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ANNEX

to the

COMMISSION DECISION

of 17/11/2020

approving an Advance Purchase Agreement on COVID-19 vaccines

Sensitive*
RELEASABLE TO: Need to know basis

EUROPEAN COMMISSION
Directorate-General for Health and Food Safety

ADVANCE PURCHASE AGREEMENT ("*APA*")[1] for the development, production, advance purchase and supply of a COVID-19 vaccine for EU Member States

NUMBER - SANTE/2020/C3/049 - SI2.838442

1. The European Commission (the **"Commission"**), acting on behalf and in the name of the Member States listed in **Annex I** (the **"participating Member State(s)"**)[2] being represented for the purposes of the signature of this *APA* by Ms Stella Kyriakides, Commissioner for Health and Food Safety

and

2. **CUREVAC AG,** Friedrich-Miescher-Str. 15, 72076 Tübingen, Deutschland, HRB 754041, Stuttgart District Court, DE 221 393 632,

(the **"contractor"**), represented for the purposes of the signature of this *APA* which has the form of a framework contract by [redacted]r,

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 – Template *Vaccine Order Form*

Annex III – Annex 7 to Commission Decision C(2020) 4192 final of 18 June 2020 - Agreement between the *Commission* and Member States on procuring COVID-19 vaccines on behalf of the Member States and related procedures

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.

2 As provided for in Article 4(5)(b) of Council Regulation (EU) 2016/369 of 15 March 2016 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.

[redacted]

Annex IV – Preliminary *Specification* of the *Product*

Annex V – List of (planned) manufacturing network partners

Annex VI – Template *Goods Received Form*

Annex VII – Description of the *contractor*'s intended utilisation of the *up-front payment* and the *second up-front payment*

which form an integral part of this *APA*.

RECITALS

A. The world is experiencing an emergency healthcare crisis due to the SARS-CoV-2 ("***COVID-19***") pandemic (the "***COVID-19* pandemic**") and the global demand for vaccines to prevent *COVID-19* virus infection is expected to be in order of magnitude of billions of doses.

B. The *contractor* and its *affiliates* are currently working to develop and manufacture an mRNA-based vaccine to help protect against *COVID-19* virus infection in humans (the "**Product**" as further defined below).

C. The *contractor*'s project for the development of the *Product* has completed dose selection and is about to enter pivotal Phase IIB/III clinical trial studies towards regulatory submission. Furthermore, the *contractor* is currently establishing its own and external manufacturing capacities in Europe through partnerships with experienced contract manufacturing organisations ("**CMOs**") in order to meaningfully contribute to controlling the *COVID-19 pandemic*. While the *contractor* has prioritised and accelerated its efforts to develop and manufacture the *Product* in light of the current *COVID-19 pandemic*, there is nonetheless substantial uncertainty around these efforts, in particular with respect to (i) the clinical development of the *Product*, with respect to (ii) the *Product*'s ability to show sufficient efficacy to prevent a *COVID-19* infection, with respect to (iii) the question whether the *Product* might have inacceptable adverse event symptoms beyond what will be documented in the ongoing and planned clinical trials and with respect to (iv) obtaining timely *EU marketing authorisation* for the *Product* as well as with respect to (v) the establishment of sufficient production and manufacturing capacity.

D. The *Commission* intends to create the environment required to support a secure manufacturing network and optimisation for the production of vaccines against *COVID-19*. To this effect 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* at Union level.

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 a vaccine 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 cleared by the competent regulatory bodies.

G. According to the Agreement between the *Commission* and the Member States[3] 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 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 complemented by a *Vaccine Order Form* ("**Vaccine Order Form**") between each of the *participating Member States* and the *contractor*. A template *Vaccine Order Form* for the agreement 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* require significant investments by the *contractor* to increase the speed of vaccine research and development and clinical trials and 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.

J. Pursuant to these terms and conditions, access to *Product doses* will be allocated to Member States according to a population distribution key, unless a different allocation would be communicated by the *Commission* to the *contractor*. The up-

[3] 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 III to this *APA*).

front payments, 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 accelerated development timelines to deliver the clinical trial and follow-up programme agreed with EMA means that the *contractor* under no circumstance can warrant, or assume any liability, at the time of entry into force of this *APA* that the *Product* will be ultimately available or will produce the desired results, i.e. shows sufficient efficacy to prevent a *COVID-19* infection, or be without inacceptable side effects. The *participating Member States* are willing to share those risks, which includes an obligation of the *participating Member States* to indemnify the *contractor* and its CMOs in case of liability incurred, settlements paid and certain costs relating to third party claims with respect to those risks under the conditions set out in this *APA*. The *Commission* and *participating Member States* acknowledge that the use of *Products* 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*.

L. The *participating Member States* acknowledge that, in light of the uncertainties both with respect to the development of the *Product* and the accelerated establishment of sufficient manufacturing capacities, the delivery dates set out in this *APA* are the *contractor*'s current best estimates only and subject to change. Due to possible delays in the authorisation, production and release of the *Product*, no *Product* or only reduced volumes of the *Product* may be available at the estimated delivery dates set out in this *APA*. In the case of delays to the anticipated availability of the *Product*, the *contractor* aims to allocate the *doses* of the *Product* fairly across the demand of *doses*, which the *contractor* has or will contractually commit to towards its present and future customers, as such *doses* become available.

M. The *participating Member States* further acknowledge that the *specification* of the *Product* has not yet been fully determined and still contains target specifications, which are being refined as supporting data emerges. In particular, the vaccination regimen (anticipated to be two doses, twenty-eight (28) calendar days apart) and product shelf-life and stability profile have not yet been fully established. Also, the final presentation of the *Product* is still under consideration. The preliminary *specification* provided in Annex IV to this *APA* is therefore only indicative. The final *specification* will be determined by the *EU marketing authorisation*.

N. 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 225 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 180 million additional *doses* of the *Product* within 30 days from the *contractor* obtaining (conditional) *EU marketing authorisation*, subject to the terms and conditions of this *APA*.

This *APA* sets out:

a. the procedure and conditions by which the *Commission* and the *participating Member States* shall pay for the purchase from and supply of the *Product* by the *contractor*;
b. the supply obligations of the *contractor* for the *Product* and the estimated delivery schedule;
c. the provisions that apply to any *Vaccine Order Form* which the *participating Member States* and the *contractor* may conclude under this *APA*; and
d. 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 this *APA*, including all annexes.

(b) The provisions set out in the special conditions and the general conditions (including all annexes other than Annexes II and VI) take precedence over those in the template *Vaccine Order Form* (Annex II) and in any *Vaccine Order Form* concluded between a *participating Member State* and the *contractor*.

(c) The provisions set out in the special conditions and the general conditions (including all annexes other than Annex VI) take precedence over Annex VI.

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. DEFINITIONS

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

'Additional Doses up-front payment': the up-front payment relating to the *Additional European Doses* as specified in Article I.17.2(b).

'Additional European Doses': the additional number of *doses*, which may be ordered by the *Commission* in accordance with Article I.7.2.

