ANNEX
to the

COMMISSION DECISION

approving an Advance Purchase Agreement on COVID-19 vaccines
ADVANCE PURCHASE AGREEMENT ("APA")\(^1\) for the development, production, priority-purchasing options and supply of a successful COVID-19 vaccine for EU Member States

NUMBER — SANTE/2020/C3/087 - S12.854725

1. The European Commission (the 'Commission'), acting on behalf and in the name of the Member States listed in Annex I (hereinafter referred to as "Participating Member States") being represented for the purposes of signature of this APA by Ms. Stella Kyriakides, Commissioner for Health and Food Safety:

on the one part

and

2. Novavax, Inc.,

a Delaware corporation,

Delaware file number: 2129598

21 Firstfield Road, Gaithersburg, Maryland 20878 USA

VAT Registration Number [redacted]

hereinafter referred to as the "Contractor"), represented for the purposes of the signature of this APA by John A. Herrmann III, Chief Legal Officer and Corporate Secretary

and

Novavax CZ

a Czech corporation,

\(^1\) This APA is based on the agreement between the Commission and the Member States as approved by Commission Decision C(2020)4192 final on approving the agreement with Member States on procuring Covid-19 vaccines on behalf of the Member States and related procedures
Represented for the purposes of the signature of this APA by [name]

on the other part,

Contractor and Novavax CZ — henceforth collectively referred to as ‘the signatories’ — shall be responsible towards the Commission and the Participating Member States for the performance of this APA and any and all Vaccine Order Forms signed under this APA.

The Commission, acting on behalf and in the name of the Participating Member States, and the Contractor are together referred to as the “Parties” and each individually as a “Party”

HAVE AGREED

to the special conditions and the general conditions of this APA and the following annexes:

Annex I List of Participating Member States
Annex II Model for Vaccine Order Form
Annex III Agreement between the Commission and Member States on procuring Covid-19 vaccines on behalf of the Member States and related procedures, annexed to the Commission Decision C (2020) 4192 final of 18 June 2020
Annex IV Description of the Contractor’s utilization of the Down Payment
Annex V List of confirmed and planned manufacturing network partners including the location(s) of manufacturing and subcontractors
Annex VI Preliminary Specifications of the Product

which form an integral part of this APA.

RECALLS

A. The world is experiencing an emergency healthcare crisis due to the COVID-19 pandemic (the “COVID-19 pandemic”) and the global demand for vaccines to prevent COVID-19 infection is expected to be in order of magnitude of billions of doses. COVID-19 is an infectious disease caused by Sars-COV-2 virus strain.

B. The Contractor is currently working to develop and manufacture NVX-CoV2373 a protein subunit vaccine comprised of a stable, prefusion protein antigen derived from the genetic sequence of the SARS-CoV-2 coronavirus spike (S) protein and adjuvanted with Novavax’ proprietary Matrix-M™ adjuvant, to help protect against COVID-19 infection in humans.

C. The Commission intends to create the environment required to support a secure manufacturing network and optimisation for the production of vaccines against COVID-19 in the European Union.
The Commission has concluded an agreement with all Member States of the European Union to conclude, on behalf and in the name of the Member States, Advance Purchase Agreements with vaccine manufacturers with the objective to procure vaccines for the purposes of combating the COVID-19 pandemic in the European Union.

The Commission wishes to secure supply of the Product for human use for the Participating Member States during the COVID-19 pandemic as promptly as possible.

The intention of the Commission, on behalf of the Member States, is to ensure that the population in the European Union will be able to access an efficacious vaccine, including against mutations or variants of SARS-CoV-2, in sufficient quantities and at a fair price, but also in safe conditions. The vaccine should only be available to the population once its safety and efficacy will have been demonstrated to the competent regulatory bodies, and the relevant authorisations will have been obtained. Security of supply with the vaccine must be ensured and any adapted versions of the vaccine against mutations or variants of SARS-CoV-2 or other versions, including in particular for a paediatric population, should be made available for supply under this APA.

According to the Agreement between the Commission and the Member States and in particular Article 4 thereof, the Commission can conclude an Advance Purchase Agreement that contains a right and an obligation for Participating Member States to acquire vaccine doses. Where the Commission intends to enter into such an agreement, it shall inform the Member States of such intention and the detailed terms. In case a Member State does not agree with the conclusion of an APA containing an obligation to acquire vaccine doses or its terms, it has the right to opt out by explicit notification to the Commission. All Participating Member States not having opted out in accordance with the Agreement between the Commission and the Member States are deemed to have authorised the Commission to negotiate and conclude an Advance Purchase Agreement with the vaccine manufacturer in their name and on their behalf.

This APA is such an agreement which the Commission enters into on behalf and in the name of the Participating Member States which have not opted out of the agreement. These Participating Member States will then have an obligation to acquire the Product and a right to be supplied with the respective Product doses. While the APA is legally binding upon those Participating Member States, it will be further implemented by means of the conclusion of contracts between the Participating Member States and the Contractor. The present APA will be implemented by a Vaccine Order Form ("Vaccine Order Form") between each of the Participating Member States and the Contractor. A model Vaccine Order Form

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2 Such agreement is based on Article 4(1)(b) of Regulation (EU) 2016/369 of 15 March 2016 on the provision of emergency support within the Union, OJ L 70, 16.3.2016, p. 1, as amended by Council Regulation (EU) 2020/521 of 14 April 2020 activating the emergency support under Regulation (EU) 2016/369, and amending its provisions taking into account the COVID-19 outbreak, OJ L 117, 15.4.2020, p. 3. The agreement was approved Decision C(2020) 4192 final of 18 June 2020 (see Annex III to this APA).
for the contract between each of the Participating Member States and the Contractor is attached in Annex II.

I. The development, production, advance sale and supply of the Product as per this APA requires significant investments by the Contractor to increase the speed of the preparation of the at-scale production capacity along the entire production value chain in the EU required for a rapid deployment of the millions of doses of the Product. The Commission as well as the Participating Member States are willing to contribute to financing of those investments in the form of up-front payments in return for the warranties and rights set out in this APA.

J. Pursuant to these APA terms and conditions, access to Product doses will be allocated to Participating Member States according to a population distribution key, unless a different allocation is communicated by the Commission to the Contractor prior to execution of any Vaccine Order Forms for Participating Member States. The up-front payment, paid by the Commission, should be taken into account in equal terms per dose ordered by the Member States.

K. The Parties recognise that the timelines to develop, produce, sell and supply the Product which includes an obligation of the Participating Member States to indemnify the Contractor and its Indemnified Persons subject to the conditions laid down in Article II.5.1, in case

L. Against this background, the Commission wishes to enter into, on behalf and in the name of the Participating Member States, an Advance Purchase Agreement with the Contractor to secure the availability of a total of a minimum of 20 million and a maximum of 100 million doses of the Product, to be allocated among the Participating Member States in accordance with the allocation principles set out in this APA. The Commission, on behalf and in the name of the Participating Member States, shall furthermore have the option to order up to a total of 100 million additional doses of the Product, subject to the terms and conditions of this APA.

This APA sets out:

1. the procedure and conditions by which the Commission and the Participating Member States may pay for the Product from the Contractor;
2. the provisions that apply to any Vaccine Order Form which the Participating Member States and the Contractor may conclude under this APA; and
3. the obligations of the Parties during and after the duration of this APA.
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I. Special Conditions

I.1. Order of priority of provisions

If there is any conflict between different provisions in this APA, the following rules must be applied:

(a) The provisions set out in the special conditions take precedence over those in the other parts of the APA.
(b) The provisions set out in the general conditions take precedence over those in the Vaccine Order Form (Annex II) and other Annexes.

All documents issued by the Contractor (such as end-user agreements, general terms and conditions, etc.) are held inapplicable, unless they are issued under or in accordance with this APA (such as the final specifications, formal notifications, etc.). In all circumstances, in the event of contradiction between this APA and documents issued by the Contractor, this APA prevails, regardless of any provision to the contrary in the Contractor's documents.

I.2. Subject matter

The subject of this APA is the development, production, advance purchase, and supply of a minimum of 20 million doses and a maximum of 100 million doses of the Product, as described below in Article 1.4.2, to be allocated among the Participating Member States by the Commission in accordance with the allocation principles set out below in Article 1.4.3. Additionally, this APA gives the Commission the opportunity to order during the term of the APA, on behalf and in the name of the Participating Member States, up to 100 million additional doses of the Product in one or more tranches in accordance with Article 1.4.4. Such Option Increase is to be allocated between the Participating Member States by the Commission as set out below in Article 1.4.4.

On the basis of this APA, the Contractor commits to use Reasonable Best Efforts to obtain Marketing Authorisation for the Product as regards its use in the entire adult population in the EU. To this effect the Contractor undertakes to submit an application to EMA for Marketing Authorisation (including conditional marketing authorisation) as soon as possible. In particular, the Contractor will ensure that such application for Marketing Authorisation is submitted to EMA on a concurrent timeline with any other stringent regulatory authorities (SRA) (as defined by the World Health Organization) applications for Marketing Authorisation or equivalent made in other jurisdictions, and, in any event, not later than the first application for any such authorisation is made anywhere in the world. The Contractor also commits to establish sufficient manufacturing capacities to enable the manufacturing and supply of the contractually foreseen volumes of the Product to the Participating Member States in accordance with the delivery schedule and planning schedule set out below in Article 1.4.7.

Each Participating Member State shall issue a Vaccine Order Form as regards to its allocation of the Fixed Initial Doses, through which the Contractor shall supply to the Participating Member States the Product doses in accordance with the terms of this APA. Each Participating Member State shall also issue a Vaccine Order Form with regard to any Flexible Initial Doses allocated to such Participating Member State pursuant to the process set forth in Article 1.4.2. If the
Commission acting on behalf and in the name of the Participating Member States decides to exercise the Option Increase under Article 1.4.4, each Participating Member State shall issue a Vaccine Order Form with regard to any Additional Option Doses allocated to it in connection with such Option Increase.

The delivery of the Product to the individual Participating Member States shall be carried out in accordance with the terms and conditions of this APA and in particular in accordance with the allocation notified to the Contractor by the Commission, as well as the additional delivery details set out in the Vaccine Order Forms to be concluded between the Contractor and the Participating Member States using the model Vaccine Order Form provided as Annex II to this APA.

I.3. Entry into force and duration of the APA

I.3.1 The APA enters into force on the date on which the Contractor and the Commission have signed it.

I.3.2 Unless earlier terminated in accordance with Article II.16 or expired in accordance with Article I.3.5, the APA is concluded for a period of 24 months with effect from the date of its entry into force.

I.3.3 The APA duration may be extended upon written agreement by the Parties. The Participating Member States and the Contractor may not sign any Vaccine Order Form after the APA expires.

I.3.4 The APA continues to apply to signed Vaccine Order Forms after its expiry. Articles which survive the termination of both the APA and signed Vaccine Order Forms are defined in Article I.3.6.

I.3.5 The APA shall automatically expire on (i) the date on which all the Initial Doses have been delivered and paid in full, in the event the Commission has not elected an Option Increase in accordance with Article I.4.4, or (ii) the date on which all of the Initial Doses and the Option Doses have been delivered and paid in full, in the event the Commission has elected an Option Increase in accordance with Article I.4.4.

I.3.6 Articles I.3.6, I.4.6, I.4.7.1.1, I.4.7.2, I.5, I.6, I.9, I.10, I.11.1-I.11.6, I.12, I.11, I.13, I.14, I.15, I.17, I.16.5, I.18.4, I.19.2, and I.20 shall survive the termination or expiry of this APA and Vaccine Order Forms. Further, neither Party shall be relieved of any obligation that accrued prior to such effective date of termination or expiry of the APA or Vaccine Order Form. Except as otherwise expressly provided herein, all rights and obligations of each Party hereunder will cease upon termination or expiry of this APA and Vaccine Order Forms.

I.4. Implementation of the APA

I.4.1 Implementation of the APA

The APA shall be implemented following signature between the Commission on behalf and in the name of the Participating Member States and the Contractor as follows:
Following entry into force of this APA, this APA is binding upon the Contractor, the Commission and all Participating Member States on behalf and in the name of which the Commission has concluded this APA, as identified in Annex I.

Following entry into force of this APA, the Commission will determine the allocation of the contractually agreed doses of the Product between the Participating Member States in accordance with the procedure set out below in Article 14.3 and will formally notify this allocation to the Contractor. The allocation notified to the Contractor by the Commission on behalf and in the name of the Participating Member States is binding upon all Participating Member States.

Each Participating Member State and the Contractor will conclude a Vaccine Order Form, using the model Vaccine Order Form attached as Annex II to this APA, setting out the details of the delivery of the doses of the Product allocated to the respective Participating Member State in accordance with Article 14.3.

14.2. Initial Doses

Without prejudice to the Option Increase (see Article 14.4), the Contractor agrees to supply an initial aggregate number of 100 million doses of the Product (the “Initial Doses”) to the Participating Member States in accordance with the terms of this APA and the applicable Vaccine Order Forms.

The delivery schedule for the first 20 million Initial Doses in the Initial Delivery Schedule set forth in Article 14.7.1 is fixed (the “Fixed Initial Doses”).

For the remaining 80 million Initial Doses (the “Flexible Initial Doses”), the following rules shall apply: the Initial Planning Schedule for Flexible Initial Doses in Article 14.7.1 sets out the volume of Flexible Initial Doses that the Contractor has earmarked for delivery to the Participating Member States as Flexible Initial Doses under this APA. At least 30 days before the delivery of the Product to the Commission on behalf of the Participating Member States, the Contractor shall communicate to the Commission its demand of Flexible Initial Doses for delivery to the Confederate States, as well as the desired delivery schedule and expression of demand for the subsequent delivery ("Expression of Demand").

