover, the Supplier shall indemnify and hold PHAS harmless from all losses, costs and damages, which are caused by wilful misconduct or gross negligence by the Supplier.
- 19.5 To the extent that the Supplier is not fully covered by the Pharmaceutical Insurance scheme referred to under article 20 below (meaning that such insurance scheme does not make actual payments in full, or does not release the Supplier, for any reason) for losses, costs or damages that the Supplier may be held liable for under the Swedish Torts Act (Sw. *skadeståndslagen (1972:207)*) and the Swedish Product Liability Act (Sw. *produktansvarslagen (1992:18)*), and without prejudice to article 19.3 above, PHAS shall indemnify and hold the Supplier harmless from all losses, costs and damages, which are related to the use and administration of the Pandemic Vaccines, including losses, costs and damages related to safety, characteristics or efficacy of the Pandemic Vaccine. PHAS shall also indemnify the Supplier for all losses, costs and damages that are caused by the product not being in compliance with its Specifications if this ought to have been discovered by PHAS' inspections in accordance with articles 9.4 to 9.6 above and for all losses, costs or damages that are attributable to PHAS' or any other governmental authority's or any of its or their suppliers' or agents' handling of the Pandemic Vaccine.
- 19.6 The Supplier shall be liable for and indemnify PHAS against any claim, including costs for necessary legal assistance, arising out of any actual or suspected infringement of any third-party Intellectual Property as a result of PHAS' possession or distribution of the Pandemic Vaccine, provided that PHAS as soon as possible provides written notice to the Supplier of the initiation of any action or proceeding that may reasonably lead to a claim of indemnification.

19.7 Neither Party shall be liable for any indirect, incidental, special or consequential damages, including loss of profits, revenue, production, reputation, data or use, incurred by the other Party or for damages or losses beyond what is set forth in article 15.2 and this article 19.



19.9 Both Parties shall notify the other Party in writing promptly of any claim upon which such party intends to base a request for indemnification under article 19. The Supplier shall have the right to solely conduct any negotiation and/or litigation with any person or party making a claim to which the indemnity under article 19.2, 19.3, 19.4 or 19.6 applies, and PHAS shall have the right to solely conduct any negotiation and/or litigation with any person or party making a claim to which the indemnity under article 15.2 or 19.5 applies, provided, however, that neither party when indemnifying the other shall be able to make a settlement of the case concerned without first having obtained prior written consent by the other party, such consent not to be unreasonably withheld. The Parties agree to collaborate in good faith and the indemnifying Party shall keep the other Party informed of the progress of the negotiation and/or litigation relating to the claim. The indemnified party shall, at the indemnifying party's request and expense, furnish such records, information and testimony as may be reasonably requested by the indemnifying party.

20 INSURANCE

The Supplier shall be a member of LFF Service AB or its successor and thus a member of the Swedish Pharmaceutical Insurance (Sw. *Läkemedelsförsäkringen*) and shall remain a member for the duration of this APA and during any deliveries of Pandemic Vaccine being made after the termination of this APA.

21 CONFIDENTIALITY

The Parties undertake to keep confidential during and after the term of this APA all electronic, oral or written communications from the other Party to the extent such communications are designated or should reasonably be regarded as constituting confidential information, trade secrets or proprietary information, and to use or disclose such information only as necessary to exercise a Party's rights or perform a Party's obligations under this APA. For the avoidance of doubt, this confidentiality clause shall not prevail to the extent PHAS has disclosure obligations according to the Swedish Freedom of Information and Secrecy Act (Sw. *Offentlighets- och sekretesslagen (2009:400)*) or to the extent PHAS has general obligations to inform the Swedish public on health issues.

22 FORCE MAJEURE

Neither Party shall be liable to the other Party for any failure to perform or delay in the performance of any obligation under this APA, to the extent such failure to perform or delay in performance is caused by an event of Force Majeure, provided that the Party whose performance is prevented or delayed by such event gives prompt written notice thereof to the other Party. For the avoidance of doubt, a Pandemic Declaration shall not per se be regarded

as a Force Majeure event. The Party whose performance is so prevented or delayed is required to take reasonable measures seeking to relieve and/or remove the circumstance causing the Force Majeure situation.

23 REPEATED PANDEMIC INFLUENZA

For the avoidance of doubt, all provisions of this APA shall apply to all Pandemic Periods occurring during the term of this APA. However, to the extent more than one Pandemic Period shall occur simultaneously, the Parties acknowledge that only one Pandemic Vaccine may be produced at a time and therefore, all obligations of Supplier with respect to the subsequent Pandemic Period shall be suspended until such time as Supplier acting diligently, can reasonably perform the Production Switch.

24 TERM AND TERMINATION

24.1 This APA shall enter into force on the Effective Date, and shall thereafter remain in force for a term of four (4) years, unless terminated earlier in accordance with article 24.2 or 24.3. Any Firm Orders made prior to termination of the agreement, shall be completed on the terms and conditions of this APA.