'Affiliate': any company, partnership or other entity that controls, is controlled by, or is under common control with the *contractor*. For purposes of this definition only, "control" means (a) to possess, directly or indirectly, the power to direct the management or policies of an entity, whether through ownership of voting securities, by contract relating to voting rights or corporate governance or otherwise, or (b) to own, directly or indirectly, more than 50 % of the outstanding voting securities or other ownership interest of such entity, provided that, if applicable law requires a minimum percentage of local ownership, control will be established by direct or indirect beneficial ownership of 100 % of the maximum ownership interest that may, under such applicable law, be owned by foreign interests, provided, however, that regarding the *contractor*, the term affiliate shall not include [redacted] and/or any other companies controlled by [redacted] that are not subsidiaries of the *contractor*.

'Apparent defect': any defect of the *Product* existent at the moment of delivery at the *delivery site* of the relevant *participating Member State* that has been identified or could have been identified upon visual inspection of the pallet or grouping box of the *Product* or the temperature monitoring device. It may include a physical damage, a leakage, an incorrect labelling or temperature readings or recordings that deviate from the required cold chain specifications.

'Breach of obligations': failure by the *contractor* to fulfil one or more of its contractual obligations, unless the *APA* (i) states explicitly that the non-fulfilment of an obligation shall not result in any consequences or (ii) provides for a specific consequence other than those set forth in Article II.14.

'CMO': a contract manufacturing organisation.

'Commission': the European Commission.

'Confidential information or document': any information or document disclosed or given between the *Parties* or on their behalf in the context of the negotiation and conclusion of the *APA* (including the terms of the *APA* and the *Vaccine Order Forms*) and/or the performance of the *APA*. It does not include any information (i) the receiving *Party* can prove was known to it prior to the date of disclosure; (ii) the receiving *Party* can prove was lawfully obtained from a third party without any obligation of confidentiality; (iii) is or becomes part of the public domain other than through any act or omission of the receiving *Party*; or (iv) is independently developed by the receiving *Party* without use of or reference to the disclosing *Party*'s *confidential information or documents*, as evidenced by the receiving *Party*'s records.

'Conflict of interest': a situation where the impartial and objective performance of this *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 this *APA*, it being understood that the conclusion, implementation and performance of further agreements on the provision of the *Product* shall not constitute a *conflict of interest*.

'Contractor': CUREVAC AG with its seat in Tübingen, registered with the commercial register of the local court of Stuttgart under HRB 754041.

'*COVID-19* pandemic': the pandemic as further described in the Recitals.

'Delivery site(s)': the delivery site as indicated in the relevant *Vaccine Order Form*.

'Dose': the amount of the *Product* as specified in Article I.6.3.

'EMA': the European Medicines Agency.

'EU 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 *Product* for vaccination in the territory of the European Union, including conditional marketing authorisation in accordance with Article 14-a of Regulation 726/2004 and Commission Regulation 507/2006/EC.

'Final specification': the final specification of the *Product* as to be determined by *contractor* in accordance with in Article I.6.2.

'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*. 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 due diligence. Defaults of service, defects in equipment or material or delays in making them available, labour disputes, strikes and financial difficulties may not be invoked as *force majeure*, unless they are caused by a relevant case of *force majeure*.

'Formal notification' (or '**formally notify**'): form of communication between the *Parties* made in writing by mail or e-mail in English, which provides the sender with compelling evidence that the message was delivered to the specified recipient.

'Fraud': an 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, incorrect or incomplete statements or documents, which has as its effect the misappropriation or wrongful retention of funds or assets from the Union budget, ii) the 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.

'GDP': good distribution practices in accordance with standards currently required by EU legislation, regulation and guidance, in particular those set out in its Guidelines of 5 November 2013 on Good Distribution Practice of medicinal products for human use published by the European Commission (2013/C 343/01) and other applicable regulation pertaining to distribution practices throughout the supply chain, all as updated, amended and revised from time to time.

'GMP': good manufacturing practices in accordance with standards currently required by EU legislation, regulation and guidance and in particular those set out in Directive 2001/83/EC (as amended), Directive 2003/94/EC, Directive 2017/1572 and the guidelines set out in EudraLex - Volume 4 of the Rules Governing Medical Products in the European Union entitled "Good Manufacturing Practice (GMP)", all as updated, amended and revised from time to time.

'Goods Received Form': acknowledgement of receipt of the *Products* in the form of the template attached as Annex VI to be issued by the *participating Member States* as specified in Article I.14.5.

'Grave professional misconduct': a violation of applicable laws or regulations or ethical standards of the profession to which a contractor or a related person belongs, including any conduct leading to sexual or other exploitation or abuse, or any wrongful conduct of the *contractor* or a related person which has an impact on its professional credibility where such conduct denotes wrongful intent or gross negligence.

'Hidden defect': a physical damage or product manufacturing defect of the *Product* that does not qualify as an *apparent defect*.

'Indemnified Person(s)': the persons specified as *Indemnified Persons* in Article I.23.3.

'Initial European Doses': the initial number of *doses* as specified in Article I.7.1.

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

'Loss(es)': any harm, damage or loss as specified in Article I.23.3.

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

'Participating Member States': the Member States listed in Annex I.

'Party' (or **'Parties'**): the persons specified as *Parties* in the beginning of this Agreement..

'Performance of a *Vaccine Order Form*': the delivery of the *Product* by the *contractor* to the *participating Member State*.

'Product': the pandemic *COVID-19* vaccine as specified in Article I.6.

'Product IP Rights': the intellectual property rights generated during the development, manufacture, and supply of the *Product*, including know-how, as specified in Article I.20.1.

'Product Price': the price for the *Product* per *dose* as specified in Article I.16.1.

'Professional conflicting interest': a situation in which the *contractor*'s previous or ongoing professional activities affect its capacity to implement this *APA* or to perform a *Vaccine Order Form* to an appropriate quality standard, it being understood that the conclusion, implementation and performance of further agreements on the provision of the *Product* shall not constitute a *professional conflicting interest.*

'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*.

'Reasonable best efforts': a reasonable degree of best effort to accomplish a given task, acknowledging that such things as, without limitation, the complex and highly regulated nature of the *Product*; the timely availability of raw materials, inventories and liquid funds; yield of process; the success of necessary clinical trials programs to support safety and immunogenicity data for the *Product*; the approval of the final *Product* formulation; *contractor*'s commitments to other purchasers of the *Product*; other reasons relating to the uncertainties of producing a new vaccine for a new disease with an mRNA platform for which vaccines have not yet been registered by regulatory authorities; and any other currently unknown factors which may delay or render impossible, *contractor*'s successful completion of the particular task, including without limitations, developing a suitable production process as may be required for a new strain of virus, ramping up capacity at contract manufacturing partners, meeting delivery schedules and obtaining the *EU marketing authorisation* may be beyond the complete control of the *contractor*, provided, however, that the *contractor* shall not be required to take any actions inconsistent with past practice, ordinary course of business, prudent and reasonable business behaviour and/or the *contractor*'s budget plannings at the date hereof.

'Result': any intended outcome of the implementation of the *APA*, whatever its form or nature. A *result* may be further defined in this *APA* as a deliverable. A *result* may, in addition to newly created materials produced specifically for the *participating Member States* by the *contractor* or at its request, also include pre-existing materials.

'Second up-front payment': the further up-front payment as specified in Article I.17.2(a).

[redacted]

'Specific deliveries': the delivery terms under the *Vaccine Order Form* as specified in Article I.8.4.