For clarity, the initial Expression of Demand shall be due, with the subsequent Expression of Demands due on 11 November 2019. In a situation where Variant Product is available pursuant to Article 11.7.9, the Expression of Demand may cover (i) only quantities of Variant Product; (ii) only quantities of Product, or (iii) any combination of both. In such situation, the Expression of Demand shall set out the quantities of Variant Product and/or Product requested per month.

Within 30 days of receipt of the Expression of Demand, the Contractor shall propose to the Commission the delivery schedule for the Flexible Initial Doses, containing all quantities specified in the Expression of Demand for which they have been requested and the delivery schedule during which these quantities can be delivered by the Contractor ("Flexible Initial Doses Delivery Schedule"). If the Expression of Demand is the Initial Planning Schedule for the Flexible Initial Doses set
out in Article 1.4.7.1, the Flexible Initial Doses Delivery Schedule shall contain at least the quantities included in that Initial Planning Schedule.

The Commission, on behalf of the Participating Member States, shall confirm the final quantities to be delivered to the Participating Member States. Within [REDACTED] of receipt of the Flexible Initial Doses Delivery Schedule, the Commission shall communicate to the Contractor the allocation of Flexible Initial Doses between the Participating Member States, and the Participating Member States shall issue Vaccine Order Forms.

For the avoidance of doubt, if the amounts included in the Flexible Initial Doses Delivery Schedule for [REDACTED] are [REDACTED] included in the Expression of Demand, the Commission, on behalf of the Participating Member States, shall be allowed to express demand for the difference in a subsequent Expression of Demand.

The Flexible Initial Doses Delivery Schedule shall qualify as an Updated Delivery Schedule within the meaning of Article 1.4.7.1.1, so that in particular the rules of Article 1.4.7.2 apply to deliveries made under the Flexible Initial Doses Delivery Schedule. In addition, the cancellation right of Article 1.4.7.1.1, third and fourth subparagraphs (other than the right to [REDACTED]), shall apply mutatis mutandis if the delivery dates foreseen in the Flexible Initial Doses Delivery Schedule are [REDACTED] in the Expression of Demand. For the avoidance of doubt, Article 1.4.7.1.1, first and second subparagraphs, shall not apply to the Flexible Initial Doses Delivery Schedule.

Any amounts of Flexible Initial Doses for which no demand has been expressed in Expressions of Demand issued by [REDACTED] shall be automatically and fully cancelled. Such automatic cancellation shall take effect as from [REDACTED]. For the avoidance of doubt, the choice of whether or not to express demand for Flexible Initial Doses is not subject to any conditions and is at the sole discretion of the Commission acting on behalf of the Participating Member States.

The Commission, on behalf of the Participating Member States, and the Contractor may agree [REDACTED] on the delivery of Flexible Initial Doses in 2023. In that case, the cancellation right and automatic cancellation foreseen in the previous paragraphs shall apply mutatis mutandis in 2023.

1.4.3. Allocation between Participating Member States; Vaccine Order Forms

The Commission shall coordinate with the Participating Member States to agree to the allocation of the Initial Doses to be purchased from the Contractor. The Commission shall provide to the Contractor in writing the allocation for distribution of the Fixed Initial Doses among the Participating Member States within [REDACTED] Such allocation shall indicate for each Participating Member State the precise volume of Initial Doses to be delivered to each Participating Member State. The Commission shall communicate the allocation for distribution of the (i) Flexible Initial Doses among the Participating Member States pursuant to
the procedure specified in Article 1.4.2 and (ii) \textit{Option Doses} pursuant to the procedure specified in Article 1.4.4.

Within [blank] after the notification by the 	extit{Commission} of the allocation for distribution of the \textit{Product} among the \textit{Participating Member States}, each \textit{Participating Member State} shall place an order for its full allocated portion of the \textit{Product} by sending the \textit{Contractor} the duly completed and signed \textit{Vaccine Order Form} (the format for which is set out in Annex II) in PDF format by email to the \textit{Contractor}'s email address as specified in the \textit{Vaccine Order Form}.

Within [blank] of receipt of the \textit{Vaccine Order Form} from a \textit{Participating Member State}, the \textit{Contractor} must send back to the \textit{Participating Member State} the \textit{Vaccine Order Form} duly signed and dated in PDF format by email to the \textit{Participating Member State}'s e-mail address specified in the \textit{Vaccine Order Form}. If the \textit{Contractor} refuses without valid reason to sign the \textit{Vaccine Order Form} at the conditions laid down in the APA and in Annex II, the \textit{Contractor} may be considered in breach of its obligations under this APA as set out in Article 11.16.2. If the \textit{Participating Member State} refuses without valid reason to sign the \textit{Vaccine Order Form} at the conditions laid down in the APA and in Annex II, the \textit{Participating Member State} may be considered in breach of its obligations under this APA.

1.4.4. \textit{Option Increase}

During the term of the APA and subject to the terms of Article 1.4.7.1., the \textit{Commission}, acting on behalf of one or more of the \textit{Participating Member States}, may elect to increase the number of doses of \textit{Product} by up to an additional 100 million doses of the \textit{Product} in one or more tranches (the "\textit{Option Increase}") at the times set forth below.

At the request of the \textit{Commission}, the \textit{Contractor} shall provide to the \textit{Commission} an estimated delivery schedule for the \textit{Product} comprising the \textit{Option Increase}, in one or more tranches, for delivery during the calendar year 2022 and/or 2023 to enable the \textit{Commission} and the \textit{Participating Member States} to determine whether or not to exercise an \textit{Option Increase}. The estimated delivery schedule shall detail timelines of supply of the \textit{Option Increase} for two scenarios. The first scenario will detail an estimated delivery schedule supplied exclusively from \textit{EU Manufacturing Facilities} and the second scenario will detail an estimated delivery schedule supplied from \textit{EU Manufacturing Facilities} and other manufacturing facilities which have the necessary regulatory approvals in the EU and are listed in the Marketing Authorisation. The \textit{Commission} and/or \textit{Participating Member States} may choose which schedule the \textit{Contractor} uses to supply \textit{Additional Option Doses}.

On or prior to [blank] after delivery of the estimate, the \textit{Commission} will be entitled to exercise the \textit{Option Increase} by written notice from the \textit{Commission} to the \textit{Contractor}, which written notice shall specify which supply schedule it elects, the \textit{Participating Member States} participating in such \textit{Option Increase} (the "\textit{Exercising Member States}"), the aggregate number of doses of \textit{Product} to be purchased for the \textit{Option Increase}, and the allocation of doses of \textit{Product} to be purchased and delivered to each such \textit{Exercising Member State} (the "\textit{Additional Option Doses}"). For clarity, if the \textit{Commission} exercises the \textit{Option Increase}, in one or more tranches, for less than one hundred million (100,000,000) doses in the aggregate, then all references to \textit{Option Increase} in this APA will be limited to the amount of doses of \textit{Product} so exercised.
The Parties shall memorialize the number of doses of Product in the Option Increase (the "Option Doses"), and schedule of delivery in writing and Contractor and the Exercising Member States shall execute Vaccine Order Forms for the Option Doses. The Option Doses will be paid by the Exercising Member States within a period of after the receipt of the Contractor's invoice following each delivery of such Option Doses to the Exercising Member States. The provisions of this APA apply to such Option Increase mutatis mutandis unless otherwise agreed.

1.4.5. Development timeline; Special Commitments

Contractor's COVID-19 Vaccine is eligible for review under the centralized procedure with European Medicines Agency (EMA). Contractor commits to submit data packages as soon as they become available to accelerate review. The rolling review process has begun with the non-clinical package. The clinical and Chemistry, Manufacturing and Controls (CMC) packages should be available for submission throughout the review.

The Contractor shall have sufficient manufacturing capacity to be capable of manufacturing and supplying the Product to the Commission on behalf of the Participating Member States in accordance with the provisions of this APA. The Contractor may not manufacture or have manufactured the Product at manufacturing sites located outside the territory of the European Union (EU) or the European Economic Area without the prior written consent of the Commission, which consent may not be unreasonably withheld, conditioned or delayed if the manufacturing at such sites is required to accelerate production and supply under this APA. For the avoidance of doubt, consent may be withheld in particular in case the relevant manufacturing site does not comply with applicable Union law or regulatory requirements, including Good Manufacturing Practices, or when the manufacturing site is not listed in the Marketing Authorisation. The manufacturing sites as identified in Annex V are deemed approved for the duration of the APA, subject to each one of these sites fulfilling at any point in time all applicable Union law regulatory requirements, including being listed in the Marketing Authorisation.

The Contractor has invested in building out a robust supply chain with the majority of facilities located within the EU. The Contractor shall use Reasonable Efforts to supply the Products to the Participating Member States using only manufacturing facilities of itself or of contract manufacturers located in the European Union.

1.4.6. Right of the Participating Member State to re-sell and/or donate

The Participating Member States shall be entitled to re-sell or donate any of the Products supplied to them pursuant to this APA to any other EU or EEA Member State and Switzerland provided they have paid Contractor for such Product and are not otherwise in breach of this APA and their Vaccine Order Form. Any such recipient EU Member State, EEA Member State or Switzerland shall execute with Contractor a Vaccine Order Form, or in the case of EEA Member States or
Switzerland, an agreement equivalent to a Vaccine Order Form.

The Participating Member States shall take the appropriate measures to ensure that the Products supplied to them pursuant to this APA will not be (i) re-sold or (ii) donated to another country outside the EU and EEA and Switzerland, including for donation directly or indirectly without prior written consent of the Contractor. Provided a Participating Member State has paid Contractor for Product and are not otherwise in breach of this APA and their Vaccine Order Form, the Contractor shall not unreasonably withhold, condition or delay such consent to the re-sale or donation. The Contractor acknowledges that such re-sale or donation of the Products to countries outside the EU and EEA and Switzerland may be required in order to provide a global solution to COVID-19 Pandemic and limit the risk of emergence of new variants of the COVID-19.

The Parties understand and agree, however, that in connection with any re-sale or donation the following shall apply: (a)

(b)

For the avoidance of doubt, the Contractor may not require the re-selling or donating Participating Member State to guarantee in relation to the Contractor the performance of any obligations of the recipient country including the indemnification by the recipient country nor can the Contractor require the re-selling or donating Participating Member State to commit to any indemnification of losses arising out of use and deployment of resold or donated doses outside the re-selling or donating Participating Member State’s jurisdiction.

The Parties acknowledge that, should re-sale to any third country, including EEA Member States and Switzerland, take place, the Participating Member State re-selling the Product has an obligation to reimburse the Commission the Down Payment per dose paid by the Commission to the Contractor.

In addition, the Participating Member State envisaging a re-sale or donation shall ensure, at its expense or at the expense of the receiving country, that the required regulatory/quality/GMP/GDP processes to enable such re-sale or donation (i.e. for the transport of the Product from the Participating Member State envisaging such re-sale or donation to the central warehouse of the receiving country) are in place.

In case of a donation or a re-sale to another EU or EEA Member State or Switzerland, the Contractor may, at its sole discretion and without incurring additional costs, attempt to support or execute implementation of regulatory/quality/GMP/GDP requirements, particularly if the
Products have not yet been delivered to the Participating Member State.

1.4.7. Delivery and Manufacturing Sites

The Contractor shall deliver the Product doses to the Participating Member States in accordance with the allocation and the other terms and conditions of this APA. The Contractor shall use Reasonable Best Efforts, to manufacture, the Products only at the Contractor’s or its contract manufacturers’ manufacturing facilities located in the European Union. The Contractor shall deliver Product doses to the Participating Member States in a rolling non-discriminatory manner on the schedule and in the quantities as set out in the following initial delivery schedule (“Initial Delivery Schedule”).

To support supply of doses the Additional Option Doses delivered in connection with the Option Increase, Contractor commits to establish the necessary additional manufacturing facilities located in the European Union and/or will have presented a plan to the Commission that In each instance these European facilities would be used for the purpose of providing prioritized supply to the Commission and/or Member States (“EU Manufacturing Facilities”).

1.4.7.1. Initial Delivery Schedule and Initial Planning Schedule

The Fixed Initial Doses shall be delivered according to the following Initial Delivery Schedule based on an estimated Marketing Authorisation by the Commission. The Flexible Initial Doses are earmarked for the Participating Member States on the basis of the following Initial Planning Schedule for Flexible Initial Doses:

**Initial Delivery Schedule (for Fixed Initial Doses)**

<table>
<thead>
<tr>
<th>Week</th>
<th>Number of Fixed Initial Doses</th>
<th>Cumulative Fixed Initial Doses</th>
</tr>
</thead>
<tbody>
<tr>
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</table>

**Initial Planning Schedule (for Flexible Initial Doses)**

<table>
<thead>
<tr>
<th>Week</th>
<th>Number of Flexible Initial Doses</th>
<th>Cumulative Flexible Initial Doses</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The Commission and the Participating Member States further acknowledge that the Initial Delivery Schedule above and the initial delivery of Product (“Delivery Start Date”) in such Initial Delivery Schedule is based on the assumption that Contractor will have submitted final documentation for consideration of Marketing Authorization to EMA on or before
The precise Delivery Start Date will be dependent on receipt of Marketing Authorization.

