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SENSITIVE

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ANNEX
to the

COMMISSION DECISION

approving an Advance Purchase Agreement on COVID-19 vaccines



Contract No: SANTE/2020/C3/087 - S12.854725



EUROPEAN COMMISSION
Directorate-General for Health and Food Safety

Sensitive*

RELEASABLE TO: Need to know basis

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.



Bohumil 138
281 63 Jevany
Czech Republic
VAT Registration Number: [REDACTED]

represented for the purposes of the signature of this APA by [REDACTED]

on the other part,

Contractor and Novavax CZ – hereinafter collectively referred to as ‘the signatories’ – shall be [REDACTED] 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*.

RECITALS

- 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 NVAX-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.

- D. 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 combatting the *COVID-19 pandemic* in the European Union.
- E. 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.
- F. 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*.
- G. According to the Agreement between the *Commission* and the *Member States*² 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.
- H. 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

² Such agreement is based on Article 4(5)(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 II 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* [REDACTED] 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 [REDACTED]
- 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 I.4.2, to be allocated among the *Participating Member States* by the *Commission* in accordance with the allocation principles set out below in Article I.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 I.4.4. Such *Option Increase* is to be allocated between the *Participating Member States* by the *Commission* as set out below in Article I.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 [REDACTED] after 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 I.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 I.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 I.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 [REDACTED] 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. [REDACTED]

[REDACTED] 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, II.1, II.3, II.4, II.5, II.7, II.16.5, II.18.4, II.19.2, and II.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 I.4.3 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 I.4.3.

I.4.2. Initial Doses

Without prejudice to the *Option Increase* (see Article I.4.4), 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 I.4.7.1 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 I.4.7.1 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 [REDACTED] before the [REDACTED] the *Commission* on behalf of the *Participating Member States* shall communicate to the *Contractor* its demand of *Flexible Initial Doses* for [REDACTED], as well as the desired delivery schedule [REDACTED] ("*Expression of Demand*"). For clarity, the initial [REDACTED] *Expression of Demand* shall be due [REDACTED] and communicate the demand for [REDACTED], with the subsequent [REDACTED] *Expression of Demands* due on [REDACTED]. In a situation where *Variant Product* is available pursuant to Article I.11.9, 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 [REDACTED] 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* [REDACTED] for which they have been requested) and the [REDACTED] during which these quantities can be delivered by the *Contractor* ("*Flexible Initial Doses Delivery Schedule*"). If the *Expression of Demand* is [REDACTED] the *Initial Planning Schedule* for the *Flexible Initial Doses* set

out in Article I.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*. [REDACTED]

The *Flexible Initial Doses Delivery Schedule* shall qualify as an *Updated Delivery Schedule* within the meaning of Article I.4.7.1.1, so that in particular the rules of Article I.4.7.2 apply to deliveries made under the *Flexible Initial Doses Delivery Schedule*. In addition, the cancellation right of Article I.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* is [REDACTED] in the *Expression of Demand*. For the avoidance of doubt, Article I.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.

I.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) *Option Doses* pursuant to the procedure specified in Article 1.4.4.

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

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

1.4.4. Option Increase

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

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

On or prior to [REDACTED] after delivery of the estimate, the *Commission* will be entitled to exercise the *Option Increase* by written notice from the *Commission* to the *Contractor*, which written notice shall specify which supply schedule it elects, the *Participating Member States* participating in such *Option Increase* (the "*Exercising Member States*"), the aggregate number of doses of *Product* to be purchased for the *Option Increase*, and the allocation of doses of *Product* to be purchased by and delivered to each such *Exercising Member State* (the "*Additional Option Doses*"). For clarity, if the *Commission* exercises the *Option Increase*, in one or more tranches, for less than one hundred million (100,000,000) doses in the aggregate, then all references to *Option Increase* in this *APA* will be limited to the amount of doses of *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 [REDACTED] 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.

I.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 [REDACTED]. The clinical and Chemistry, Manufacturing and Controls (CMC) packages should be available for submission throughout [REDACTED]

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 Best Efforts* to supply [REDACTED], the *Products* to the *Participating Member States* using only manufacturing facilities of itself or of contract manufacturers located in the European Union.

[REDACTED]

I.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 [REDACTED] 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 resale 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) [REDACTED]

(b) [REDACTED]

For the avoidance of doubt, the *Contractor* may not require the reselling 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 reselling 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 reselling 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 [REDACTED], 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 [REDACTED] delivery schedule ("*Initial Delivery Schedule*").