'Temporary national authorisation': the temporary distribution authorisation granted by the relevant *participating Member State* in accordance with national laws and Article 5 (2) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.

'Third Party Claim': any damages claim brought against any of the *Indemnified Persons* as specified in Article I.23.9.

'Up-front payment': the up-front payment specified in Article I.17.1.

'Vaccine Order Form': a contract concluded between the *contractor* and a *participating Member State*, substantially in the form of Annex II as attached to this *APA*, specifying details of the *delivery site*.

I.3. SUBJECT MATTER

The subject of this *APA* is the advance purchase of 225 million *doses* of the *Product*, as defined below in Article I.6, to be allocated among the *participating Member States* by the *Commission* in accordance with the allocation principles set out below in Article I.8.1. Additionally, this *APA* gives the *Commission* the option to order, on behalf and in the name of the *participating Member States*, up to 180 million additional *doses* of the *Product* once *EU marketing authorisation* has been granted, such additional *doses* to be allocated between the *participating Member States* by the *Commission* as set out below in Article I.8.3.

On the basis of this *APA*, the *contractor* commits to use *reasonable best efforts* (i) to obtain *EU marketing authorisation* for the *Product* and (ii) to establish sufficient manufacturing capacities to enable the manufacturing and supply of the contractually agreed volumes of the *Product* to the *participating Member States* in accordance with the estimated delivery schedule set out below in Article I.11 once at least a conditional EU marketing authorisation has been granted.

The delivery of the *Product* to the individual *participating Member States*, which, without prejudice to Article I.6.2, shall in principle be subject to the grant of at least a conditional EU marketing authorisation, shall be carried out in accordance with the terms and conditions of this *APA* and in particular the allocation decision *formally notified* by the *Commission*, as well as the additional detailed terms of delivery set out in the *Vaccine Order Forms* to be concluded between the *contractor* and the *participating Member States* using the template *Vaccine Order Form* provided as Annex II to this *APA*.

I.4. ENTRY INTO FORCE AND DURATION OF THE APA

I.4.1. This *APA* enters into force on the date on which the *contractor* and the *Commission* have signed it.

I.4.2. This *APA* has a term of 24 months from the date of its entry into force. Its duration may be extended if at the end of the term of 24 months not all of the *Initial European Doses* or *Additional European Doses*, as the case may be, have been supplied. In

such case, its duration will be extended until the delivery of all of the *Initial European Doses* or all of the *Additional European Doses*, as the case may be.

I.4.3. During the term of this *APA*, the *contractor* shall not enter into any agreements or accept any commitments which would impede the *contractor*'s ability to fulfil its main performance obligations under this *APA*.

I.4.4. The *participating Member States* and the *contractor* may not sign any *Vaccine Order Form* after this *APA* expires.

Articles I.23 and II.6 shall remain in full force and effect, and this *APA* continues to apply to all *Vaccine Order Forms* signed prior to its expiry, even after the expiry of this *APA*.

I.5. IMPLEMENTATION OF THE APA

This *APA* shall be implemented following entry into force as follows:

I.5.1. 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.

I.5.2. 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.8 and will *formally notify* this allocation to the *contractor*. The allocation *formally 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*.

I.5.3. Each *participating Member State* and the *contractor* will conclude a *Vaccine Order Form*, using the template *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*. For the avoidance of doubt, each *participating Member State* is obligated to purchase and pay for the *doses* contractually allocated to it as *formally notified* by the *Commission* regardless of whether such *Vaccine Order Form* is concluded or not. The general conditions and the special conditions under this *APA* shall apply to, and, pursuant to Article I.1, prevail over, the *Vaccine Order Forms*.

I.5.4. Wherever this *APA* provides that certain rights enjoyed by the *participating Member States* under the *APA* shall be exercised by the *Commission*, the *Commission* alone shall be entitled to notify the *contractor* of the exercise of such rights. Such *notification* shall be binding upon all *participating Member States*.

I.5.5. Wherever this *APA* provides that certain *notifications* of the *contractor* shall be issued to the *Commission*, such *notification* to the *Commission* shall bind all *participating Member State(s)*. The *Commission* is acting on behalf and in the name of the *participating Member States* in such cases.

I.5.6. The foregoing Articles I.5.4 and I.5.5 shall not apply to the *Vaccine Order Forms*, unless provided otherwise in the *APA* or the relevant *Vaccine Order Form*. The

Vaccine Order Forms shall only be implemented, performed and consummated by the *contractor* and the relevant *participating Member State* (but not the *Commission*).

I.6. PRODUCT

I.6.1. The "**Product**" to be supplied by the *contractor* under this *APA* is a pandemic preservative-containing mRNA-based CVnCoV *COVID-19* vaccine. More specifically, the mechanism of the technology of the vaccine will be an mRNA-based vaccine coding for the full length pre fusion conformation stabilised version of the full length spike (S) protein of SARS-CoV-2 virus.

I.6.2. An indicative specification of the *Product* is provided in Annex IV to this *APA*. However, due to the early stage of development of the *Product*, this specification is subject to change. The "**final specification**" of the *Product* will be determined by the *contractor*'s documentation of the *Product* as approved in the *EU marketing authorisation*. If a *participating Member State* should request delivery of the *Product* prior to the grant of the *EU marketing authorisation* and if *contractor* accepts such request (where the withholding of such acceptance is at the *contractor*'s discretion pursuant to Article I.7.1), the relevant specification of the *Product* will be determined by the documentation submitted by the *contractor* as approved in the *temporary national authorisation* granted by that *participating Member State*.

I.6.3. In the context of this *APA*, a "**dose**" of the *Product* refers to the amount of vaccine, including diluent, needed for one injection; this amount corresponds to [redacted], the dose which is taken forward to the pivotal Phase III clinical trial.

I.6.4. The *Product* will be provided in the form of a [redacted] that will require a [redacted] on [redacted]. However, the packaging characteristics (final presentation) are still in consideration. The [redacted] will likely be presented in [redacted] boxes and the [redacted]. Packaging will also include [redacted] co[redacted]. The injected volume for one *dose* is expected to be 0.5 ml (after dilution).

It is expected that a vaccination regimen will encompass two (2) *doses*, i.e. two (2) *doses* will be necessary to vaccinate one person, those *doses* will be injected with 28 days between prime and boost *doses*.

I.7. CONTRACT VOLUME

I.7.1. Subject to the grant of an *EU marketing authorisation*, the *contractor* agrees to supply to the *participating Member States* a total of 225 million *doses* of the *Product* (the "**Initial European Doses**") in accordance with the estimated delivery schedule set out in Article I.11 below (as adjusted pursuant to Article I.12, as the case may be). The *contractor* also agrees to supply to a *participating Member State* the

[redacted]

relevant portion of the *Initial European Doses* in accordance with the estimated delivery schedule set out in Article I.11 below (as adjusted pursuant to Article I.12, as the case may be) if the *participating Member State* in question has granted a *temporary national authorisation* and if the *contractor* accepts the supply on the basis of such *temporary national authorisation*, it being understood that such acceptance may not be unreasonably withheld, provided, however, that the *contractor* may, inter alia, reject its acceptance if it sees a potential risk of undermining the public's confidence (in the relevant country or more broadly, in Europe given cross-border social media reach) in the safety and efficacy of potential vaccines without the approval of the Commission.