The Delivery Start Date shall be as soon as possible, but in any case within [redacted] after the granting of the Marketing Authorisation irrespective of when Marketing Authorisation is granted. The Contractor commits to meet this anticipated Delivery Start Date in the EU, and will consequently have to advance fill, finish, label and pack Product in anticipation of receipt of Marketing Authorisation. Accordingly, the Commission and the Participating Member States accept and agree that shipments of Product prior to [redacted] may have a shorter shelf life (but not below [redacted] 18 months) upon delivery to the Participating Member States. Product delivered from [redacted] onwards will have the regular shelf life as per the Marketing Authorisation. Contractor commits to work expediently and continuously on the extension of shelf life, and to deliver the Product with the longest possible shelf life.

Under no circumstances will any delivery of Product doses be required under this APA prior to receipt of Marketing Authorisation for the Product unless mutually agreed by the Commission, the relevant Participating Member State(s) and the Contractor. The Contractor shall use Reasonable Best Efforts as referred to in Article 1.12 to obtain Marketing Authorisation for the Product as soon as reasonably possible in order to meet the anticipated Delivery Start Date under the Initial Delivery Schedule.

14.7.1.1. Updated Delivery Schedules Prior to Obtaining Marketing Authorization

The Contractor shall, [redacted], communicate any anticipated changes to the Expected Submission Date and/or the Initial Delivery Schedule to the Commission prior to obtaining Marketing Authorisation. At least [redacted] in advance of expected date of receipt of Marketing Authorisation, the Contractor shall inform the Commission in writing of the date of the actual Delivery Start Date and provide the Commission an updated delivery schedule which details the anticipated amounts and dates of each of delivery of Product ("Updated Delivery Schedule"). The Delivery Start Date shall be at most [redacted] after the receipt of Marketing Authorisation irrespective of the date of granting of the Marketing Authorisation.

Provided that the Marketing Authorisation is granted on or before [redacted], the Updated Delivery Schedule shall be identical to the Initial Delivery Schedule. In case the Marketing Authorisation is not granted by [redacted], the Contractor acknowledges the strong interest of the Participating Member States, given the current pandemic situation, in receiving the Product in accordance with the Initial Delivery Schedule and acknowledges in this context also the importance of security of supply. Therefore, the Contractor shall use its Reasonable Best Efforts to ensure that deliveries of Product doses set out in the Updated Delivery Schedule are made within a schedule that is as close as reasonably possible to the Initial Delivery Schedule, and the Contractor shall make all possible efforts to catch up in its deliveries with the Initial Delivery Schedule. To this effect, if Marketing Authorisation is received after [redacted] then the Updated Delivery Schedule will reflect the delay between [redacted] and the date of the Marketing Authorisation.
If the anticipated delivery date of Product doses per an Updated Delivery Schedule is more than 20 days after the corresponding delivery date for such Product doses in the Initial Delivery Schedule, a Participating Member State (or the Commission, acting on its behalf) may cancel its order for the number of Product doses that will be more than 20 days late by providing written notice to the Contractor within 7 days of the Commission’s receipt of such Updated Delivery Schedule. For the avoidance of doubt, if more than one Updated Delivery Schedule is communicated by the Contractor, the cancellation right pursuant to this paragraph shall also exist if the cumulative anticipated delay foreseen in those Updated Delivery Schedules exceeds 20 days after the corresponding delivery date on which the Product would have been delivered as per the Initial Delivery Schedule.

If a Participating Member State elects to cancel delivery of Product pursuant to this Article 1.4.7.1.1, the Participating Member State shall and the Contractor shall be relieved of its obligation to deliver such Product units. The Down Payment attributable to such undelivered Product units (10% of the price per dose of Product) will be reimbursed to the Commission within 7 days of Contractor’s receipt of written notice and/or credited against outstanding invoices and invoices of future deliveries of Product as the case may be.

1.4.7.2. Actual Late Deliveries, and Cancellation

The Commission acknowledges that Contractor is in the process of scaling up and optimizing Product manufacturing and that manufacture and delivery of Product may be subject to disruptions outside of Contractor’s control such as the Acknowledged Root Causes for Delivery Delays mentioned below; accordingly, that notwithstanding anything herein to the contrary, the quantity of Product actually delivered may vary by 10% of the total amount of doses under the Vaccine Order Form for such Participating Member State.

The Contractor, throughout the term of this APA, will have in place an effective supply management system that includes, inter alia, an early alert system.

In the event that the Contractor has a delay in delivery of more than 20 days of the doses foreseen for a given period in the Updated Delivery Schedule and that the delay exceeds a period of 20 days after delivery was foreseen as per the Updated Delivery Schedule, (“Late Delivery(ies”), the following provisions shall apply. The Contractor shall regularly inform the Commission and the Participating Member States of the expected delivery date of any product subject to Late Delivery.

If the Late Delivery is made more than 20 days after delivery was foreseen in the Updated Delivery Schedule, the Contractor shall
If the Late Delivery is made more than _______ after _______ in which delivery was foreseen in the Updated Delivery Schedule, the Contractor shall _______.

If the Late Delivery is made more than _______ after _______ which delivery was foreseen in the Updated Delivery Schedule, the Contractor shall _______.

If a Late Delivery delay exceeds a period of _______ after _______ in which delivery was foreseen as per the Updated Delivery Schedule, Contractor shall provide the Participating Member State (or the Commission acting on its behalf) without delay a supply schedule reflecting delivery timeframes for any doses from the Late Delivery not yet delivered. In such event, the Participating Member State (or the Commission acting on its behalf) shall either accept the revised supply schedule for such doses or cancel up to _______ of the amount of doses from the Late Delivery that have not yet been delivered. The Participating Member State (or the Commission acting on its behalf) will provide written notice to the Contractor of its decision within _______ following its receipt of the revised supply schedule.
If a Participating Member State elects to cancel delivery of Product pursuant to Article I.4.7.2, the Participating Member State shall be relieved of its obligation to pay for such undelivered Product units and the Contractor shall be relieved of its obligation to deliver such Product units. The Contractor will issue a credit for the Down Payment for any doses for which the Down Payment was paid but that were cancelled in accordance with the previous sentence. Such credit will be applied against outstanding payments for deliveries with any remaining credit being refunded to the Commission.

In case not all the Fixed Initial Doses are delivered by [date], the Commission shall have the unconditional right to cancel the delivery of the doses and in addition the unconditional right to terminate the APA.

The Commission acknowledges that Contractor is in the process of scaling up and optimizing Product manufacturing, which involves biomanufacturing that may be inherently difficult to predict, especially during a pandemic. The Parties understand that, next to situations of Force Majeure, there may be a number of situations or events that can lead to a shortfall of doses and a delay in delivery of the Product; these situations relate to timing of regulatory approvals of the manufacturing sites in Annex V, exceptional consumables and raw material shortages, strikes and/or third country export controls preventing successful shipments of crucial materials to their intended destinations, provided that such situation or event is not attributable to error or negligence on the part of the Contractor or on the part of its subcontractors and proven to be inevitable despite the Contractor exercising due diligence ("Acknowledged Root Causes for Delivery Delays"). Total supply of Product may be impacted by such events, and should not be seen by the Commission or Participating Member States as evidence of Contractor’s intentions to treat the Commission or the Participating Member States in an unfair manner.

I.4.7.3 Overall Delivery Considerations

In addition to the updates regarding the Initial Delivery Schedule per __ and per __, the Contractor shall provide the Commission and the Participating Member States with an estimated delivery schedule detailing the relevant delivery of delivery. The Contractor will provide the Commission and the Participating Member States without delay with any possible change of delivery. The Contractor may agree with the Participating Member States to make multiple deliveries over a __ or over __, in varying quantities, and will do so on a rolling non-discriminatory basis as between all Participating Member States. Such deliveries will be prorated to each Participating Member State based on the allocation provided by the Commission pursuant to Article I.4.3, subject to the Contractor’s minimum delivery volume and cooperation with the Participating Member States.

The Contractor has put in place an effective supply management system so that the Contractor and its subcontractors will have sufficient raw materials, materials and other input items to manufacture and supply the Product in accordance with the applicable Delivery Schedule to the extent possible under current pandemic conditions. To limit exposure to risks of disruption in the supply chain, the Contractor also shall use its Reasonable Best Efforts to use contract manufacturing organizations located in the European Union.
1.4.7.3.1 Form of Delivery

The supply of Product doses will be delivered by the Contractor to the Participating Member States.

1.4.7.4 Distribution

Following delivery of the Product doses, each Participating Member State will solely control and assume all responsibility, at such Participating Member State's own cost and expense, for conducting all distribution and related activities relating to the Product doses in the Participating Member State's territory.

1.5. Acceptance/Rejection of Product

1.5.1 Subject to the terms of this Article, and without prejudice of Article I.5.1, a Participating Member State may claim a remedy described in this Article 1.5.5 (a "Product Claim") for any unit of Product delivered to such Participating Member State by the Contractor which at the time of delivery (a) does not comply with the final specifications for the Product as approved in the Marketing Authorisation for the Product or (b) has been affected by a failure to comply with GMP or any applicable laws ("Deficient Product"). Such Participating Member State will visually inspect the Product, or review documentation provided by or on behalf of the Contractor, upon delivery or receipt (as applicable) and will no later than within [blank] (the "Inspection Period") following Contractor's delivery of Product give the written notice of the Product Claim. Notwithstanding the foregoing, a Participating Member State has the right to extend the Inspection Period for an additional [blank] period with at least [blank] advance notice and a detailing of the circumstances for such extension. A Participating Member State will be deemed to have accepted a delivery of Product if not rejected prior to expiry of such Inspection Period. In the case of any deficiency at the time of delivery to such Participating Member State that was not reasonably susceptible to discovery upon such delivery or receipt (a "Latent Defect"), a Participating Member State will not later than [blank] after discovery by such Participating Member State give the written notice of the Product Claim; provided Product will not be eligible for a Latent Defect Product Claim if its shelf life date has been exceeded, provided that the minimum shelf life requirements of the APA on delivery were respected by the Contractor.

1.5.2 The Contractor will have no obligation for any Product Claims to the extent the Deficient Product was caused exclusively by actions or omissions of such Participating Member State or Third Parties not acting on behalf of the Contractor occurring after the time of delivery of the Product by the Contractor or its designee.

1.5.3 Upon receipt of a Product Claim, the Contractor will have [blank] to advise the Participating Member State by notice in writing whether it disagrees with the content of the Product Claim. If, after joint testing or investigation has been performed, the Parties still cannot agree on whether such Product is Deficient Product (a "Technical Dispute"), the Contractor or
the Participating Member State may refer such Technical Dispute to a technical expert for resolution in accordance with Article 1.5.4.

1.5.4 If any Technical Dispute arises, the Contractor and the Participating Member State will first try to resolve it amicably. The Contractor or the Participating Member State will send a notice of a Technical Dispute to the other, and each Party will appoint, within 28 days from receipt of the notice, an appropriate single representative having full power and authority to resolve the dispute. The representatives will meet as necessary in order to resolve the Technical Dispute. If the representatives fail to resolve the matter within 28 days from their appointment, or if a Party fails to appoint a representative as required above, the expert determination procedure below may be started by either Party. Within 28 days after the written request, the Contractor and the Participating Member State will appoint a single, independent, mutually agreed expert with experience and expertise in the subject matter of the dispute. If the Contractor and the Participating Member State do not appoint a mutually agreed expert within such period of each Party is entitled to have the expert appointed in court, in accordance with Article 1.10.2(b). As a condition of the expert’s appointment, the Contractor and the Participating Member State will ensure that the expert agrees to disclose any actual or potential conflicts of interest promptly as they arise. The Contractor and the Participating Member State do not intend that the expert acts as an arbitrator and therefore any matters requiring legal interpretation or adjudication including disputes relating to the conduct of the Technical Dispute are solely reserved for the dispute resolution procedure under Article 1.11.2. For the avoidance of doubt, any technical determination by the expert under a Technical Dispute may be used as evidence under Article 1.11.2. The Contractor and the Participating Member State will require the expert to provide an opinion on each referred issue (reasonably detailed reasoning) within 28 days of a written request from the expert to do so. At all times the Contractor and the Participating Member State will co-operate and seek to narrow and limit the issues to be determined. The technical determination of the expert will, except for fraud or manifest error or where an unapproved conflict of interest is discovered, be final and binding upon the Contractor and the Participating Member State with respect to the referred Technical Dispute. Each of the Contractor and the Participating Member State will bear its own costs for any matter referred to an expert under this Article 1.5.5 and, in the absence of express agreement to the contrary, the costs and expenses of the expert will be shared equally by the Contractor and the Participating Member State.

1.5.5 If a Participating Member State makes a Product Claim pursuant to this Article 1.5 and (a) the Contractor and the Participating Member State agree the Product that is the subject of such Product Claim is Deficient Product (such agreement not to be unreasonably withheld, conditioned or delayed) or (b) any previously delivered Product is determined to be Deficient Product due to a Latent Defect, the Contractor will replace such Deficient Product as soon as reasonably practicable after the time of such agreement or determination (and in no event later than [_____] after the time of such agreement or determination). If such replacement products are not delivered within this time limit and without prejudice to Article 1.4.7.1.1 and 1.4.7.2, the Participating Member States shall have the choice, at their own discretion, whether to opt for a
later delivery of replacement products, or to obtain reimbursement of the purchase price for the Deficient Product to the Participating Member States in question in so far as that purchase price was already paid.

1.5.6 Upon resolution of a Product Claim as specified in in Article 1.5.5, the Participating Member State shall dispose of the Deficient Product in compliance with applicable laws and regulations. The Contractor will bear the cost of destruction of any such Deficient Product.

1.5.7 Without prejudice to the no limitations of liability provision set out in Article II.4.6, the remedies described in Article 1.5.5 shall be a Participating Member State’s sole and exclusive remedy and Contractor’s entire liability for a Product Claim for the supply of specific units of Deficient Product.