24.2 Notwithstanding article 24.1 above, this APA may be terminated by:

24.2.1 either Party in case a material breach of this APA has not been cured by the defaulting Party within 21 calendar days after receipt of written notice by the other Party; or

24.2.2 by PHAS in the event of an application of insolvency of the Supplier under applicable law.

24.3 Notwithstanding article 24.1 above, this APA may be terminated by PHAS if the Supplier for any reason loses the right to operate under the Marketing Authorisation for use of the Pandemic Vaccine in Sweden.

24.4 Termination of this APA does not relieve a Party of its obligations accrued prior to termination. The respective rights and obligations of the Parties under articles 19, 20 and 21 shall survive the termination or expiration of this APA.

25 ASSIGNMENT

This APA may neither in whole nor in part be assigned without the other Party's prior written consent, provided, however, that the Supplier may assign this APA (in whole or in part) to an Affiliate under the condition that the Supplier remains responsible for such Affiliate's compliance with the provisions of this APA, that PHAS receives written notice from the Supplier about such assignment and that the Affiliate to which this APA is assigned in whole or in part has the right, power and authority, and has taken all action necessary to, execute, deliver, exercise their rights and perform their obligations under this APA.

26 AMENDMENTS

Any amendment to the main part of this APA shall be made in writing, dated and signed by both Parties to be legally binding. Any amended Appendix shall be signed and dated by both Parties and shall replace the Appendix that required to be amended, and shall keep the same Appendix number.

27 PRIORITY

In the event of any conflict between the provisions of the main part of this APA and its Appendices, the wording of the former shall prevail.

28 GOVERNING LAW AND JURISDICTION

28.2 This APA shall be governed by the laws of Sweden, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this APA to the substantive law of another jurisdiction.

28.3 Any dispute arising out of or relating to the existence, validity or interpretation of this APA shall be settled in accordance with the Arbitration Rules of the Stockholm Chamber of Commerce. The arbitration procedures shall take place in Stockholm. The proceedings, including any outcome, shall be confidential. The language of the arbitration proceedings shall be English, unless otherwise agreed in writing.

29 INVOICES, REPORTS AND NOTICES

Any invoices, reports or notices under this APA shall be made in writing in English, and sent postage prepaid, return receipt requested, by overnight delivery or by email with confirmed receipt as follows:

To PHAS:	To the Supplier:
Public Health Agency of Sweden, FE 774, SE-838 74 Frösön, Sweden Attention: Salumeh Bastami E-mail: salumeh.bastami@folkhalsomyndigheten.se and anita.lundin@folkhalsomyndigheten.se	Seqirus UK Limited 100 New Bridge Street, London, UK EC4V 6JA Attention: [REDACTED] E-mail: [REDACTED] and [REDACTED]

* Orders shall be placed in accordance with article 8.

** Information on drug reaction shall be sent in accordance with article 17.3 above.

30 APPENDICES

- Appendix 1** Pandemic Facilities
- Appendix 2** Specifications
- Appendix 3** Price list, including Preparedness Fee
- Appendix 4** Delivery addresses
- Appendix 5** Service and technical assistance

31 SIGNATURES


In witness whereof, the Parties hereto, through their authorized representatives, have executed this APA whereby they evidence their intent to be legally bound.

31 SIGNATURES

In witness whereof, the Parties hereto, through their authorized representatives, have executed this APA whereby they evidence their intent to be legally bound.

Signed for and on behalf of
The Public Health Agency of Sweden

Signed for and on behalf of
Seqirus UK Limited

By: 
Signature

By: 
Signature

Name **JOHAN CARLSON**
Position **Director General**
Place and date *Solna, Sweden 22 April 2016*

Name *Gordon Naylor*
Position *Director*
Place and date *20 April 2016*

By: 
Signature

Name *Ken Lim*
Position *Secretary*
Place and date *20 April 2016*

APPENDIX 1 – PANDEMIC FACILITIES

Supplier is using its facilities in Liverpool, England as the bulk manufacturing site for the Pandemic Vaccine.

The site is approved by the local authorities and holds a product license for at least one product licensed in the US and one product licensed in Europe. The site is licensed for supply of seasonal influenza vaccines in the EU.

Manufacturing site Liverpool, England:

MHRA SITE NUMBER: 29956
SITE NAME: SEQIRUS VACCINES LTD

ADDRESS:
GASKILL ROAD, SPEKE,
LIVERPOOL, MERSEYSIDE,
L24 9GR, UNITED KINGDOM

Storage sites Liverpool, England:

MHRA SITE NUMBER: 29956
SITE NAME: SEQIRUS VACCINES LTD

ADDRESS:
GASKILL ROAD, SPEKE,
LIVERPOOL, MERSEYSIDE,
L24 9GR, UNITED KINGDOM

6963 ALLOGA UK LIMITED

AMBER PARK 1, 2 AND 3, BERRISTOW
LANE, SOUTH NORMANTON,
ALFRETON,
DERBYSHIRE, DE55 2FH,
UNITED KINGDOM

APPENDIX 2 – SPECIFICATIONS

APPENDIX 3 – Price List, including Preparedness Fees

Pandemic Vaccine

The Pandemic Vaccine purchase price is [REDACTED] per Dose delivered [REDACTED], excluding VAT.