I.7.2. The *Commission* may, on behalf and in the name of the *participating Member States*, place an additional order for up to 180 million *doses* of the *Product* by *formal notification* to the *contractor* within 30 days following the grant of the *EU marketing authorisation* for the *Product* (the "**Additional European Doses**").

I.7.3. The *Initial European Doses* and *Additional European Doses* correspond to the maximum number of *doses* of the *Product* that the *contractor* is able to allocate to this *APA* in accordance with the delivery schedule set out below in Article I.11.

I.7.4. In addition to these contractually agreed volumes under this *APA*, the *contractor* agrees to discuss in good faith any *participating Member State*'s request to purchase additional quantities of the *Product* after satisfying its contractual commitments to other partners and customers. Until the date that the *COVID-19 pandemic* is considered to be over, the *contractor* agrees to apply a price for such additional quantities no different from the price set out in Article I.16.1; for this purpose, the *contractor* and the *participating Member State* concerned will decide in good faith, taking into account expert advice, including the advice of the WHO, the date that the *COVID-19 pandemic* is considered to be over. For the avoidance of doubt, any such additional quantities requested are subject to a separate agreement between the *participating Member State* and the *contractor* outside the scope of this *APA*. For the avoidance of doubt, the *contractor* shall not be required to enter into any such separate agreement or be held liable under this *APA* for failure to enter into any such separate agreement.

I.8. ALLOCATION AND VACCINE ORDER FORMS

I.8.1. The *Initial European Doses* will be allocated by the *Commission* among the *participating Member States* according to a population distribution key, unless a different allocation would be communicated by the *Commission* to the *contractor*. The *contractor* will plan deliveries to each *participating Member State* in accordance with the allocation key communicated by the *Commission* pursuant to the foregoing sentence. In order to avoid too small deliveries which could put the supply chain at risk and increase complexity and costs of the deliveries, the *Parties* agree that the minimum size per delivery will be the lower of either 1,000,000 *doses* or 12% of the total number of *doses* allocated to the relevant *participating Member State* in accordance with the first sentence of this Article.

I.8.2. The *Commission* will *formally notify* to the *contractor* the volumes of the *Product* allocated to each *participating Member State* under this *APA* within thirty (30)

calendar days after entry into force of this *APA*. This *formal notification* is binding upon all *Parties*.

I.8.3. The *Commission* will allocate the *Additional European Doses* between the *participating Member States* in accordance with the principles set out above in Article I.8.1 and will *formally notify* the allocation decision to the *contractor* within thirty (30) calendar days following its order of the *Additional European Doses*. This *formal notification* is binding upon all *Parties*.

I.8.4. Following the *formal notification* of the allocation decision by the *Commission* pursuant to Article I.8.2 or I.8.3 above, as the case may be, the *participating Member States* and the *contractor* will conclude *Vaccine Order Forms* using the template *Vaccine Order Form* attached to this *APA* as Annex II. The purpose of these *Vaccine Order Forms* is to specify further details of the delivery to the respective *participating Member State*, such as the place of delivery (the "**specific deliveries**"). Each *Vaccine Order Form* shall be signed by the relevant representative of the *participating Member State* and the *contractor*.

The *participating Member States* shall send the completed and duly signed *Vaccine Order Form* attached to this *APA* as Annex II, within fifteen (15) calendar days after the *Commission formally notifies* to the *contractor* its allocation decision. The terms of such *Vaccine Order Form*, in particular but without limitation, the volume stated therein, shall be aligned with – and do not affect in any manner – the overall volumes, dates and phasing set forth in the delivery schedule set out in Article I.11 below. Within ten (10) calendar days as of receipt of a *Vaccine Order Form* in compliance with the terms of this *APA*, in particular the allocation decision of the *Commission* and the delivery schedule set out Article I.11 below, the *contractor* will send back to the *participating Member States* the *Vaccine Order Form* duly signed and dated.

I.9. DEVELOPMENT TIMELINE; SPECIAL COMMITMENTS

I.9.1. The *contractor* is currently concluding a dose escalating Phase I clinical trial for the *Product* and is preparing recruitment and start of pivotal Phase IIb/III clinical trial studies. The *contractor* currently anticipates that the rolling submission of the dossier to the EMA for *EU marketing authorisation* of the *Product* will begin in February 2021 and that conditional *EU marketing authorisation* may be granted within one or two months after submission, based on anticipated accelerated EMA timelines. However, the *Parties* acknowledge that there is a risk that (i) a conditional EU marketing authorisation may not be granted and that the placing of the *Product* on the market may instead require a full EU marketing authorisation and that (ii) an *EU marketing authorisation* may not be granted at all.

I.9.2. Subject to Article I.7.1, the delivery of the *Product* to the *participating Member States* is in principle subject to prior grant of *EU marketing authorisation* for the *Product*.

I.9.3. The *contractor* commits to perform required clinical trials on specific relevant populations such as the elderly, individuals with comorbidities and pediatric populations, as to be further discussed and agreed with EMA, to obtain the *EU marketing authorisation*.

I.9.4. To produce the *Initial European Doses*, the *contractor* may not manufacture or have manufactured the *Product* at manufacturing sites located outside the territory of the European Union, the UK, the EEA or Switzerland without the prior consent of the *Commission*, which consent may not be unreasonably withheld or delayed if the manufacturing at such sites is required to accelerate the production of the *Initial European Doses*. The *CMOs* and their manufacturing sites as identified in Annex V are deemed pre-approved.

I.10. RIGHT OF THE PARTICIPATING MEMBER STATES TO RE-SELL, EXPORT AND/OR DISTRIBUTE THE PRODUCT

I.10.1. The *participating Member States* will be entitled to re-sell, export and/or distribute any of the *Products* supplied to them pursuant to this *APA* to any other EU or EEA Member State and Switzerland, provided however that such re-sale, export and/or distribution may not take place before the concerned other EU or EEA Member State or Switzerland expressly agrees in writing to fully assume the indemnity obligations as set out under Article I.23 below and to provide a formally executed confirmation to the *contractor*.

I.10.2. 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) exported, distributed or donated for free to another country outside the EU and EEA and Switzerland, including for donation via NGOs or the World Health Organization, without prior consent of the *contractor*.

I.10.3. The *contractor* is free to grant or withhold its consent to a re-sale pursuant to Article I.10.2 (i) at its own discretion, it being understood, however, that (i) no re-sale pursuant to Article I.10.2 (i) shall take place at a price higher than the *Purchase Price* as agreed in this *APA* and (ii) no re-sale pursuant to Article I.10.2 (i) shall take place unless the receiving country first confirms to the satisfaction of the *contractor* (i) that it will fully assume the indemnity obligations as set out under Article I.23 below or, alternatively, that there are other protection arrangements that the *contractor* accepts as being adequate (such acceptance not to be unreasonably withheld) and (ii) that the indemnity by the receiving country or other protection arrangement (as the case may be) is equivalent to the rights of the *contractor* under Article I.23 below, both from a legal and commercial perspective. 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 *doses* has an obligation to reimburse the *Commission* the *up-front payment* per *dose* paid by the *Commission* to the *contractor*.