I.6. Warranties

1.6.1. The Contractor warrants to the Commission and the Participating Member States that

(a) all Product doses supplied to the Participating Member States shall at the time of delivery conform with the final specifications for the Product as approved in the Marketing Authorisation for the Product;

(b) all Product doses supplied to the Participating Member States shall at the time of delivery have been manufactured in conformance with GMP and all applicable laws (together with the warranty in (a), the "Production Warranties"); and

(c) at the time of delivery, it has good title to the Product doses delivered to the Participating Member States pursuant to this APA and it shall pass such title to the Participating Member States free and clear of any security interests, liens, or other encumbrances, including, to the knowledge of the Contractor, having obtained any necessary intellectual property rights.

(d) any claimed breach of the Production Warranties of specific units of the Product shall be resolved pursuant to Article I.5, without prejudice to Article II.5.1.

(e) as of the date hereof, this APA has been duly executed and is a legal, valid and binding obligation on it, enforceable against it in accordance with its terms; and as of the date hereof, it is not under any obligation, contractual or otherwise, to any Third Party that conflicts with or is inconsistent in any respect with the terms of this APA or that would impede the complete fulfillment of its obligations under this APA.

(f) the Contractor has not entered and shall not enter into any contractual agreement with any Affiliate or third party with the effect of diverting to any third party, or of impeding or limiting the delivery of, the Product to be delivered to the Participating Member States under any of the delivery schedules under this APA. This clause does not pertain to Contractor’s obligations to GAVI under its existing advanced purchase agreement.
(g) Except for the foregoing express warranties, to the fullest extent not prohibited by applicable law, the Contractor expressly disclaims all other representations, warranties and covenants of any kind, whether express or implied.

1.7. Prices

1.7.1. Price per Dose of Product

The price per single dose of Product is specified in the following table and is based on the aggregate volume of doses of Product the Commission and Participating Member States procure for delivery in 2021 and/or 2022 and/or 2023 and reflects amongst other factors, the price for building capacity in the European Union and holding that capacity available:

[Table]

Upon execution of the APA, the price per single dose of Product is [blank] USD based on the Commission’s and Participating Member States’ commitment to procure the Fixed Initial Doses and the total price of the Fixed Initial Doses equals [blank] USD (i.e., USD [blank] multiplied by 20 million doses).

Additional doses procured for delivery in 2022 and/or in 2023 by the Commission through the Expression of Demand process set forth in Article 1.4.2 or Option Increase process set forth in Article 1.4.4 shall count toward the aggregate number of doses of Product for purposes [Table]

If by [blank] (or by [blank] in case of an exercise of the Option Increase for 2023), the amount of credit owed a Participating Member State exceeds the amount due to the Contractor, Contractor will issue a refund to such Participating Member State in an amount equal to such excess.

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All payments shall be made in Euros converted pursuant to the methodology specified in Article 1.8.4.

The price is exclusive of any and all governmental taxes, including, without limitation, value added tax, customs, charges or levies of every kind ("Taxes") that Contractor may be required to collect or pay upon sale, transfer or shipment of Product to the Participating Member State under any applicable laws or regulations. Taxes will be added to the price where applicable. Each Participating Member State will be solely responsible for all such Taxes, including any interest and penalties.

1.7.2. Down payment under the APA

To ensure proper and rapid research and development of a vaccine against COVID-19, and to enable the Contractor to conduct the activities contemplated in Article 1.8.2, the Commission will make an up-front payment of [_____] of the total price of the Fixed Initial Doses set forth in Article 1.7.1 (the "Down Payment"), payable within [_____] after the receipt of an invoice following signature of this APA.

The Down Payment is [_____] which is based on USD [_____] calculated using the Exchange Rate Methodology and equals [_____] of the total price of the Fixed Initial Doses as laid down in Article 1.7.1. The Down Payment shall be fully deductible from the price of each dose of the Fixed Initial Doses at a rate of [_____] per single dose. The price for each dose for the Fixed Initial Doses remaining for the Participating Member States after deduction of the Down Payment is consequently USD [_____] in.

1.8. Payment Arrangements

1.8.1. Pre-financing (Payment of the Down Payment)

Within [_____] following signature of the APA, the Contractor shall send to the Commission an invoice for the payment of the Down Payment in paper format or in PDF format by email. The invoice shall indicate the reference number of the APA and comply with the invoicing terms of the APA.

The Down Payment shall be paid in a single installment.

The invoice for the Down Payment must contain the following information:
- Name of the addressee
- APA number
1.8.2. Utilisation of the Down Payment

1.8.3. Payment for Supply of Product

After the Commission pays the Down Payment, the balance of payments for the supply of Initial Doses will be paid by each Participating Member State in accordance with the allocation and the relevant signed Vaccine Order Form(s).

The Contractor must send an invoice in paper format or in PDF format by email to the Participating Member States for payment by the Participating Member States under Articles 1.4.2, 1.4.4 and 1.7.2.

The Contractor will send the invoices to each Participating Member State along with each delivery of Product. All amounts set forth in each invoice for a delivery of Product not rejected pursuant to Article 1.5.1 shall be payable by a Participating Member State within [ ] of the date of a Participating Member State’s receipt of such invoice.
The Contractor must send an invoice in paper format or in PDF format by email for payment due under the Vaccine Order Form accompanied by the following documentation (as applicable):

- Proof of delivery of the Products to the place(s) of delivery indicated by the Participating Member State concerned in the Vaccine Order Form.

Each invoice must contain the following information:
- Name of concerned Member State
- APA and Vaccine Order Form number/reference
- Order reference
- Date of receipt of Marketing Authorisation for the Product
- Product
- Quantity delivered
- Delivery reference and date
- Contractor name and bank account.

The Participating Member States must approve the submitted documents or deliverables and pay within 30 days from receipt of the invoice.

1.8.4. Currency

Any payments to be made by the Commission or the Participating Member States under this APA, including under any Vaccine Order Form, shall be made, and any invoices issued pursuant to this APA shall be issued, in Euros (EUR).

All payments required under this APA (including any Vaccine Order Form) are based on a unit price set in United States Dollars (USD). As a currency conversion in EUR will be required in connection with such invoices, the amounts payable hereunder shall be expressed in EUR equivalent using the Exchange Rate Methodology (as defined below).

The “Exchange Rate Methodology” is calculated as the average of the Euro Foreign Exchange Reference Rates as published by the European Central Bank from the beginning of each calendar year up to the penultimate day of the month preceding the invoice, whereby all days are taken into account on which the Euro Foreign Exchange Rate is published. For the purposes of the Down Payment the conversion between the euro and USD is calculated by applying the average exchange rate of the Euro Foreign Exchange Reference Rates as published by the European Central Bank from the first semester of 2021, i.e., from 1 January 2021 to 30 June 2021, whereby all days are taken into account on which the Euro Foreign Exchange Rate is published (the “Benchmark Rate”). This rate is USD: 

For future invoicing under the APA, the Parties agree that the rates resulting from the exchange rate methodology in the paragraph above shall reside in a band from 

the Benchmark Rate.

1.8.5. Bank account
Payments must be made to the Contractor's bank account denominated in euro identified as follows:

Bank:


18.6. Communication Details

For the purpose of this APA, communications must be sent to the following addresses:

The Commission:
European Commission
Directorate-General for Health and Food Safety
E-mail:

Participating Member States will provide the communication details in the Vaccine Order Forms.

Contractor (or leader in the case of a joint tender):

Novavax, Inc.
21 Firstfield Road, Gaithersburg, Maryland 20878 USA
E-mail:

By derogation from this Article, different contact details for the Commission, the Participating Member States or the Contractor may be provided in Vaccine Order Forms.

19. Vaccine IP rights

The Commission and the Participating Member States acknowledge and agree that the Contractor shall be the sole owner of all intellectual property rights generated during the development, manufacture, and supply of the Product, including all know-how (collectively, the "Vaccine IP Rights"). The Contractor shall be entitled to exclusively exploit any such Vaccine IP Rights. Except as expressly set forth in this APA, the Contractor does not grant to the Commission or any of the Participating Member States by implication, estoppel or otherwise, any right, title, license or interest in the Vaccine IP Rights. All rights not expressly granted by the Contractor hereunder are reserved by the Contractor. To the extent a Participating Member State, directly or indirectly, creates, discovers, reduces to practice or otherwise generates intellectual property relating to the composition or method of use of the Product and in connection with the activities contemplated by this APA, such intellectual property will be solely owned by the Contractor. The Participating Member State shall assign, and hereby does assign, to the Contractor all such intellectual property.
and will take reasonable actions requested by the Contractor, at the Contractor's expense, to record and confirm the Contractor's ownership thereof, including signing formal documentation evidencing the Contractor’s ownership thereof.

1.10. Applicable law and settlement of disputes

1.10.1. This APA shall be governed by the laws of Belgium.

1.10.2. Dispute Resolution

(a) In the event of a dispute relating to or in connection with this APA or a Vaccine Order Form between the Contractor and the Commission or a Participating Member State, the Parties shall first refer such dispute to informal dispute resolution discussions between their respective representatives. The Contractor or the Commission on behalf of itself or of the Participating Member States may initiate such informal dispute resolution by sending written notice of the dispute to the other Party, and, within seven (7) days of such notice, the representatives shall meet and attempt to resolve the dispute by good faith negotiations.

(b) The Commission, the Participating Member States, the Contractor and Novavax CZ irrevocably submit to the exclusive jurisdiction of the courts located in Brussels, Belgium to settle any dispute which may arise under or in connection with this APA or the legal relationships established by this APA including under a Vaccine Order Form.

The Contractor and Novavax CZ acknowledge that the Commission is duly authorised by each Participating Member State (i) to send a notice of default to the Contractor and Novavax CZ on behalf of the Participating Member States, (ii) to introduce and pursue legal proceedings and enforce any resulting judgment on behalf of the Participating Member States, and (iii) to take any other action or legal or procedural act related to (i) and (ii) on behalf of the Participating Member States, which the Commission considers useful or necessary to protect the Member States' interests under this APA or any Vaccine Order Form.

1.11. Other special conditions

1.11.1 Each Participating Member State and the Contractor will each maintain records necessary to permit a Recall of any Product delivered to such Participating Member State.

1.11.2 Each Participating Member State and the Contractor will notify the other Party promptly after notifying the European Medicines Agency of any information which might affect the safety or effectiveness of the Product or which might result in the Recall or seizure of the Product in the Participating Member State’s territory.

1.11.3 Upon receiving this notice or upon this discovery, such Participating Member State and the Contractor will stop making any further shipments of any Product specific to the Product lot under recall in their possession or control in such Participating Member State's territory until a decision has been made whether a Recall or some other corrective action is necessary.
1.11.4 The decision to initiate a Recall or to take any other corrective action, if any, with respect to the Product in such Participating Member State's territory will be made by the competent authority concerned, or by the Contractor, in agreement with the competent authority(ies) concerned.

1.11.5 If (i) any regulatory authority issues a decision, order or, following the issuance of a safety warning or alert about a Product, a written request that any Product be Recalled in such Participating Member State's territory; (ii) a court of competent jurisdiction orders a recall in such Participating Member State's territory; or (iii) the Contractor in agreement with the concerned competent authority(ies) determines that any Product should be recalled in such Participating Member State's territory (such a 'Recall'), then the Contractor, the Participating Member State(s) and the competent authority(ies) shall assist each other in the Recall process, as appropriate, having regard to all applicable laws, and especially (a) the EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human Use and Veterinary Use – Part 1 – Chapter 8 “Complaints, Quality Defects and Product Recalls” and (b) the compilation of Community procedures on inspections and exchange information in the meaning of article 3 (i) of the Commission Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use.

In the event of any Recall,

Further, in the event of any Recall not attributable to a Participating Member State's act or omission, the Contractor shall, at Contractor's own election, either (i)

(ii)

1.11.6 The Contractor shall keep the Commission and the Participating Member States informed about any signal detected during the pharmacovigilance or Product monitoring programmes in relation to the Products which are the object of this APA promptly after notifying the European Medicines Agency in accordance with the European Medicines Agency’s guidelines on good pharmacovigilance practices.

1.11.7 The Contractor shall use Reasonable Best Efforts to obtain Marketing Authorisation for the Product as regards its use in the entire adult population in the EU. To that end, Contractor participated in a pre-submission review meeting with EMA, the Rapporteur, Co-Rapporteur, and Peer Reviewer on [ ] to discuss the status of the program and submission procedures and timelines. In Q1 2021, Contractor initiated Rolling Submission / Review procedures in accordance with the COVID-ETF immediately following endorsement by the CHMP. If the Contractor first obtains a conditional Marketing Authorisation for the Product, the Contractor shall use Reasonable Best Efforts to obtain full Marketing Authorisation as soon as possible upon completion of the dataset necessary to obtain such full Marketing Authorisation.
1.11.8 The Contractor shall provide information to the Commission and the Participating Member States, via the Commission, the following information as part of and until its submission for Marketing Authorisation and GMP-compliant production:

(a) 

(b) 

(c) 

For the duration of this APA, the Contractor shall also provide information to the Commission and the Participating Member States, via the Commission, information on 

1.11.9. The Parties acknowledge (a) the interest of the Participating Member States to purchase a vaccine that is effective also against variants and mutations of the SARS-CoV-2 coronavirus 2019 strain identified as the cause of the pandemic outbreak in early 2020, and (b) the Contractor may develop one or more alternative versions of the Product to target any variants or mutations identified to COVID-19 Virus (each a "Variant Product"). The Contractor shall use Reasonable Best Efforts to ensure the continued efficacy of the vaccine to enable the Participating Member States to immunize its citizens as most appropriate.