Preparedness Fee per year

The annual Preparedness Fee shall be [REDACTED] per Dose excluding VAT.

The total amount due per year reserved is calculated on the basis of the Reserved Volume multiplied by the applicable Preparedness Fee per Dose. The amount of Preparedness Fee is to be paid annually in advance.

(As set forth in article 5.3, the Preparedness Fee will be suspended during an actual Pandemic Period.)

APPENDIX 4 – DELIVERY ADDRESS

[insert details]

APPENDIX 5 – Information on availability of support and technical assistance relating to the vaccine's pharmaceutical quality; description of routines, capacity, response times, language etc. regarding handling of inquiries (by phone, email etc.)

Pharmacovigilance

Novartis Vaccines and Diagnostics Ltd. (NVD), owned by Seqirus UK Ltd, has established a pharmacovigilance system for the collection and notification of any adverse events and coordination of risk-minimization measure in accordance with EU regulatory requirements. Specifically, NVD Pharmacovigilance is responsible for the collection, processing and reporting of post-marketing adverse event (AE) reports from all sources (spontaneous, authorities, literature, non-interventional organized data collection schemes) for the products registered by Novartis Vaccines Influenza SRL, Siena, Italy (NVI SRL) as the Market Authorization Holder. NVI SRL is owned by Seqirus UK Ltd.

NVD Pharmacovigilance is processed by:

Scratch Pharmacovigilance GmbH, Schlossstr. 25, 35510 Butzbach, Germany; www.scratch-pv.com;

Phone: +49 (0) 6033 74 53 55 - 0; Fax: +49 (0) 6033 74 53 55 - 9 Email: kontakt@scratch-pv.com

The EU/EEA Qualified Person for Pharmacovigilance of NVD and its product Foclivia [REDACTED], Scratch Pharmacovigilance GmbH.

To accomplish national pharmacovigilance activities for the collection, processing and regulatory reporting of individual AE case reports, NVD Pharmacovigilance is collaborating with Novartis Pharma Drug Safety & Epidemiology (NPH DS&E) country organizations. Accordingly, there is a Global Pharmacovigilance service level agreement between Novartis Pharma Country Pharma Organizations and NVD.

In case of a pandemic and the use of Foclivia in Sweden a local contact will be set up, which will take first line questions and potential AE reports and collaborate closely with the global organization as described above.

Pharmaceutical technical complaints

Novartis Vaccines and Diagnostics Ltd (NVD) has a system in place for collecting and handling Pharmaceutical Technical Complaint ("PTC") from the market.

Pharmaceutical Technical Complaint ("PTC"), such complaints shall be reported to Novartis Vaccines and Diagnostics Ltd by email to the following address ptc.management@novartis.com including the details underlying the complaint as well as pictures of the defective unit, within one business day from receipt. Where available, complaint samples should be provided to Novartis Vaccines and Diagnostics Ltd at an address provided by the Quality Organization at the time of the complaint. Novartis Vaccines and Diagnostics Ltd (NVD) will complete the investigation no later than 30 (thirty) calendar days from the date that the complaint was received at NVD by complainant and will inform the complainant in writing about the result of root cause investigations. Defective products related to the technical complaint will be replaced as early as possible.

Medical Information

Novartis medical information services i.e. comprises directly responding to solicited and unsolicited questions from health care providers and patients related to epidemiology, vaccine application, vaccine composition and potential contraindications of vaccination.

Medical information for pandemic vaccines such as Foclivia will in principle be handled by the local Medical Affairs group within NVD.

For all first line medical information offices collaborating with NVD and covering inter-pandemic products: all questions and answers are recorded in a medical information database. The same system will operate for pandemic vaccines during a pandemic.

In case of a pandemic and the use of Foclivia in Sweden a first line medical information service will be established in Sweden (= local access point), which will collaborate closely with the below mentioned Global Medical Affairs associates of the Supplier. Additional Global Medical Affairs colleagues of the supplier will be involved in such activities, too.

Global Medical Affairs associates are based in Europe and in the US. They can belong to different legal entities, which are all owned by Seqirus UK Ltd, too.

Current contact person for medical information globally is:

██ NVS Influenza Vaccines, Cambridge, MA
02139, USA, Tel.: +1- 617-871-8072; Cell: +1-617-448-764

For Europe it is:

██ Novartis Influenza Vaccines Marburg GmbH,
Emil-von Behring Str. 76, 35041 Marburg, Germany, Tel. +49-6421-39-2529, Cell: +49-172-
6745242.

First level medical information, when established in Sweden, will be provided in Swedish and in English language, while second level support will be provided in English language.