To support supply of doses the *Additional Option Doses* delivered in connection with the *Option Increase*, *Contractor* commits [REDACTED], to establish the necessary additional manufacturing facilities located in the European Union and/or will have presented a plan to the *Commission* that [REDACTED]

[REDACTED] 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*"). [REDACTED]

1.4.7.1. Initial Delivery Schedule and Initial Planning Schedule

The *Fixed Initial Doses* shall be delivered according to the following [REDACTED] *Initial Delivery Schedule* based on an estimated [REDACTED] *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)

	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Number of Fixed Initial Doses	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Cumulative Fixed Initial Doses	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

Initial Planning Schedule (for Flexible Initial Doses)

	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Number of Flexible Initial Doses	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Cumulative Flexible Initial Doses	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

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 [REDACTED]

█ ("Expected Submission Date") 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 █ 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 █ may have a shorter shelf life (but not below █) upon delivery to the Participating Member States. Product delivered from █ 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 I.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.

1.4.7.1.1. Updated Delivery Schedules Prior to Obtaining Marketing Authorization

The Contractor shall, █, 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 █ in advance of expected date of receipt of Marketing Authorization, 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 █ 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 █, the Updated Delivery Schedule shall be identical to the Initial Delivery Schedule. In case the Marketing Authorisation is not granted by █ 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 █ then the Updated Delivery Schedule will reflect the delay between █ and the date of the Marketing Authorisation.

If the anticipated delivery date of *Product* doses per an *Updated Delivery Schedule* is more than [REDACTED] 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 [REDACTED] late by providing written notice to the *Contractor* within [REDACTED] 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 [REDACTED] 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 [REDACTED] and the *Contractor* shall be relieved of its obligation to deliver such *Product* units. The *Down Payment* attributable to such undelivered *Product* units ([REDACTED] % of the price per dose of *Product*) will be reimbursed to the *Commission* within [REDACTED] 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, [REDACTED] 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 [REDACTED] may vary by [REDACTED] 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. [REDACTED]

In the event that the *Contractor* has a delay in delivery of more than [REDACTED] of the doses foreseen for a given [REDACTED] in the *Updated Delivery Schedule* and that the delay exceeds a period of [REDACTED] s after [REDACTED] in which 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 [REDACTED] after [REDACTED] in which delivery was foreseen in the *Updated Delivery Schedule*, the *Contractor* shall [REDACTED]

[REDACTED]

If the *Late Delivery* is made more than [REDACTED] after [REDACTED] in which delivery was foreseen in the *Updated Delivery Schedule*, the *Contractor* shall [REDACTED]

[REDACTED]

If the *Late Delivery* is made more than [REDACTED] after [REDACTED] which delivery was foreseen in the *Updated Delivery Schedule*, the *Contractor* shall [REDACTED]

[REDACTED]

If a *Late Delivery* delay exceeds a period of [REDACTED] after [REDACTED] 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 [REDACTED] 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 [REDACTED] following its receipt of the revised supply schedule.

[REDACTED]

If a *Participating Member State* elects to cancel delivery of *Product* pursuant to this 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 [REDACTED] the *Commission* shall have the unconditional right to cancel the delivery of the doses and in addition the unconditional right to terminate the *APA*.

[REDACTED] 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 [REDACTED] 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 Members States* in an unfair manner.

I.4.7.3 Overall Delivery Considerations

In addition to the updates regarding the *Initial Delivery Schedule* per [REDACTED] and per [REDACTED], the *Contractor* shall provide the *Commission* and the *Participating Member States* with an estimated [REDACTED] delivery schedule detailing the relevant [REDACTED] of delivery. The *Contractor* will provide the *Commission* and the *Participating Member States* without delay with any possible change of that schedule. The *Contractor* may agree with the *Participating Member States* to make multiple deliveries over a [REDACTED] or over [REDACTED], in varying quantities, and will do so on a rolling non-discriminatory basis as between all *Participating Member States*. Such deliveries will be pro rata 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 [REDACTED] 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 organisations 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* [REDACTED]

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 II.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 [REDACTED] (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 [REDACTED] period with at least [REDACTED] 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 [REDACTED] 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 [REDACTED] 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 I.5.4.

I.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 [REDACTED] 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 [REDACTED] 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 [REDACTED] 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 [REDACTED] each *Party* is entitled to have the expert appointed in court, in accordance with Article I.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 I.11.2. For the avoidance of doubt, any technical determination by the expert under a *Technical Dispute* may be used as evidence under Article I.11.2. The *Contractor* and the *Participating Member State* will require the expert to provide an opinion on each referred issue (with reasonably detailed reasoning) within [REDACTED] (or as agreed by the *Contractor* and the *Participating Member State* with the expert). The *Contractor* and the *Participating Member State* will give to the expert all the evidence and information within their respective possession or control as the expert may reasonably request, which they will disclose promptly and in any event within [REDACTED] 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 I.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*.