I.10.4. The contractor shall not unreasonably withhold its consent to the export, distribution or donation for free pursuant to Article I.10.2 (ii), it being understood, however, that no export, distribution or donation pursuant to Article I.10.2 (ii) shall take place unless the receiving country first confirms to the satisfaction of the *contractor* (i) that it will fully assume the indemnity obligations as set out under Article I.23 below or, alternatively, that there are other protection arrangements that the *contractor* accepts as being adequate (such acceptance not to be unreasonably withheld) and (ii) that the indemnity by the receiving country or other protection arrangement (as the case may be) is equivalent to the rights of the *contractor* under Article I.23

below, both from a legal and commercial perspective.

I.10.5. In addition, the *participating Member State* envisaging a re-sale, export, distribution or donation pursuant to Articles I.10.1 or I.10.2 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, export, distribution or donation (i.e. for the transport of the *Product* from the *participating Member State* envisaging such re-sale, export, distribution or donation to the central warehouse of the receiving country) are in place, for instance as pertains to (re)-labelling, validated transportation or cold chain integrity assurance. For the avoidance of doubt, the *participating Member State* envisaging such re-sale, export, distribution or donation shall bear (or have the receiving country bear) any liabilities, claims, costs (including costs for the transport of the *Product* from the *participating Member State* envisaging such re-sale, export, distribution or donation to the central warehouse of the receiving country), damages and other losses resulting from such re-sale, export, distribution or donation.

I.10.6. 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*.

I.11. DELIVERY; ESTIMATED DELIVERY SCHEDULE; DELAYS

I.11.1. The *Products* must be delivered according to DAP Incoterms 2020 at the *delivery site* as indicated in the relevant *Vaccine Order Form*, it being noted, however, that each *participating Member State* shall select one single place of delivery, within the EU territory, applicable to all deliveries to the said *participating Member State* as per this *APA*. The *participating Member States* will be responsible for securing – and provide the *contractor* with – any required import license to the *delivery site*.

I.11.2. Title to, and risk of loss of, the *Product* shall pass upon delivery in accordance with DAP Incoterms 2020.

I.11.3. The *Parties* acknowledge that the placing on the market, making available, distribution and administration of the *Product* may require additional authorisations under local laws of the *participating Member State*. The responsibility for compliance with local laws, including those regarding the handling, distribution and administration of the *Product*, after the delivery at the relevant *delivery site* remains exclusively with the *participating Member States*.

I.11.4. Estimated Delivery Schedule

(a) Subject to Article I.7.1, availability of the *Product* is subject to successful development of the *Product*, the granting of the *EU marketing authorisation* and the successful manufacturing ramp up.

(b) Subject to the above and subject to the *EU marketing authorisation* being granted by end of Q1 2021, the estimated delivery schedule for the *Products* is as follows:

Estimated delivery periods	Volume (in millions of doses)
INITIAL EUROPEAN DOSES	**225**
Q1 2021	15
Q2 2021	40
Q3 2021	50
Q4 2021	60
Q1 2022	60
ADDITIONAL EUROPEAN DOSES	**180**
Q2 2022	60
Q3 2022	60
Q4 2022	60

(c) The first delivery to a *participating Member State* shall take place at the latest by the later of (i) the end of the estimated delivery periods as specified in Article I.11.4(b) above or (ii) the end of a period of thirty (30) calendar days after the *EU marketing authorisation* or the relevant *temporary national authorisation* (as the case may be) is granted or (iii) the end of a period of forty-five (45) calendar days after the *EU marketing authorisation* in case the authorisation granted requires package labelling in deviation from the standardised generally acceptable packaging as set out in Article I.13.1 below. Whilst the preceding sentence indicates the latest delivery dates for the first delivery, the *Parties* agree that *doses* will be delivered if and when lots are released and not necessarily at the end of a quarter, the 30-days period or the 45-days period (as the case may be).

I.12. DELAYS

I.12.1. The *Parties* acknowledge that there is a risk that (i) the time-line for the *EU marketing authorisation* or (ii) the time-line for scaling up the production of the *Product* may be delayed or that (iii) an *EU marketing authorisation* may not be granted at all or (iv) the production of the *Product* may not be feasible.

I.12.2. If there is a delay in the supply of the *Product* compared to the *estimated delivery schedule*, the *contractor* will inform the *Commission* as soon as reasonably possible, explain the reasons for such delay and submit a revised delivery schedule to the *Commission* which should be as close as possible to the *estimated delivery schedule* while taking into account the reasons for the delay.

I.12.3. The consequences if no *EU marketing authorisation* is granted or the production of the *Product* is not feasible are exclusively dealt with in Article II.14.

I.13. PACKAGING; LABELLING

I.13.1. Unless and to the extent required otherwise under Union law or the laws of a *participating Member State*, the *Product* supplied under this *APA* and/or under the *Vaccine Order Forms* shall be in a standardised generally acceptable international packaging, including the package inserts and trade dress. For the sake of clarity, this means that the *Product* packaging and/or inserts shall be in the English language or multilingual, but will not necessarily include the specific languages of each of the *participating Member States*. To the extent that the *contractor* should be required to modify the *Product* packaging (and/or package inserts) from the aforementioned planned packaging due to the regulatory requirements in a certain *participating Member State*, the impact of such regulatory requirements on the timeline for availability of the *Product* shall be taken into account in the Estimated Delivery Dates as set forth in Article I.11.4(c) above.

I.13.2. The *contractor* shall comply with labelling requirements for the *Product* under Union law and the respective laws of a *participating Member State* in all material respects, subject to any exceptions or procedural relief that may be granted by a competent authority under such laws.

I.14. WARRANTIES; ACCEPTANCE MECHANISM

I.14.1. The *contractor* warrants to the *Commission* and the *participating Member States* that

(a) 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

(b) as of the date hereof, it is not under any obligation, contractual or otherwise, to any third party in respect of the delivery of the *Initial European Doses* or that conflicts with or is inconsistent in any material respect with the terms of this *APA* or that would impede the complete fulfillment of its obligations under this APA.

I.14.2. The *contractor* warrants to the *Commission* and the *participating Member States* that

(a) all *Products* supplied to the *participating Member States* shall at the time of delivery comply with the *final specifications*;

(b) all *Products* supplied to the *participating Member States* shall at the time of delivery be free from any product manufacturing defects; and

(c) at the time of delivery, it has good title to the *Products* 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 having obtained any necessary IP rights.

I.14.3. Given the current status of the clinical development program and in light of the extraordinary circumstances of the execution and performance of this *APA*, the *contractor*, in particular, does not warrant that the *Products* will show sufficient efficacy to prevent a *COVID-19* infection and/or be without inacceptable adverse event symptoms beyond what will be documented in the ongoing and planned

clinical trials or what will be documented in the leaflet of the *Product*.

I.14.4. The *participating Member States*' sole remedy for a breach of a warranty set forth in Article I.14.2 above and in respect of any circumstances relating to the status and condition of the *Product*, shall be, at the *contractor*'s election, (i) the issuance to the relevant *participating Member State* and/or to the *Commission* of a credit note (or refund) for the payments made in accordance with Articles I.17.1 and I.17.2 with respect to the non-conforming *Product* or (ii) the supply of a replacement *Product* to the relevant *participating Member State* for the non-conforming *Product* in a timeframe (of 90 calendar days at maximum) mutually agreed to by the *contractor* and the relevant *participating Member State*. Any other right of the *Commission* and/or the *participating Member States* with respect to breaches of the warranty set forth in Article I.14.2 above shall be excluded.