For clarity, the Contractor may develop a given Variant Product under a new Marketing Authorisation or as a variation under the Marketing Authorisation for the Product. In the event that the Contractor elects to submit a new Marketing Authorisation application or to seek a variation under the Marketing Authorisation for the Product, the Contractor will ensure that such application for Marketing Authorisation is submitted to EMA on a concurrent timeline with similar applications made in other jurisdictions, and, in any event, not later than after the first application for Authorisation is made anywhere in the world.

In case the Contractor intends to submit an application for Marketing Authorisation for a Variant Product (including through a variation of the Marketing Authorisation for the Product) to the EMA, the Contractor shall provide information ("Variant Product Information"). The Contractor acknowledges and agrees that if Marketing Authorisation for a Variant Product is obtained, the Participating Member States shall have the right to purchase such Variant Product, and
Once Contractor has determined the total number of doses of Variant Product available, including for the Commission/Participating Member States, Contractor will notify the Commission in writing of both the amount of available doses allocated to this APA and estimated delivery schedule. The amount of available Variant Product doses allocated to this APA, including the Flexible Initial Doses as referred to in Article 1.4.2 and 1.4.7.1.

The Commission shall, within [ ] of receipt of such estimated delivery schedule, notify Contractor in writing of the Participating Member States' intention of whether or not to obtain Variant Product. If the Commission elects to obtain the Variant Product, Contractor and each Participating Member State obtaining Variant Product shall execute a modification to their Vaccine Order Form memorializing the terms of the Variant Product request, including how many units of Product will be substituted for Variant Product.

If the Commission elects to continue to receive the remaining deliveries of Product, Contractor shall continue to deliver Product pursuant to the APA. If the Commission elects to cancel receipt of the Product, Contractor shall deliver the following deliveries of Product, and the Down Payment attributable to the remainder of undelivered Fixed Initial Doses of the price per dose of Product) will be reimbursed to the Commission within [ ] of Contractor's receipt of written notice and/or credited against outstanding invoices and invoices of future deliveries of Product as the case may be.

The above process will result in an agreed delivery schedule, containing the number of doses of Variant Product and/or Product to be delivered to the Participating Member States ("Variant Product Delivery Schedule"). The Variant Product Delivery Schedule shall qualify as an Updated Delivery Schedule within the meaning of Article 1.4.7.1, so that the rules of Article 1.4.7.2 apply to deliveries made under the Variant Product Delivery Schedule. For the avoidance of doubt, Article 1.4.7.1 shall not apply to the Variant Product Delivery Schedule.

If the Participating Member State(s) elect not to request Variant Product, Contractor shall be free to reallocate such Variant Product to its other bilateral customers and Commission/Participating Member States.

For clarity, if Marketing Authorisation is granted for a Variant Product prior to the date that an Option Increase is exercised in accordance with Article 1.4.4, the Option increase can be exercised, in whole or in part in accordance with the preceding paragraphs, for the Variant Product.

In the event an Option Increase is exercised for Variant Product or Paediatric Product, the right of the Commission and/or Participating Member States to terminate the APA on [ ] pursuant to Article 1.4.7.2 for failure to deliver the Fixed Initial Doses of Product shall expire and be of no further force and effect.
11.10 If the Contractor accrues the necessary data required by EMA for paediatric use, the Contractor commits to use its Reasonable Best Efforts to obtain Marketing Authorisation for paediatric use (i.e. use in the population under 18 years old) for the Product ("Paediatric Product") and For the avoidance of doubt, the extension of the authorised indication to include any or all sections of the paediatric population without any adaptation to the formulation or dosage compared to the adult vaccine should not be considered a Paediatric Product. If the Contractor has submitted an application for authorisation of its product for paediatric use to the EMA, Article 11.9 shall apply mutatis mutandis to the Paediatric Product.

1.12. Definitions

For the purpose of this APA, the following definitions (indicated in italics in the text) apply:

'Acknowledged Root Causes for Delivery Delays': has the meaning set forth in Article I.4.7.1.1.

'Affiliate': with respect to a Party, any other individual, partnership, corporation, limited liability company, association, a joint stock company, trust, joint venture, unincorporated organization, or a governmental entity (or any department, agency, or political subdivision thereof) ("Person") that controls, is controlled by, or is under common control with such Person. For the purpose of this definition only, "control" (including, with correlative meaning, the terms "controlled by" and "under the common control") means the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of any Person, whether by the ownership of more than 50% of the voting securities of such Person, by contract or otherwise.

'APA': has the meaning set forth in the preamble;

'Benchmark Rate': has the meaning set forth in Article I.8.4;

'Breach of obligations': failure by a Party to fulfil one or more of its contractual obligations under this APA;

'Claim': has the meaning set forth in Article II.5.1;

'CMOs': has the meaning set forth in Article II.16.5;

'Commission': has the meaning set forth in the preamble;

'Contractor': has the meaning set forth in the preamble;

'Confidential information or document': any information or document received by either Party from the other or accessed by either Party in the context of the implementation of the APA, that any of the Parties has identified in writing as confidential. It may not include information that is publicly available;
'Conflict of interest': a situation where the impartial and objective implementation of the APA by the Contractor is compromised for reasons involving family, emotional life, political or national affinity, economic interest, any other direct or indirect personal interest, or any other shared interest with the Commission, the Participating Member State or any Third Party related to the subject matter of the APA;

'COVID-19': has the meaning set forth in the Recitals;

'COVID-19 Pandemic': has the meaning set forth in the Recitals;

'Deficient Product': has the meaning set forth in Article 1.5.1;

'Delivery Start Date': has the meaning set forth in Article 1.4.7.1;

'Down Payment': has the meaning set forth in Article 1.7.2;

'European Institutions': has the meaning set forth in Article II.7.6;

'EU Manufacturing Facilities': has the meaning set forth in Article 1.4.7;

'Exchange Rate Methodology': has the meaning set forth in Article 1.8.4;

'Exercising Member State': has the meaning set forth in Article 1.4.4;

'Expected Submission Date': has the meaning set forth in Article 1.4.4;

'Expression of Demand': has the meaning set forth in Article 1.4.2;

'Extended Term': has the meaning set forth in Article II.5.3;

'Financial Statement': has the meaning set forth in Article II.16.5;

'Fixed Initial Doses': has the meaning set forth in Article 1.4.2;

'Flexible Initial Doses': has the meaning set forth in Article 1.4.2;

'Flexible Initial Doses Delivery Schedule': has the meaning set forth in Article 1.4.2;

'Force majeure': any unforeseeable, exceptional situation or event beyond the control of the Parties that prevents either of them from fulfilling any of their obligations under the APA, including explosion, fire, earthquakes, flood and other natural disasters, embargoes, terrorist acts, war or civil war, insurrections, blockade, sabotage, plant breakdown, epidemic and pandemics, shortages, legislative measures or regulations promulgated by supranational, state or governmental authorities or acts, omissions or delays in acting by any supranational, state or governmental authority. The situation or event must not be attributable to error or negligence on the part of the Parties or on the part of the subcontractors and must prove to be inevitable despite their exercising
reasonable due diligence. Defaults in performance of service, defects in equipment or material, labour disputes, strikes and financial difficulties may not be invoked as *force majeure*, unless they stem from a relevant case of *force majeure* as set out above. For the avoidance of doubt, the Covid-19 Pandemic may not be invoked as *Force Majeure*;

‘Formal notification’ (or ‘formally notify’): form of communication between the Parties made in writing by mail or email, which provides the sender with compelling evidence that the message was delivered to the specified recipient;

‘Fraud’: an intentional act or omission committed in order to make an unlawful gain for the perpetrator or another by causing a loss to the Union’s financial interests, and relating to: i) the use or presentation of false or incorrect statements or documents, which has as its effect the misappropriation of wrongfu retention of funds or assets from the Union budget, ii) the intentional non-disclosure of information in violation of a specific obligation, with the same effect or iii) the misapplication of such funds or assets for purposes other than those for which they were originally granted, which damages the Union’s financial interests;


‘Gross Negligence’ means ____________________________

‘Implementation of the APA’: the performance of the APA, the purchase of the Product envisaged in the APA, the signing and performance of Vaccine Order Forms;

‘Indemnified Persons’: has the meaning set forth in Article 11.5.1;

‘Initial Doses’: has the meaning set forth in Article 14.2;

‘Initial Delivery Schedule’: has the meaning set forth in Article 14.7.1;

‘Initial Planning Schedule’: has the meaning set forth in Article 14.7.1;

‘Inspection Period’: has the meaning set forth in Article 15.1;

‘Irregularity’: any infringement of a provision of Union law resulting from an intentional act or omission by an economic operator, which has, or would have, the effect of prejudicing the Union’s budget;

‘Late Delivery(ies)’: has the meaning set forth in Article 14.7.2;

‘Latent Defect’: has the meaning set forth in Article 15.1;
has the meaning set forth in Article 1.4.7.2;

'Losses': has the meaning set forth in Article 1.5.1;

'Marketing Authorisation': the approval under the relevant provisions of Regulation (EC) 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervisions of medicinal products for human and veterinary use and establishing a European Medicines Agency, by the European Commission necessary for the placing on the market of the Vaccine in the territory of the European Union, including conditional marketing authorisation in accordance with Article 14-a of Regulation 726/2004 and as amended or varied from time to time;

'Non-Indemnifiable Loss' shall mean a Loss which a Participating Member State is legally prohibited from indemnifying pursuant to national or Union legislation;

'Notification' (or 'notify'): form of communication between the Parties made in writing including by electronic means;

'Option Doses': has the meaning set forth in Article 1.4.4;

'Option Increase': has the meaning set forth in Article 1.4.4;

'Party' and 'Parties': have the meaning set forth in the preamble;

'Performance of a Vaccine Order Form': the execution of tasks and delivery of the Product by the Contractor to the Participating Member State;

'Product': the finished and packaged form of the Contractor's vaccine against COVID-19 as well as any changes to the product following the initial marketing authorisation, including any improved version of that vaccine or any adapted version for the purpose of addressing mutations or variants of the SARS-CoV-2 virus (i.e., Variant Product) and/or any new formulation, including for the use in adolescents or in children (i.e., Paediatric Product);

'Product Claim': has the meaning set forth in Article 1.5.1;

'Production Warranties': has the meaning set forth in Article 1.6.1(h);

'Professional conflicting interest': a situation in which the Contractor's previous or ongoing professional activities affect its capacity to implement the APA or to perform a Vaccine Order Form to an appropriate quality standard;

'Reasonable Best Efforts': means,
'Recall': has the meaning set forth in Article I.11.5;

'Refundable Items': has the meaning set forth in Article I.16.5;

'Related person': any natural or legal person who is a member of the administrative, management or supervisory body of the Contractor, or who has powers of representation, decision or control with regard to the Contractor;

'Vaccine IP Rights': has the meaning set forth in Article I.9;

'Vaccine Order Form': has the meaning set forth in the Recitals;

'Taxes': has the meaning set forth in Article I.7.1;

'Technical Dispute': has the meaning set forth in Article I.5.3;

'Third Party': any Person other than (a) the Commission or any of the Participating Member States or (b) the Contractor or its Affiliates;

'Third Party Claim': has the meaning set forth in Article I.5.8;

'Trademark': trademarks, service marks, certification marks, trade dress, internet domain names, trade names, identifying symbols, designs, product names, company names, slogans, logos or insignia, whether registered or unregistered, and all common law rights, applications and registrations therefor, and all goodwill associated therewith;

'Union': means the European Union;

'Unspent Amounts': has the meaning set forth in Article I.16.5;

'Updated Delivery Schedule': has the meaning set forth in Article I.4.7.1.1;

'Updated Notice': has the meaning set forth in Article I.4.2;

'Variant Product': has the meaning set forth in Article I.11.9;

'Variant Product Delivery Schedule': has the meaning set forth in Article I.11.9;

'Variant Product Information': has the meaning set forth in Article I.11.9;
‘Willful Misconduct’ means

SIGNATURES
For the Contractor,
John A. Herrmann III, EVP, CLO

For the Commission, on behalf and in the name of the Participating Member States,
Ms Stella Kyriakides, Commissioner for Health and Food Safety

In the event of a joint tender submitted by a group of economic operators and where the group does not have legal personality or legal capacity, one member of the group is appointed as leader of the group.

Signature:
Done at [place], [date]
For Novavax CZ

Signature:
Done at Brussels, [date]

In duplicate in English.
II. GENERAL CONDITIONS FOR THE APA

II.1. Severability

Each provision of this APA is severable and distinct from the others. If a provision is or becomes illegal, invalid or unenforceable to any extent, it must be severed from the remainder of the APA. This does not affect the legality, validity or enforceability of any other provisions of the APA, which continue in full force and effect. The illegal, invalid or unenforceable provision must be replaced by a legal, valid and enforceable substitute provision which corresponds as closely as possible with the actual intent of the Parties under the illegal, invalid or unenforceable provision. The replacement of such a provision must be made in accordance with Article II.11. The APA must be interpreted as if it had contained the substitute provision as from its entry into force.

II.2. Provision of Product

II.2.1 The Contractor must produce and supply the Product in accordance with GMP, the applicable laws in the Participating Member States and the provisions of this APA.

II.2.2 The Contractor must comply with the requirements provided for in this APA in all material respects.

II.2.3 All periods specified in the APA are calculated in calendar days, unless otherwise specified.

II.2.4 The Contractor must immediately inform the Commission of any changes in the exclusion situations as declared, according to Article 137 (1) of Regulation (EU) 2018/1046.