I.5.5 If a *Participating Member State* makes a *Product Claim* pursuant to this Article I.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 [REDACTED] after the time of such agreement or determination). If such replacement products are not delivered within this time limit and without prejudice to Article I.4.7.1.1 and I.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 11.4.6, 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*.

1.6. 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 1.5, without prejudice to Article 11.5.1.
- (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:



Upon execution of the *APA*, the price per single dose of *Product* is [REDACTED] 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 [REDACTED] USD (i.e., USD [REDACTED] 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



If by [REDACTED] (or by [REDACTED] 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.



[REDACTED]

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 [REDACTED] of the total price of the *Fixed Initial Doses* set forth in Article 1.7.1 (the "*Down Payment*"), payable within [REDACTED] after the receipt of an invoice following signature of this *APA*.

The *Down Payment* is [REDACTED] which is based on USD [REDACTED] calculated using the Exchange Rate Methodology and equals [REDACTED] 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 [REDACTED] 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 [REDACTED].

1.8. Payment Arrangements

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

Within [REDACTED] 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 instalment.

The invoice for the *Down Payment* must contain the following information:

- Name of the addressee
- *APA* number

– *Contractor's name and bank account.*

The *Commission* must approve the submitted documents and pay the *Down Payment* within [REDACTED] after receipt of the invoice and the supporting documents.

1.8.2. Utilisation of the Down Payment

[REDACTED]

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 States* 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 [REDACTED] 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 [REDACTED] 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 pen-ultimate 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 [REDACTED].

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 [REDACTED] 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:

[REDACTED]

[REDACTED]

1.8.6. 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:

[REDACTED]

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

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

[REDACTED]

Novavax, Inc.

21 Firstfield Road, Gaithersburg, Maryland 20878 USA

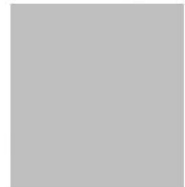
E-mail:

[REDACTED]

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*.

1.9. 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 [REDACTED] 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 some 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 (each 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 (1) 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*, [REDACTED]

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) [REDACTED]

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 [REDACTED] 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 [REDACTED] 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) [REDACTED]
- (b) [REDACTED]
- (c) [REDACTED]

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

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 [REDACTED] 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 [REDACTED]

[REDACTED] ("*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 [REDACTED]

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* [REDACTED] including the *Flexible Initial Doses* as referred to in Article 1.4.2 and 1.4.7.1.

The *Commission* shall, within [REDACTED] 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*. [REDACTED]

[REDACTED] 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 [REDACTED] deliveries of *Product*, and the *Down Payment* attributable to the remainder of undelivered *Fixed Initial Doses* [REDACTED] of the price per dose of *Product*) will be reimbursed to the *Commission* within [REDACTED] 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 [REDACTED] 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 1.4.7.1.1, 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 1.4.7.1.1 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 [REDACTED] 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.

1.11.10 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 [REDACTED] 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 1.11.9 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 security 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 I.5.1;

'Delivery Start Date': has the meaning set forth in Article I.4.7.1;

'Down Payment': has the meaning set forth in Article I.7.2;

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

'EU Manufacturing Facilities': has the meaning set forth in Article I.4.7;

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

'Exercising Member State': has the meaning set forth in Article I.4.4;

'Expected Submission Date': has the meaning set forth in Article I.4.7;

'Expression of Demand': has the meaning set forth in Article I.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 I.4.2;

'Flexible Initial Doses': has the meaning set forth in Article I.4.2;

'Flexible Initial Doses Delivery Schedule': has the meaning set forth in Article I.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 or wrongful 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;

‘Good Manufacturing Practices’ or ‘GMP’: means the current practices for manufacture required by the standards, rules, principles and guidelines set out in Directive 2001/83/EC as last amended, Directive 2003/94/EC, Directive 2017/1572 and *EudraLex - Volume 4 of the Rules Governing Medicinal Products in the EU* entitled “EU Guidelines to Good Manufacturing Practice Medicinal Products for Human and Veterinary Use”;

‘Gross Negligence’ means [REDACTED]

‘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 1.4.2;

‘Initial Delivery Schedule’: has the meaning set forth in Article 1.4.7.1;