I.14.5. Upon delivery, the *participating Member States* shall immediately conduct a visual inspection of (i) the pallet(s) or grouping boxes of the *Product* and (ii) the temperature monitoring device. The relevant *participating Member State* shall conduct such visual inspection in a manner allowing it to complete the *Goods Received Form* properly and promptly. The *Parties* agree that, if reasonably requested by the *contractor*, such inspection shall be conducted in the presence of a representative and/or designee of the *contractor*.

I.14.6. If an *apparent defect* is detected in the course of the visual inspection pursuant to Article I.14.5, the relevant *participating Member State* shall (i) document such *apparent defect* in the form of detailed comments in the relevant section of the *Goods Received Form* and (ii) provide comprehensive proof of the relevant issue in the form of photographs or other digital recordings together with the *Goods Received Form*. The *participating Member State* shall hand-over to the courier a copy of the *Goods Received Form* properly completed in accordance with Article I.14.5 and this Article I.14.6 and, as the case may be, transmit (by email) the comprehensive proof of the *apparent defect* to the *contractor* as soon as possible and no later than four (4) calendar days after delivery.

I.14.7. If the *Goods Received Form* does not document any *apparent defect* or if a *participating Member State* fails to comply with Article I.14.5 and/or I.14.6, then the *Product* at stake shall be conclusively presumed to be free of *apparent defects* and the *contractor* shall be authorised to send the corresponding invoice, this even if the *participating Member State* did not issue formal proof of delivery. The *contractor* shall in that case have no liability or further obligation to the *participating Member State* or the *Commission* in relation to such *Product* with respect to *apparent defects*.

I.14.8. For any *hidden defect*, the *participating Member State* will be obligated to notify the *contractor* in writing within ten (10) calendar days following discovery of the said *hidden defect*. If *participating Member State* fails to provide such notification within ten (10) calendar days, the *participating Member State* ceases its defect-related rights.

I.14.9. The *participating Member States* shall observe and comply with such storage, handling, stock control and operational requirements relating to *Product* as set forth in the *final specification* or otherwise required by the *Product* labelling and applicable laws.

I.15. PRODUCT RECALLS

The *contractor* and the *participating Member States* shall maintain at their own cost records necessary to permit a recall of any *Product* delivered to a *participating Member State*. Each *Party* shall promptly notify the other *Parties* of any information, which might affect the marketability, safety, or effectiveness of the *Product* or which might result in the recall or seizure of the *Product* in a *participating Member State*. Upon receiving this notice or upon this discovery, each *Party* shall stop making any further shipments, administration and/or use of any *product* in the relevant country in its possession or control until a decision has been made whether a recall or some other corrective action is necessary. The *contractor* is responsible for making any required notifications to EMA and/or any relevant national competent authority with respect to a potential recall or abnormal restriction on supply. The decision to initiate a recall or to take some other corrective action, if any, with respect to the product will be made by the *contractor* and/or the competent authority in accordance with applicable laws. The relevant *participating Member State* shall implement such recall with respect to any *Product* delivered to such *participating Member State* in close coordination with the *contractor* at the costs of such *participating Member State*. The *participating Member State*'s costs related to *Product* recalls shall be reimbursed to the relevant *participating Member State* by the *contractor* if the recall was caused by (i) a defect of the *Product* that is attributable to non-conformity of the *Product* with the *final specification* or (ii) production that does not comply with GMP including applicable quality control (as defined in European Directive 2001/83/EC and its implementing regulations).

I.16. PRICE OF THE PRODUCT

I.16.1. The *Product Price* (as defined in Article I.16.2 below applies to both the *Initial European Doses* and the *Additional European Doses*.

I.16.2. The "**Product Price**" for the *Product* per *dose* shall be EUR [redacted].

I.16.3. The *Product Price* (including, for the avoidance of doubt, the *up-front payments* on the *Product Price* pursuant to Article I.17.1 below), is exclusive of sales, value-added and other taxes, as well as customs and import fees and duties (sales, value-added and other taxes, as well as customs and import fees and duties together, the "**ancillary expenses**") to the *delivery site*. Such *ancillary expenses* will be charged in addition to the *Product Price* if applicable and provided that no exemption for the respective *participating Member State* applies.

I.16.4. The *participating Member States* will be responsible, at their own expenses and risks, for any secondary distribution, storage and administration of the *Product*.

I.17. PAYMENT OBLIGATIONS

I.17.1. Up-front payment

(a) In order to de-risk the necessary investments of the *contractor* to increase the speed of vaccine research and development and clinical trials and the preparation of the at-scale production capacity along the entire production value

[redacted]

chain in the EU required for a rapid deployment of the millions of *doses* of the *Product* according to the terms of this *APA*, and in full understanding of the uncertainties associated with the aforementioned process, subject to *EU marketing authorisation* or *temporary national authorisation* (as the case may be), the *Commission*, acting on behalf and in the name of the *participating Member States*, and the *participating Member States* themselves shall contribute to financing the relevant costs in the form of an up-front payment on the total *Product Price* of the *Initial European Doses* (the "**up-front payment**") as set forth in this Article I.17.1 as well as in the form of the *second upfront payment* as set forth in Article I.17.2 and, as the case may arise, in the form of the *Additional Doses up-front payment* as set forth in this Article I.17.2.

(b) The *up-front payment* is EUR 450 million total (which will equal an up-front payment of EUR 2 per *dose*).

(c) Within five (5) calendar days following entry into force of the APA, the *contractor* shall send to the *Commission* a payment request for the payment of the *up-front payment* in accordance with Article II.15 below.

(d) The *Commission*, acting on behalf and in the name of the *participating Member States*, shall pay the *up-front payment* within twenty (20) calendar days after receipt of a payment request from the *contractor* in accordance with Article I.17.1(c) above.

I.17.2. Payments under Vaccine Order Forms

Pursuant to this Article I.17.2 and in accordance with their respective *Vaccine Order Forms*, the *participating Member States* shall make further payments to the *contractor* as follows:

(a) With respect to the *Initial European Doses*, each *participating Member State* shall make a further up-front payment to the *contractor* in the amount of EUR 2.25 per *dose* for the volumes of the *Product* allocated to it pursuant to Articles I.8.1 and I.8.2 (the "**second up-front payment**"). The *second up-front payment* (plus value-added taxes, if any) shall be paid by the *participating Member State* within twenty (20) calendar days after *notification* by the *contractor* that the interim data package has been submitted to the EMA for the purpose of obtaining *EU marketing authorisation* for the *Product*, but no sooner than ten (10) calendar days after receipt of a corresponding payment request from the *contractor* in accordance with Article II.15 below.

(b) With respect to the *Additional European Doses*, and assuming that the *Commission* has formally notified the *contractor* that a *participating Member State* wishes to acquire *Additional European Doses* in accordance with Article I.8.3, each such *participating Member State* shall make an up-front payment to the *contractor* in the amount of [redacted] of the Purchase Price per *dose* for the volumes of the *Product* allocated to it pursuant to Article I.8.3 (the "**Additional Doses up-front payment**"). Such *Additional Doses up-front payment* (plus value-added taxes, if any) shall be paid by the *participating Member State* within twenty (20) calendar days after conclusion of the relevant *Vaccine Order Form* (or, if a participating Member State refuses to conclude the relevant *Vaccine Order Form*, twenty (20) calendar days after the *contractor*'s explicit

[redacted]

request to sign the relevant *Vaccine Order Form*), but no sooner than twenty (20) calendar days after receipt of a corresponding payment request from the *contractor* in accordance with Article II.15 below.