II.3. Communication between the parties

II.3.1 Form and means of communication

Any communication of information, notices or documents under the APA must:

(a) be made in writing in paper or electronic format in the language of the contract;
(b) be in the English language;
(c) bear the APA number and, if applicable, the Vaccine Order Form number;
(d) be made using the relevant communication details set out in Article I.8.6; and
(e) be sent by mail or email.

If a Party requests written confirmation of an e-mail within a reasonable time, the other Party must provide an original signed paper version of the communication as soon as possible.

The Parties agree that any communication made by email has full legal effect and is admissible as evidence in judicial proceedings.

II.3.2 Date of communications by mail and email

Any communication is deemed to have been made when the receiving Party receives it, unless this APA refers to the date when the communication was sent.
E-mail is deemed to have been received by the receiving Party on the day of dispatch of that e-mail, provided that it is sent to the e-mail address indicated in Article 1.6.6 and that the sending Party has received a delivery report or the receiving Party has acknowledged receipt. The sending Party must be able to prove the date of dispatch. Receiving Party shall acknowledge receipt as soon as e-mail is received. In the event that the sending Party receives a non-delivery report, it must make every effort to ensure that the other Party actually receives the communication by email or mail. In such a case, the sending Party is not held in breach of its obligation to send such communication within a specified deadline.

Mail sent to the Commission or the Participating Member State is deemed to have been received on the date on which the department responsible referred to in Article 1.6.6 acknowledges its receipt.

Formal notifications are considered to have been received by the receiving Party on the date of receipt indicated in the proof received by the sending Party that the message was delivered to the specified recipient.

II.4. Liability

II.4.1 Without prejudice to Article II.5, the Commission and the Participating Member States are not liable for any damage or loss caused by the Contractor, including any damage or loss to Third Parties during or as a consequence of Implementation of the APA.

II.4.2 If required by the relevant applicable legislation, the Contractor must take out an insurance policy against risks and damage or loss relating to the Implementation of the APA. It must also maintain customary insurance as is standard practice in the pharmaceutical industry for companies of Contractor’s stage and size. Upon request, the Contractor must provide evidence of insurance coverage to the Commission.

II.4.3 If a third party brings any action against the Commission or the Participating Member State in connection with the performance of the APA or any Vaccine Order Form, including any action for alleged breach of intellectual property rights, the Contractor will provide reasonable assistance to the Commission or the Participating Member State as appropriate, including by intervening in support of the Commission or the Participating Member State upon request.

II.4.4

II.4.5 Without prejudice to Article II.4.6, in no event will the Contractor’s aggregate liability in respect of claims made by the Commission or Participating Member States, of whatever nature, arising out of, under or in connection with this APA and/or any Vaccine Order Form or otherwise as a consequence of Implementation of the APA exceed
II.5. Indemnification

II.5.1. The Commission, on behalf of the Participating Member States, declares that the use of the Product produced under the APA will happen under epidemic conditions requiring such use, and that the administration of the Product will therefore be conducted under the sole responsibility of the Participating Member States. Hence, each Participating Member State shall indemnify and hold harmless the Contractor, its Affiliates and its and their respective sub-contractors, sub-licensees, officers, directors, employees and other agents and representatives (together, the “Indemnified Persons”) from and against any and all

II.5.2. Intentionally omitted

II.5.3. Such indemnification will only be available to the Indemnified Persons if such Losses arise with respect to:

- In the event that
- If such
- grounds are present, the Commission and the Contractor will agree
- If the Contractor and the Commission agree that such grounds are not present, the Contractor and the Commission will
- If those grounds are still (partially) present, the Contractor and the Commission will

II.5.4. Indemnification will not be available to the extent that
II.5.5 Intentionally omitted.

II.5.6 Assistance. In case liability has been incurred by the Indemnified Persons for Losses defined in Article II.5.1, the Contractor shall give the Participating Member State in question, or an independent expert as referred to in Article II.5.7, access to all information for the Participating Member State to indemnify the Indemnified Persons and to verify whether the conditions pursuant to Articles II.5.1 and II.5.4 are fulfilled.

II.5.7 Access to Information. The Participating Member State shall be allowed to access the information as referred to in Article II.5.6 through an independent expert in the field of damages claims, in particular in the field of public health; provided that such independent expert is bound by a confidentiality agreement reasonably acceptable to the Contractor. In that case, the Participating Member State shall notify the Contractor in advance of its intention to use an expert and the identity of such expert. The Contractor shall be allowed to object to the use of an expert within counted from such notification, if it puts forward reasonable grounds on the basis of which the specific expert in question should not be permitted access to such information, such as conflict of interest. In such case, the Participating Member State shall be allowed to appoint a new independent expert and notify that expert to the Contractor. If the Contractor also refuses that expert, the Participating Member State is entitled to seek a court appointed expert, in accordance with Article I.10.2(b).

II.5.8 Procedure. The Contractor shall promptly inform the relevant Participating Member State of any damages claim brought against any of the Indemnified Persons before the courts of that Participating Member State or other forum (“Third Party Claim”), stating the nature and basis of the damages claim in question and the maximum estimated amount of damages; provided that any failure or delay in providing such written notice will not relieve the Participating Member State of its indemnification obligations except to the extent the Participating Member State can demonstrate actual prejudice due to such delay or lack of notice. The Contractor shall keep the Participating Member State informed of any material developments relating to such Third Party Claim, including updates in the estimated maximum amount of damages.

II.5.9 Obligations. The Contractor shall ensure that the Indemnified Persons (i) use to defend themselves against Third Party Claims and (ii) cooperate with the Participating Member State and their legal representatives in the investigation and defense of any matter which is the subject of indemnification.
II.6. Conflict of interest and professional conflicting interests

II.6.1 The Contractor must take all the necessary measures to prevent any situation of conflict of interest or professional conflicting interest.

II.6.2 The Contractor must notify the Commission and the Participating Member States in writing of any situation that could constitute a conflict of interest or a professional conflicting interest during the Implementation of the APA. The Contractor must immediately take action to rectify the situation.

The Commission or the Participating Member States as applicable may do any of the following:
(a) verify that the Contractor’s action is appropriate;
(b) require the Contractor to take further action within a specified deadline;
(c) decide not to enter a Vaccine Order Form with the Contractor.

II.6.3 The Contractor must pass on all the relevant obligations in writing to:

(a) its personnel;
(b) any natural person with the power to represent the Contractor or take decisions on the Contractor’s behalf;
(c) Third Parties involved in the Implementation of the APA, including subcontractors.

The Contractor must also take reasonable precautions to ensure that the persons referred to above are not placed in a situation which could give rise to conflicts of interest.

II.7. Confidentiality

II.7.1 The Commission, the Participating Member State and the Contractor must treat with confidentiality any information or documents, in any format, disclosed in writing, relating to the Implementation of the APA and identified in writing as confidential.

II.7.2 The Commission, the Participating Member State and the Contractor shall:

(a) not use confidential information or documents for any purpose other than to perform its obligations or exercise and/or enforce its rights under the APA or a Vaccine Order Form without the prior written agreement of the other Party;
(b) ensure the protection of such confidential information or documents with the same level of protection as its own confidential information or documents and in any case with due diligence and no less than a reasonable level of protection;
(c) not disclose, directly or indirectly, confidential information or documents to Third Parties unless such Third Parties have a need to know such confidential information for the purposes set forth in Article II.7.2 and agree to comply with this Article or are subject to substantially similar confidentiality obligations as provided in this Article.
II.7.3 The confidentiality obligations set out in this Article are binding on the Commission, the Participating Member States and the Contractor during the Implementation of the APA and for as long as the information or documents remain confidential unless:

(a) the disclosing Party agrees to release the receiving Party from the confidentiality obligation earlier;
(b) the confidential information or documents become public through other means than a breach of the confidentiality obligation;
(c) the applicable law requires the disclosure of the confidential information or documents. Prior to making any such disclosure, the receiving Party shall promptly inform the disclosing Party of the requirement to disclose as soon as the receiving Party becomes aware that such a requirement might become effective. The receiving Party shall disclose only that portion of the disclosing Party's confidential information or documents that it is required to disclose.

II.7.4 The Contractor shall obtain from any natural person with the power to represent it or take decisions on its behalf, as well as from Third Parties involved in the Implementation of the APA, a commitment that they will comply with this Article or ensure that such person or Third Party is subject to substantially similar confidentiality obligations. At the request of the Commission, the Contractor must provide a document providing evidence of this commitment.

II.7.5 Notwithstanding the other provisions of this Article, the Commission, the Participating Member States and the Contractor may issue a press release and/or other public statement relating to this APA. The Parties shall consult together on and aim to agree the timing, contents and manner of any press release and/or other public statement relating to this APA, prior to any issuance of such press release and/or other public statement. A Party may subsequently publicly disclose any information previously contained in any public announcement made in accordance with this Article.

II.7.6 The Contractor acknowledges that the Commission, along with other agencies and offices of the European Union (collectively, the “European Institutions”), are subject to requirements under Regulation (EC) 1049/2001, which may require the European Institutions to disclose information to Third Parties on request. The Commission commits itself to assess any request for access to a document that relates to this contract according to the exclusions or exceptions set forth in Regulation (EC) 1049/2001 and consult with the Contractor regarding the same to the extent required under such regulation.

II.8. Processing of personal data

II.8.1 Processing of personal data by the Commission

Any personal data included in or relating to the APA, including its implementation, shall be processed in accordance with Regulation (EU) 2018/1725. Such data shall be processed solely for the purposes of the implementation, management and monitoring of the APA by the data controller. For the purpose of this provision, the data controller for the Commission shall be the Director-

The Contractor or any other person whose personal data is processed by the data controller in relation to this APA has specific rights as a data subject under Chapter III (Articles 14-25) of Regulation (EU) 2018/1725, in particular the right to access, rectify or erase their personal data and the right to restrict or, where applicable, the right to object to processing or the right to data portability.

Should the Contractor or any other person whose personal data is processed in relation to this APA have any queries concerning the processing of its personal data, it shall address itself to the data controller. They may also address themselves to the Data Protection Officer of the data controller. They have the right to lodge a complaint at any time to the European Data Protection Supervisor.

II.8.2 Processing of personal data by the Contractor

The processing of personal data by the Contractor shall meet the requirements of Regulation (EU) 2018/1725 and be processed solely for the purposes set out by the controller.

II.9. Subcontracting

II.9.1 The Contractor shall be responsible for, and liable to the Commission and the Participating Member States for the acts or omissions of any subcontractor it engages to have the APA implemented.

II.9.2 In the case of subcontracting, the Contractor remains bound by its contractual obligations and is solely responsible for the Implementation of the APA.

II.9.3 The Contractor must ensure that the subcontract does not affect the rights of the Commission and the Participating Member States under this APA.

II.9.4 The Commission may request the Contractor to replace a subcontractor found to be in a situation provided for in one of the situations provided for in Article 136(1) and (2) of the Financial Regulation.

II.10. Amendments

II.10.1 Any amendment to the APA or a Vaccine Order Form must be made in writing. A Vaccine Order Form does not constitute an amendment to the APA.

II.10.2 No amendment can make changes to the APA or a Vaccine Order Form that might materially alter the initial conditions of the procurement procedure or result in unequal treatment of tenderers or Contractors.
II.11. Assignment

II.11.1 The Contractor cannot assign any of the rights and obligations arising from the APA, including claims for payments or factoring, without prior written consent of the Commission, such consent not to be unreasonably withheld, delayed or conditioned. In such cases, the Contractor must provide the Commission with the identity of the intended assignee. This APA will bind and inure to the benefit of the successors and permitted assigns of the respective Parties.

II.11.2 Any right or obligation assigned by the Contractor without consent of the Commission is not enforceable against the Commission or the Participating Member States.

II.12. Intellectual property rights

II.12.1 Intentionally Omitted.

II.12.2 Evidence of Vaccine IP Rights

II.13. Force majeure

II.13.1 If a Party is affected by force majeure, it must immediately notify the other Party, stating the nature of the circumstances in sufficient detail, their likely duration and foreseeable effects.

II.13.2 Excepting payment obligations, a Party is not liable for any delay or failure to perform its obligations under the APA if that delay or failure is a result of force majeure.

II.13.3 The Parties must take all necessary measures to limit any damage due to force majeure.

II.13.4 For the avoidance of doubt, except in the case of force majeure or Acknowledged Root Causes for Delivery Delays, no unforeseen circumstances whatsoever allow Contractor to amend, revise, suspend or terminate the APA or to request the APA to be amended, revised, suspended or terminated. Contractor expressly waives the right to invoke the doctrine of hardship insofar as it is applicable.
II.14. Intentionally Omitted

II.15. Suspension of the implementation of the APA

II.15.1 Suspension by the Contractor

If the Contractor is affected by force majeure, it may suspend the provision of the services and Product under a Vaccine Order Form. The Contractor must immediately notify the Commission and the Participating Member States of the suspension. The notification must include a description of the force majeure in sufficient detail and state when the Contractor expects to resume the provision of services and the Product. The Contractor must notify the Commission and the Participating Member States as soon as it is able to resume performance of the Vaccine Order Form, unless the Commission has already terminated the APA or the Vaccine Order Form.

II.15.2 Suspension by the Commission or the Participating Member State

The Commission or the Participating Member State in question may suspend the Implementation of the APA or performance of a Vaccine Order Form (of such Participating Member State) or any part of it:

(a) if the procedure for awarding the APA or a Vaccine Order Form or the Implementation of the APA proves to have been subject to irregularities, or fraud by the Contractor;

(b) in order to verify whether the Contractor's presumed irregularities, or fraud have actually occurred.