‘Initial Planning Schedule’: has the meaning set forth in Article 1.4.7.1;

‘Inspection Period’: has the meaning set forth in Article 1.5.1;

‘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 1.4.7.2;

‘Latent Defect’: has the meaning set forth in Article 1.5.1;

 has the meaning set forth in Article I.4.7.2;

'Losses': has the meaning set forth in Article II.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 I.4.4;

'Option Increase': has the meaning set forth in Article I.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 I.5.1;

'Production Warranties': has the meaning set forth in Article I.6.1(b);

'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 II.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 II.16.5;

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

: 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 [REDACTED]

SIGNATURES

For the Contractor,

John A. Hermann III, EVP, CLO

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: [REDACTED]

Done at [place], [date]

For Novavax CZ

For the Commission, on behalf and in the name of the Participating Member States,

Ms Stella Kyriakides, Commissioner for Health and Food Safety

Signature: [REDACTED]

Done at Brussels, [date]

Signature: [REDACTED]

Done at [place], [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.1.1. 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 1.8.6 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 1.8.6 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 Forms*, 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 [REDACTED]

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 [REDACTED]

[REDACTED]

11.4.6 [REDACTED]

[REDACTED]

11.5. Indemnification

11.5.1. 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 [REDACTED]

[REDACTED]

11.5.2. *Intentionally omitted*

11.5.3 Such indemnification will only be available to the *Indemnified Persons* if such *Losses* arise with respect to [REDACTED]

In the event that [REDACTED]

If such grounds are present, the *Commission* and the *Contractor* will agree [REDACTED]

If the *Contractor* and the *Commission* agree that such grounds are not present, the *Contractor* and the *Commission* will [REDACTED]

If those grounds are still (partially) present, the *Contractor* and the *Commission* will [REDACTED]

[REDACTED]

11.5.4 Indemnification will not be available to the extent that [REDACTED]

[REDACTED]

[REDACTED]

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 [REDACTED] 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 [REDACTED] 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 [REDACTED] / [REDACTED] to defend themselves against *Third Party Claims* and [REDACTED] and (ii) [REDACTED] cooperate with the *Participating Member State* and their legal representatives in the investigation and defense of any matter which is the subject of indemnification. [REDACTED]



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.

11.7.3 The confidentiality obligations set out in this Article are binding on the *Commission*, the *Participating Member State* 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.

11.7.4 The *Contractor* must 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.

11.7.5 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.

11.7.6 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) 1049/2001⁴, 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.

11.8. Processing of personal data

11.8.1 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-

⁴ Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31.5.2001, p. 43.

General of the European Commission's Directorate-General for Health and Food Safety. The data protection notice is available at https://ec.europa.eu/info/data-protection-public-procurement-procedures_en.

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

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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*. [REDACTED]

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(e).

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* [REDACTED], 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 [REDACTED] of the *Down Payment* will become due and refundable to the *Commission* [REDACTED]

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 on-going *Vaccine Order Form* in the following circumstances:

- (a) on the grounds referred to in Article I.4.7.1.1 and I.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 Regulation⁵;
- (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 have been subject to *irregularities* or *fraud* or *Contractor* is in material *breach of obligations* in the *Implementation of the APA*;
- (g) if the *Contractor* is in a situation that could constitute a *conflict of interest* or a *professional conflicting interest*;
- (h) 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

⁵ Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012, OJ L 193 of 30.7.2018, p.1 <https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1544791836334&uri=CELEX:32018R1046>

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 [REDACTED] 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 [REDACTED] s. 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. [REDACTED]

II.16.5 Effects of termination on Down Payment

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]





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, (viii) 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) [REDACTED]
- (b) [REDACTED]
- (c) [REDACTED]

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 [REDACTED] 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 [REDACTED] 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 [REDACTED]

[REDACTED] 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 [REDACTED] 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.16.5.

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) [REDACTED]
- (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) 2017/1939⁶ ('the *EPPO*') have the same rights as the *Commission*, particularly right of access, for the purpose of checks, audits and investigations.

⁶ Council Regulation (EU) 2017/1939 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 I.4.3 or I.4.4 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 I.5 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 I.4.3 or I.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 I.4.3 or I.4.4 of the APA as applicable.
3. Expiry of the Vaccine Order Form shall be without prejudice to Article I.3.6 of the APA (*Surviving Provisions*).

Article VI.

Applicable Law and Settlement of Disputes

Article I.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)(b) 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 combatting 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 manufacturers.

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 Participating 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 upfront 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 these 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