(c) Each *participating Member State* shall pay the balance (plus *ancillary expenses* (as defined in Article I.16.3) due on the *Product Price* for the volumes of the *Product* allocated to it pursuant to Articles I.8.1 through I.8.3 within twenty (20) calendar days of each delivery (or offer to deliver if the *participating Member State* illegitimately refuses acceptance of delivery), but no sooner than twenty (20) calendar days after receipt of a corresponding invoice from the *contractor* in accordance with Article II.15 below. The balance due will be calculated on the basis of the relevant *Product Price* of the delivered (or offered to deliver, as the case may be) *Products* as set out in Article I.16.1 above and under deduction of any *up-front payment*, *second up-front payment* and/or *Additional Doses up-front payment* already received by the *contractor* for the relevant volumes of the *Product* delivered (or offered to deliver, as the case may be).

I.17.3. Utilisation of the up-front payment and the second up-front payment

The *contractor* intends to use the *up-front payment* and the *second up-front payment* as further specified in Annex VII.

I.18. CONTRACTOR'S BANK ACCOUNT

Payments must be made to the *contractor*'s bank account denominated in euro, identified as follows:

[redacted]

I.19. COMMUNICATION DETAILS

For the purpose of this *APA*, communications must be made in English and sent to the following addresses:

If to the *Commission* to:

Directorate-General for Health and Food Safety

E-mail: SANTE-PROCUREMENT@ec.europa.eu

[redacted]

If to a *participating Member State* to

Cf. Annex I

If to the *contractor* to:

[redacted]

CUREVAC AG

Friedrich-Miescher-Str. 15, 72076 Tübingen, Deutschland

[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*.

I.20. EXPLOITATION OF THE RESULTS OF THE APA

I.20.1. The *Parties* 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 "**Product IP Rights**"). The *contractor* shall be entitled to exclusively exploit any such *Product IP Rights*. Except as expressly set forth in this *APA*, the *contractor* does not grant to the *Commission* and/or the *participating Member States* by implication, estoppel or otherwise, any right, title, licence or interest in the *Product IP Rights*.

I.20.2. All rights not expressly granted by the *contractor* hereunder are reserved by the *contractor*.

I.21. APPLICABLE LAW AND SETTLEMENT OF DISPUTES

I.21.1. This *APA* shall be governed by the laws of Belgium.

I.21.2. Dispute Resolution

(a) In the event of a dispute between the *Parties* arising under or in connection with this *APA* or the legal relationships established by this *APA*, the *Parties* shall first refer such dispute to informal dispute resolution discussions between their respective representatives. Each of the *contractor* and the *Commission*, on behalf of itself or on behalf of the *participating Member States* (as the case may be), may initiate such informal dispute resolution by sending written notice of the dispute to the *contractor* or the *Commission* (as the case may be), and, within twenty (20) calendar days of such notice, the representatives shall meet and attempt to resolve the dispute amicably by good faith negotiations.

(b) If the *Parties* are not able to settle their dispute in accordance with lit. (a) above, the *Commission*, the *participating Member States* and the *contractor* 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*.

[redacted]

I.22. REPORTING

I.22.1. The *contractor* will provide to the *Commission*, at the latter's request until full *EU marketing authorisation* for the *Product* has been granted, the following physical or electronic data:

(i) updates on progress made in terms of clinical development of the *Product*; included interim and final results of clinical studies of the *Product*;

(ii) progress on the build-up of manufacturing capacities;

(iii) updates on progress, challenges and opportunities on establishment of the supply chain; and

(iv) the use of the upfront payments by the Commission and the *participating Member States*, linked to points (i) to (iii), in general terms;

it being understood that the information pursuant to points (i) through (iii) above shall not be requested more than once a month and the information pursuant to point (iv) above shall not be requested more than every three (3) months.

I.22.2. In addition, the *contractor* shall keep the *Commission* and the *participating Member States* informed about any signal detected during the pharmacovigilance or vaccine monitoring programs in relation to the *Product* within five (5) working days from notifying the EMA.

I.23. INDEMNIFICATION

I.23.1. The *Commission*, on behalf of the *participating Member States*, declares that the use of the *Products* delivered under this *APA* and/or the *Vaccine Order Forms* will happen under epidemic conditions requiring such use, and that the administration of the *Products* will therefore be conducted under the sole responsibility of the *participating Member States*.

I.23.2. The *Parties* further declare that the provisions contained in this indemnification clause, including the exceptions to the indemnification undertakings, reflect the exceptional circumstances of the *COVID-19 pandemic* and the need to develop new vaccines at an unprecedented speed in order to allow for very large scale immunisation.

I.23.3. On this basis, each *participating Member State* shall indemnify and hold harmless the *contractor*, its Affiliates, sub-contractors and sub-licensees, including contract partners involved in the research, development (including pre-clinical and clinical testing), manufacturing and/or delivery; and officers, directors, employees and other agents, representatives and service providers of each (together, the "**Indemnified Persons**") for liability incurred and normally borne by them relating to harm, damages and losses (together, the "**Losses**") as further specified in Article I.23.5 arising from the use and deployment of the *Products* supplied to the *participating Member State* (or another entity appointed by that *participating Member State*)

under this *APA*, irrespective of the time when the *Losses* occur.

I.23.4. Such indemnification will not be available to the *Indemnified Persons* to the extent that (i) a causal relationship is established between the Losses and the wilful misconduct, as defined in Article I.23.6, of such *Indemnified Persons*; or (ii) a causal relationship is established between the *Losses* and a defect in the *Product* which occurred because of the *Indemnified Person*'s failure to comply with *GMP*.

I.23.5. Indemnification pursuant to Article I.23.3 will only be available for *Losses* that consist of: (i) liability towards the injured *Party* (or a third party suffering indirect damage) for death, physical, mental or emotional injury, illness, disability, cost of care, property loss or damage, loss of earnings, and business interruption; and (ii) all reasonable and necessary costs related to such Losses including legal fees, expert fees and other litigation or settlement expenses.

I.23.6. Wilful misconduct shall mean conduct which (i) constitutes an intentional act aimed at achieving a wrongful purpose, (ii) occurs in the absence of a legal or factual justification, (iii) occurs in disregard of a known or obvious risk of causing serious bodily harm, and (iv) is finally determined by a court without the possibility for further appeal. Actions consistent with any rules or guidance set out by the *Commission*, the *EMA* or other competent authority in the European Union shall be considered to have an adequate legal or factual justification.

I.23.7. In case liability has been incurred by the *Indemnified Persons* for *Losses*, the *contractor* shall give the *participating Member State* in question, or an independent expert as referred to in Article I.23.8, access to all information reasonably necessary for the *participating Member State* to indemnify the *Indemnified Persons* and to verify whether the above mentioned conditions are fulfilled.

I.23.8. The *participating Member State* shall be allowed to access the information through an independent expert in the field of damage claims, in particular in the field of public health, subject to an obligation of strict confidentiality. 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 30 days 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*.