The Commission or the Participating Member State in question must formally notify the Contractor of the suspension and the reasons for it. Suspension takes effect on the date of formal notification, or at a later date if the formal notification so provides.

The Commission or the Participating Member State in question must promptly and in good faith investigate the issue giving rise to the formal notification and formally notify the Contractor as soon as the verification is completed whether:

(a) it is lifting the suspension; or

(b) it intends to terminate the APA or its Vaccine Order Form under Article 16.2(c).

The Contractor is not entitled to compensation for so long as Implementation of the APA or a Vaccine Order Form is under suspension pursuant to this Article. The Commission will ensure the investigation is conducted expeditiously to minimize the duration of suspension period.

II.16. Termination

II.16.1 Failure to obtain Market Authorisation or Inability to provide the Product due to Clinical Failure

If the Contractor fails to receive Marketing Authorisation of the Product, then as a remedy, the Commission and the Participating Member States may terminate this APA and the Vaccine Order Forms with immediate effect upon written notice to the Contractor and any amount of the Down Payment will become due and refundable to the Commission.
II.16.2 Additional grounds for termination by the Commission or a Participating Member State

In addition to the right under Article II.16.1, the Commission may terminate the APA or a Participating Member State may terminate its ongoing Vaccine Order Form in the following circumstances:

(a) on the grounds referred to in Article 1.4.7.1.1 and 1.4.7.2;
(b) if (i) the Contractor repeatedly refuses to sign one or several Vaccine Order Form(s) without valid reason, or (ii) Contractor is in material breach of obligations under the APA or Vaccine Order Form (and there is no other express termination right provided in regard to such obligation);
(c) if the Contractor or any person that assumes unlimited liability for the debts of the Contractor is in one of the situations provided for in points (a) and (b) of Article 136(1) of the Financial Regulation;
(d) if the Contractor or any related person is in one of the situations provided for in points (c) to (h) of Article 136(1) or to Article 136(2) of the Financial Regulation;
(e) if the procedure for awarding the APA proves to be subject to irregularities or fraud or Contractor is in material breach of obligations in the implementation of the APA;
(f) if the Contractor is in a situation that could constitute a conflict of interest or a professional conflicting interest;
(g) if a change to the Contractor’s legal, financial, technical, organizational or ownership situation substantially modifies the conditions under which the APA was initially awarded, or a change occurs regarding the exclusion situations listed in Article 136 of Regulation (EU) 2018/1046 that calls into question the decision to award the contract; (i) in the event of force majeure, where either resuming implementation is impossible or the necessary ensuing amendments to the APA or a Vaccine Order Form would mean that the tender specifications are no longer fulfilled in material respects.

II.16.3 Grounds for termination by the Contractor

The Contractor may terminate the APA or the respective Vaccine Order Form in the following circumstances:

(a) If the Commission or any of the Participating Member States are in material breach of obligations under the APA or Vaccine Order Forms.
(b) In the event of force majeure, where either resuming implementation is impossible or the necessary ensuing amendments to the APA or a Vaccine Order Form would mean that the tender specifications are no longer fulfilled in material respects.

II.16.4 Procedure for termination

A Party must formally notify the other Party of its intention to terminate the APA or a Vaccine Order Form and the grounds for termination.

For terminations other than due to a breach of payment obligations to the Contractor or other than a termination by the Commission or a Participating Member State pursuant to Articles II.16.1 or II.16.2(a), the other Party has [INSERT] following the date of receipt to submit observations, including the measures it has taken or will take to continue fulfilling its contractual obligations. Failing that, the decision to terminate becomes enforceable the day after the time limit for submitting observations has elapsed. For payment obligations, the period to submit observations shall be [INSERT]. There shall be no such period for a termination associated with Article II.16.1 or II.16.2(a).

If the other Party submits observations, but in the reasonable judgement of the Party intending to terminate such observations do not address its concerns, the Party intending to terminate must formally notify the Party submitting observations of its intention to terminate this APA or a Vaccine Order Form and the grounds for termination.

II.16.5 Effects of termination on Down Payment
II.17. Invoices, Taxes, value added tax and e-invoicing

II.17.1 Payment Requests, Invoices and value added tax

Payment requests and invoices shall contain the following information: (i) the Contractor's full name and address, (ii) the reference to this APA and to the Vaccine Order Form, (iii) the full name and address of the recipient, (iv) the name of the Participating Member State concerned, (v) the invoiced amount, (vi) the quantity of Product doses delivered, or, with respect to the Down Payment, the quantity of Product doses allocated to the Participating Member States pursuant to Articles 1.4.2 and 1.4.4, (vii) the date of delivery (if relevant), and (ix) the date of issuance of the payment request or invoice.

Invoices must indicate the place of taxation of the Contractor for value added tax (VAT) purposes and must specify separately amounts not including VAT and amounts including VAT (where VAT is applicable) where required according to local applicable VAT law. VAT may be charged on doses of the Product under the conditions of national legislation. In such cases, the taxable amount may include the amount paid by the Participating Member State as well as the respective portion of the Down Payment paid by the Commission.

For the further avoidance of doubt, the Parties agree that all prices set forth in the APA shall be exclusive of VAT and that VAT, if any, shall be paid in addition to the prices set forth in the APA. Each Participating Member State acknowledges that it is registered for VAT in its respective Member State and will promptly provide such VAT registration number upon request from the Contractor.

If a Participating Member State is required under the law of any jurisdiction to deduct or withhold any sum of Taxes imposed on or in respect of any amount due or payable to Contractor, the Taxes shall be paid and borne by the Participating Member State for Participating Member State's own account. Each Participating Member State agrees to pay an additional amount required to be withheld or deducted to the relevant agency in accordance with the applicable Law and to provide evidence of payment thereof to Contractor.

II.18. Payments and guarantees

II.18.1 Date of payment
The date of payment is deemed to be the date on which the Commission’s account or the account of the Participating Member State in question is debited.

II.18.2 Costs of transfer

The costs of the transfer are borne as follows:

(a) 

(b) 

(c) 

II.18.3 Suspension of the time allowed for payment

The Commission or the Participating Member State in question may suspend the payment periods specified in Article 1.8.3 at any time by notifying the Contractor (or leader in the case of a joint tender) that its invoice cannot be processed. The reasons the Commission or the Participating Member State in question may cite for not being able to process an invoice are:

(a) because the invoice does not comply with the requirements specified in the APA; or
(b) because it disputes Contractor’s performance of services specified in such invoice.

The Commission or the Participating Member State in question must notify the Contractor as soon as possible of any such suspension (but not later than 30 days after receipt of such invoice), giving the reasons for it. In the case of the situation described in (b) above, the Commission or the Participating Member State in question shall notify the Contractor (or leader in case of a joint tender) of required corrections or (b) above, the Commission or the Participating Member State in question shall formally notify the Contractor (or leader in case of a joint tender) of the perceived performance failure.

Suspension takes effect on the date the Commission or the Participating Member State in question sends the notification. The remaining payment period resumes from the date on which the corrected invoice is provided or the dispute is resolved. If the dispute cannot be resolved within 30 days, the Contractor shall have the right to suspend its performance of further deliveries under the APA until the dispute is resolved.

II.18.4 Interest on late payment

On expiry of the payment periods specified in Article 1.8.3, the Contractor is entitled to interest on late payment at the annual rate of 4% per annum. Suspension of the payment period as provided for in Article II.18.3 is not considered as giving rise to late payment. Interest on late payment covers the period running from the day following the due date for payment up to and including the date of payment as defined in Article II.18.1.
II.19. Recovery

II.19.1 Recovery Procedure

Before any recovery permitted under this APA, the Commission or the Participating Member State in question must formally notify the contractor of its intention to recover the amount it claims, specifying the amount due and the reasons for recovery, and inviting the Contractor to make any observations within the time stated in the notice of receipt. Notwithstanding anything to the contrary herein, the Down Payment will only be subject to recovery as set forth in Articles II.16.1 and II.16.3.

If no observations have been submitted or if, despite the observations submitted, the Commission or the Participating Member State in question decides to pursue the recovery procedure, it must confirm recovery by formally notifying a debit note to the Contractor, specifying the date of payment. The Contractor must pay in accordance with the provisions specified in the debit note. If the Contractor does not pay by the due date, the Commission or the Participating Member State in question may, after informing the contractor in writing, recover the amounts due:

(a) 
(b) by taking legal action.

II.19.2 Interest on late payment

If the Contractor does not honour the obligation to pay the Unspent Amounts due by the date set by the Commission or the Participating Member State in question, the amount due bears interest at the rate indicated in Article II.18.4. Interest on late payments will cover the period starting on the day after the due date for payment and ending on the date when the Commission or the Participating Member State in question receives the full amount owed (including accrued interest). Any partial payment is first entered against charges and interest on late payment and then against the principal amount.

II.20. Checks and audits

II.20.1 The Commission and the European Anti-Fraud Office may check or require an audit on the Implementation of the APA. This may be carried out either by OLAF's own staff or by any outside body authorised to do so on its behalf, provided that the auditor may not be a competitor of the Contractor.

Such checks and audits may be initiated at any moment during business hours during the provision of the services and up to five years starting from the payment of the balance of the last specific contract issued under this APA.

The audit procedure is initiated on the date of receipt of the relevant letter sent by the Commission. Audits are carried out on a confidential basis.

II.20.2 The Contractor must keep all original documents stored on any appropriate medium, including digitised originals if authorised under national law, for a period of five years starting from the payment of the balance of the last specific Vaccine Order Form issued under this APA.
II.20.3 The Contractor must grant the appropriate right of access to sites and premises where the APA is implemented, and to all information, including information in electronic format, needed to conduct such checks and audits. The Contractor must ensure that the information is readily available at the moment of the check or audit and, if so requested, that information is handed over in an appropriate format. The auditor must, insofar possible, comply with all applicable and reasonable security measures notified to Commission by the Contractor subject to this not creating any material obstacles for the performance of the auditor’s tasks.

II.20.4 On the basis of the findings made during the audit, a provisional report is drawn up. The Commission or its authorised representative must send it to the Contractor, who has 30 days following the date of receipt to submit observations. The Contractor must receive the final report within 60 days following the expiry of the deadline to submit observations.

On the basis of the final audit findings, the Commission or the Participating Member State in question may recover all or part of the payments made in accordance with Article II.19.

II.20.5 In accordance with Council Regulation (Euratom, EC) No 2185/96 of 11 November 1996 concerning on-the-spot checks and inspection carried out by the Commission in order to protect the European Communities’ financial interests against fraud and other irregularities and Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office, the European Anti-Fraud Office may carry out investigations, including on the spot checks and inspections, to establish whether there has been fraud, corruption or any other illegal activity under the contract affecting the financial interests of the Union. Findings arising from an investigation may lead to criminal prosecution under national law.

The investigations may be carried out at any moment during the provision of the Product and up to five years starting from the payment of the balance of the last Vaccine Order Form issued under this APA.

II.20.6 The Court of Auditors and the European Public Prosecutor’s Office established by Council Regulation (EU) 2017/1396 (the "EPPO") have the same rights as the Commission, particularly right of access, for the purpose of checks, audits and investigations.

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* Council Regulation (EU) 2017/1396 of 12 October 2017 implementing enhanced cooperation on the establishment of the European Public Prosecutor’s Office.
ANNEX II: MODEL FOR VACCINE ORDER FORM

[Letterhead of Government if available]

This Vaccine Order Form is submitted by:

[The Government of [...] (the “Member State”), represented for the purposes of signing this specific order form by [forename, surname, function, department of authorising officer],

to:

Novavax, Inc.
(hereinafter referred to as “the Contractor”)

The Member State and the Contractor are together referred to as the “Parties” and each individually as a “Party”.

WHEREAS

— The Contractor and the European Commission, acting on behalf of and in the name of the Participating Member States, entered into an Advance Purchase Agreement for the purchase and supply of the Contractor’s COVID-19 vaccine for EU Member States SANTE/2021/C3/XX (the “APA”), the terms of which are binding on the Participating Member States.

— The APA provides that:

i. each Participating Member State will submit to the Contractor a Vaccine Order Form through which the Contractor shall (subject to the terms and conditions of the APA) deliver to the relevant Participating Member State a proportion of the Initial Doses, and

ii. [in the event the Commission, acting on behalf of the Participating Member State(s), has exercised the Option Increase, will submit to the Contractor a separate Vaccine Order Form through which the Contractor shall (subject to the terms and conditions of the APA) deliver to the relevant Participating Member State a proportion of the relevant Option Doses,]

both (i) and (ii) at the price and conditions as set out in the APA.

— In accordance with Article 1.4.3, the Member State hereby places its order for its allocation of Initial Doses or the relevant Option Doses (as applicable).
Article I
Definitions

Capitalized terms used but not defined in this Vaccine Order Form shall have the meaning given in the APA.

Article II
Subject matter

1. This Vaccine Order Form is submitted by the Member State to the Contractor in accordance with the terms of the APA, and forms an integral part of the APA. The terms and conditions of the APA are incorporated into this Vaccine Order Form by reference. In the event of contradiction between this Vaccine Order Form and the APA, the terms of the APA prevail regardless of any provision to the contrary.

2. This Vaccine Order Form relates to the order for the Member State's full allocated Initial Doses [or the relevant Option Doses (as applicable)] as set out in the Allocation provided by the Commission to the Contractor pursuant to Article 14.3 or 14.4 of the APA. The provision of this Vaccine Order Form by the Member State to the Contractor constitutes a binding order by the Member State for the purchase of its full allocated Initial Doses or the relevant Option Doses (as applicable) at the Price.

Article III
Delivery; Quality

1. **Delivery Address.** The mutually agreed and understood Delivery Address for the Member State is as follows:

   [* - Member State to enter location *]

2. **Quality.** The roles and responsibilities between the Contractor and the Member States in relation to acceptance/rejection matters related to the Product doses are set out in Article 15 of the APA.

Article IV
Invoices; Notices

1. **Invoice and Payments.** The Contractor shall invoice the Member State in accordance with the terms of the APA. All payments to the Contractor shall be made in accordance with the terms of the APA.
2. Notice. Any notice given under this Vaccine Order Form must be made in writing in English in paper or electronic format; bear the APA number and the number of this Vaccine Order Form; be made using the relevant communication details set out below with respect to the Member State and the Contractor (as applicable); and be sent by email:

Member State:
[Name of Member State]
[Full official address of Member State]
[Full name of addressee physical person (contact person)]
[Function of addressee physical person (contact person)]
E-mail: [complete email of addressee physical person (contact person)]

Contractor:
[complete]

Article V.
Entry into Force and Duration

1. This Vaccine Order Form shall become effective upon execution and delivery by the Member State to the Contractor in accordance with 1.4.3 or 1.4.4 of the APA as applicable.

2. This Vaccine Order Form shall automatically expire upon Delivery of the Member State's full allocated Initial Doses or the relevant Option Doses (as applicable) as set out in the Allocation provided by the Commission to the contractor pursuant to Article 1.4.3 or 1.4.4 of the APA as applicable.

3. Expiry of the Vaccine Order Form shall be without prejudice to Article 1.3.6 of the APA (Surviving Provisions).

Article VI.
Applicable Law and Settlement of Disputes

Article 1.10 (Applicable Law and Settlement of Disputes) of the APA shall apply mutatis mutandis to this Vaccine Order Form.

(Signature page follows)
SIGNATURES

For the Member State,
[forename/surname/position]

Signature: ______________________
Done at [place], [date]

For acceptance of the Vaccine Order Form,
[forename/surname/position]

Signature: ______________________
Done at [place], [date]
ANNEX III: AGREEMENT BETWEEN THE COMMISSION AND MEMBER STATES ON PROCURING COVID-19 VACCINES ON BEHALF OF THE MEMBER STATES AND RELATED PROCEDURES, ANNEXED TO THE COMMISSION DECISION C(2020) 4192 FINAL OF 18 JUNE 2020

Agreement

Preamble

Having regard to Article 4(5)(h) of Council regulation (EU) 2016/369 on the provision of emergency support within the Union as amended by Council regulation (EU) 2020/521 of 14 April 2020 activating the emergency support under regulation (EU) 2016/369, and amending its provisions taking into account the COVID-19 outbreak (hereinafter "ESI" or "ESI regulation");

***

The European Commission ("the Commission")

and

The following Member States: (XXX), hereinafter referred to as "the Participating Member States" Together referred to as "the Parties"

Agree on the Following:

Article 1: Objective and mandate of the Commission

On the basis of the present agreement, the Commission is mandated to conclude, on behalf of the Participating Member States, Advance Purchase Agreements ("APA") with vaccine manufacturers with the objective to procure vaccines for the purposes of combating the COVID 19 pandemic at Union level.

The Annex to this agreement sets out the negotiating directives for this purpose.

Article 2: Acquisition of vaccine doses

It is the Participating Member States, and not the Commission, that shall acquire vaccine doses from the manufacturers on the basis of the APAs unless otherwise agreed. All relevant vaccination policies shall therefore remain matters for the Participating Member States.

Article 3: APAs containing a right to acquire vaccine doses

Where the Commission concludes an APA in conformity with the present agreement that provides the right for the Participating Member States to acquire vaccine doses, the use of such a
right shall take place by means of the conclusion of contracts between the Participating Member States and the vaccine manufacturers. There shall be no obligation for any Participating Member State to conclude such a contract on the basis of the APA. The APA shall contain a clause to this end.

Article 4: APAs containing an obligation to acquire vaccine doses

Where the Commission intends to conclude, in conformity with the present agreement, an APA containing an obligation to acquire vaccine doses, it shall inform the Participating Member States of such intention and the detailed terms. In case a Participating Member State does not agree with the conclusion of an APA containing an obligation to acquire vaccine doses or its terms, it has the right to opt out by explicit notification to the Commission within 5 working days after the Commission has communicated its intention to conclude the APA. All Participating Member States not having opted out within the period of 5 working days are deemed to have authorised the Commission to negotiate and conclude the APA with the vaccine manufacturer in their name and on their behalf.

Article 5: The legally binding nature of APAs

Once concluded, the terms of the APA shall be legally binding on the Participating Member States, except for those who have exercised their right to opt out.

Article 6: Responsibility and liability

The present Agreement regulates only the division of potential liability and indemnification between the Commission and the Participating Member States. It does not regulate the extent to or the conditions under which potential liability of the vaccine manufacturer may be taken over or indemnified under the APAs.

The Commission shall be exclusively responsible for the procurement process and the conclusion of APAs including any liability arising out of the conduct of the negotiations.

Participating Member States acquiring a vaccine shall be responsible for the deployment and use of the vaccines under their national vaccination strategies, and shall bear any liability associated with such use and deployment. This shall extend to and include any indemnification of vaccine manufacturers under the terms and conditions of the relevant APA for liability related to the use and deployment of vaccines normally borne by such manufacturer.

Article 7: Obligation not to negotiate separately

By signing the present Agreement, the Participating Member States confirm their participation in the procedure and agree not to launch their own procedures for advance purchase of that vaccine with the same manufacturer.

In case an APA containing an obligation to acquire vaccine doses has been concluded with a specific manufacturer, the Member States having made use of the opt-out provided under
the present Agreement can enter into separate negotiations with the same manufacturer after the APA under the present Agreement has been signed.

Annex

Initial considerations

A permanent solution to the COVID-19 crisis is most likely to be brought about by the development and deployment of a safe and effective vaccine against the virus. Every month gained in the deployment of a vaccine will save many lives, many jobs and billions of Euros.

Therefore, it is the objective of the present Agreement that the EU takes steps to secure sufficient supplies of a safe and effective vaccine for Member States.

Structure and purpose of the procurement

Work on a COVID-19 vaccine is challenging for many reasons: the shortened development timeframe, the large upfront costs for manufacturers, the high failure rate during clinical trials. If vaccine producers follow their usual practice of making investments in production capacity only when they are sure of a viable product, this will result in considerably longer waiting times for a vaccine. Investments need to be made now in order to ensure that vaccines are being produced at the scale required as early as possible.

Under the present agreement, this challenge will be addressed through concluding EU-level Advance Purchase Agreements ("APA") with vaccine manufacturers when necessary, to secure access to vaccine candidates where they are successful, including up-front EU financing to de-risk essential investments to increase the speed and scale of manufacturing successful vaccines. Funding for the up-front payments will come from the Emergency Support Instrument (ESI).

The Parties understand that developing a safe and effective vaccine is a highly complex process and the risk of failure in any such venture is very high. Therefore, the aim is to put in place APAs with a number of manufacturers of leading vaccine candidates, to maximise the chances of having access to at least one successful vaccine.

The Commission will invite all vaccine manufacturers to manifest interest. In general, the Commission will give priority to negotiating specific APAs with those manufacturers that (a) have entered or have firm plans to enter clinical trials still in 2020, (b) have the capacity to develop a successful vaccine and (c) have a proven capacity to produce at scale already in 2021.

Process and governance

In order to run the procurement centrally and efficiently, the European Commission will set up a steering board for the process subject to Article 6 of the present Agreement. It will be co-
chaired by the European Commission and a Participating Member State with experience in the negotiations and production capacities for vaccines. The steering board will include senior officials from all Participating Member States to assist and provide guidance throughout the evaluation process.

The co-chairs of the steering board will propose a team of a limited number of experts with relevant experience for the ongoing negotiations from six Participating Member States with production capacities for vaccines. These experts will join with the European Commission in a negotiation team ("joint negotiation team"), which will work on a continuous basis as one unit. That joint negotiation team will start work immediately building on previous contacts with individual companies by the European Commission and Participating Member States. In order to launch negotiations with a specific manufacturer, there needs to be support from at least four Participating Member States. The joint negotiation team will make its best effort to take the advice of the steering board into account in the negotiations and will report back to the steering board on a regular basis on the progress made in negotiating with individual companies.

For compliance with the applicable rules, all members of the steering board and the joint negotiation team will obtain the status of experts associated to the procurement process as provided in the Financial Regulation. Given their access to highly sensitive business information, all those members will be required to sign strict confidentiality and no-conflict-of-interest agreements.

Assisted by the steering board, the European Commission will then decide which of the resulting APAs should be concluded, in particular if financing under ESI is insufficient to finance all relevant packages. The Commission will only consider those APAs for financing where at least four Participation Member States have expressed agreement. Before making any final decisions, the Commission will seek independent scientific advice on the state of progress and the available data on quality, safety and efficacy for the vaccine candidate in question.

Should financing under ESI be insufficient, Participating Member States can decide to top up ESI funding to make up the gap to finance all packages. In such a case where there are opportunities to conclude further APAs but money from ESI is no longer sufficient, Participating Member States will have the opportunity to express their interest in such opportunities. If at least four Participating Member States express interest, those Participating Member States will make use of the possibility of a voluntary contribution to ESI to the required amount allowing the Commission to proceed with signing the APA only on behalf of those Member States that have expressed interest and contributed the funds to ESI.

For full transparency, the European Commission will report to the IPCR at least once every two weeks on overall progress more generally.
Advanced Purchase Agreements and conditions

To conclude APAs, the joint negotiating team will negotiate funding packages with individual vaccine producers in return for the right to buy a specific number of vaccine doses in a given timeframe and at a certain price.

As outlined in the present Agreement, the European Commission also has the possibility to conclude APAs including an obligation to procure the vaccine if it becomes available, where the conditions (notably the pricing) of those APAs make this worthwhile and in line with the conditions in the present Agreement. If in such a case the distinction between up front payments and purchase price is difficult to draw, the Commission will share the total cost related to the vaccine purchase but will in any case contribute no more than 50% of the total cost.

Funding provided up front will be considered as an advance payment for any eventual purchase by Member States, thus reducing the amount that Member States will have to pay when eventually purchasing that vaccine.

The up-front payments under the APAs shall be used by manufacturers to de-risk the necessary investments related to both vaccine development and clinical trials, and the preparation of the at-scale production capacity along the entire vaccine production value chain in the EU required for a rapid deployment of millions of doses of an eventual vaccine. The relevant payments should be structured according to the need of the manufacturer, but subject to the state of the vaccine development, in particular relying on transparency of the associated clinical data and its assessment at the time of payment. This is in order to avoid obligations to pay in situations where the development work has shown a vaccine candidate likely to be unsuccessful.

The purchase price of the vaccine, as well as the amount of funding provided up front will take into account a transparent estimation of production costs (supported by independent audits where available), as well as the resources already granted from other public sources. Under the APA, the manufacturer can be asked to provide ex post proof supported by independent audits concerning the activities financed by these payments.

The aim of the negotiation is to conclude APAs with individual companies under the best possible conditions. These APAs should specify details with respect to:

a) Payments to be made, such as payment amounts, payment schedules, type of payments requested and the use of those payments related to de-risk investment, financing clinical trials, providing working capital and scaling-up production capacity;

b) Delivery details of the vaccine if successful, such as price per person immunised (or alternatively, number of doses required per person immunised and price per dose), quantity of doses to be delivered and delivery timeline following approval;

and
c) Any other relevant conditions, such as production capacity built or used in the EU or liability arrangements.

For liability arrangements, the joint negotiation team will make its best effort to limit what is required by individual companies for the purpose of indemnification to be included in the terms and conditions of the APA.

The APAs will contain provisions to clarify the law applicable to both the APA and resulting purchase orders as well as the competent courts. The Participating Member States agree that each APA negotiated by the Commission on their behalf with a vaccine manufacturer will have the same applicable law for all Participating Member States, and that the courts corresponding to that applicable law will be competent to hear disputes arising from that APA.

When taking a decision to finance individual APAs, the European Commission, in consultation with the steering board, will take into account the following elements: any available data on quality, safety and efficacy of the vaccine at time of negotiation of the contract, speed of delivery at scale, cost, risk-sharing, diversification of technologies, capacity to supply through development of production capacity within the EU, possible flexible future use of any capacity funded, engagement at an early stage with EU regulators with the intention to apply for an EU marketing authorisation for the candidate vaccine(s), commitment to supply vulnerable countries.

The procedure outlined above complies with the ESI Regulation and the Financial Regulation. The latter is aligned to the European procurement Directives, which also provide the basis for national procurement rules. Participating Member States may rely on the procedure run by the European Commission to directly purchase vaccines from the manufacturers as and when any of the vaccines becomes available based on the conditions laid down in the APA. Access to vaccine doses will be allocated to Participating Member States according to the population distribution key.

In the negotiations with the pharmaceutical industry under the present Agreement, the Commission will promote a Covid-19 vaccine as a global public good. This promotion will include access for low and middle income countries to those vaccines in sufficient quantity and at low prices. The Commission will seek to promote related questions with the pharmaceutical industry regarding intellectual property sharing, especially when such IP has been developed with public support, in order to these objectives. Any vaccines available for purchase under the APAs concluded but not needed and purchased by Participating Member States can be made available to the global solidarity effort.

Pages 63-70 have been deleted as they are fully protected by Article 4(2) first indent of Regulation (EC) No 1049/2001