I.23.9. The *contractor* shall promptly inform the relevant *participating Member State* of any damage claims brought against any of the *Indemnified Persons* (a "**Third Party Claim**"), stating the nature and basis of the damage claim in question and, if possible, the estimated amount of damages. The *contractor* shall use reasonable efforts to keep the *participating Member State* informed of any developments relating to such *Third Party Claim*, including updates on the estimated amount of damages.

I.23.10. The *contractor* shall ensure that the *Indemnified Persons* take such commercially reasonable actions to avoid, defend or settle the *Third Party Claim* and to mitigate the liability incurred. Within ninety (90) calendar days of the submission by the *contractor* of an invoice for such actually incurred Losses (also when they arise

during the course of legal proceedings or settlement discussions), the *participating Member State* shall provide written confirmation to the *contractor* that it will indemnify such losses, subject to the conditions set out in the present indemnification clause, in particular the conditions set above. In the absence of such confirmation, the losses shall be due. The *contractor* shall keep the *participating Member State* reasonably informed in relation to the *Third Party Claim* and the *contractor* may settle the *Third Party Claim* only with the prior consent of the *participating Member State* (such consent not to be unreasonably conditioned, withheld or delayed).

I.23.11. Alternatively, the *contractor* may request, to the extent possible under the applicable rules of procedure, the *participating Member State* to assume (with its own counsel and at its own costs) sole control of the defence or settlement of the *Third Party Claim*; provided that: (i) the *participating Member State* shall reasonably take the *contractor*'s interests into consideration and shall not settle such *Third Party Claim* without the prior written consent of the *contractor* (such consent not to be unreasonably conditioned, withheld or delayed); and (ii) the *contractor* shall have the right, but not the obligation, to participate in the defence or settlement of the *Third Party Claim* and to retain its own counsel in connection with such *Third Party Claim* at its own expense. The *participating Member State* shall not unreasonably refuse such request.

I.23.12. These provisions apply until a final determination by the competent courts of a ground for exception to the indemnification, as stipulated in Articles I.23.4. Any claims of *contractor* under this Article I.23 shall be time barred not earlier than six (6) months after the final expiration of all relevant statutes of limitation periods for the relevant *Third Party Claim*.

I.23.13. The *Parties* acknowledge and agree that the provisions of this indemnification clause are reasonable and necessary to protect the legitimate interest of the *Indemnified Persons*. However, if any provision in this clause were to be held to be illegal, invalid or unenforceable, in whole or in part, then such provision shall not be nullified but the *Parties*, including the *participating Member States*, shall be deemed to have agreed to such provision that conforms with the limitations imposed by applicable law and that is as close as possible to the original intention of the *Parties* and has the same or as similar as possible economic effect, and such provision shall be automatically reformed accordingly.

II. GENERAL CONDITIONS

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 *APA* must be interpreted as if it had contained the substitute provision as from its entry into force.

II.2. PROVISION OF SUPPLIES

II.2.1. The *contractor* must provide supplies that are at the time of delivery free from any *Product Manufacturing Defects*.

II.2.2. All periods specified in the *APA* are calculated in calendar days, unless otherwise specified.

II.2.3. The *contractor* must immediately *notify* 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) bear the *APA* number and, if applicable, the *Vaccine Order Form* number;

(c) be made using the relevant communication details set out in Article I.8; and

(d) be sent by mail or e-mail.

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 e-mail has full legal effect and is admissible as evidence in judicial proceedings.

II.3.2. Date of communications by mail and e-mail

Any communication is deemed to have been made when the receiving *Party* receives it, unless this *APA* contract 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 below. The sending *Party* must be able to prove the date of dispatch. 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 e-mail 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 below registers it.

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. Except as set out in Article I.23, 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 occurred during or as a consequence of the performance of the *APA* or any *Vaccine Order Forms*.

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 performance of the *APA* or any *Vaccine Order Forms*. 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* must provide reasonable assistance to the *Commission* or the *participating Member State*.

II.5. CONFLICT OF INTEREST AND PROFESSIONAL CONFLICTING INTERESTS

II.5.1. The *contractor* must take all the necessary measures to prevent any situation of *conflict of interest* or *professional conflicting interest*.

II.5.2. The *contractor* must notify the *Commission* in writing as soon as possible of any situation that could constitute a *conflict of interest* or a *professional conflicting interest* during the performance of the *APA*. The *contractor* must immediately take action to rectify the situation.

The *Commission* 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, on behalf of the *participating Member States*, not to award a *Vaccine Order Form* to the *contractor*.

II.5.3. The *contractor* must pass on all the relevant obligations in writing to:

(a) its personnel;

(b) any natural person with the power to represent it or take decisions on its behalf;

(c) third parties involved in the performance of the *APA*, including subcontractors.

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

II.6. CONFIDENTIALITY AND PUBLIC ANNOUNCEMENTS

II.6.1. The *Commission*, the *participating Member States* and the *contractor* must treat with strict confidentiality any *confidential information or documents* in connection with the APA.

II.6.2. The *Commission*, the *participating Member States* and the *contractor* shall:

(a) not use *confidential information or documents* for any purpose other than to perform their respective obligations under the *APA* or a *Vaccine Order Form* without the prior written agreement of the disclosing *Party*;

(b) ensure the protection of such *Confidential information or documents* with the same level of protection as their own *confidential information or documents* and in any case with due diligence;

(c) not disclose, directly or indirectly, *confidential information or documents* to third parties without the prior written agreement of the other *Party*.

II.6.3. Notwithstanding the above, the Parties may disclose *confidential information or documents* to their directors, officers and employees and, in the case of the *contractor*, to its subcontractors and their directors, officers and employees as well as to those of any corporation directly or indirectly controlling, controlled by, or under common control with the *contractor* (control being the ownership of more than fifty percent (50 %) of the outstanding voting stock of a corporation), and/or any company, individual or organisation retained by them to assist in the *implementation of the APA*, provided that each such company, individual and organisation must be legally bound to comply with this Article.

II.6.4. The confidentiality obligations set out in this Article are binding on the *Commission*, the *participating Member State* and the *contractor* during the performance 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*.

II.6.5. 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 performance of the *APA* a commitment that they will comply with this Article. At the request of the *Commission*, the *contractor* must provide a document providing evidence of this commitment.

II.6.6. The *contractor* acknowledges that the *Commission* is subject to requirements laid down under Regulation (EC) 1049/2001. The *Commission* commits that it will consult with the *contractor* on any disclosure request concerning documents containing *confidential information* as provided for in Article 4(4) of said Regulation.

II.6.7. Notwithstanding the above, each *Party* may issue a press release and/or other public statement disclosing the total contract volume and value of the *APA* and/or the *Vaccine Order Form*. The Parties shall consult together on the timing, contents and manner of any press release relating to this *APA*.

II.7. PROCESSING OF PERSONAL DATA

II.7.1. 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-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.7.2. 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.8. SUBCONTRACTING

II.8.1. The *contractor* may not subcontract and have the *APA* (including *Vaccine Order Forms* entered into under the *APA*) implemented by third parties without prior written authorisation of the *Commission*, it being noted that the *Commission* will not unreasonably withhold or delay such authorisation. The manufacturing network partners and their manufacturing sites as identified in Annex V are deemed pre-approved for the purpose of the foregoing sentence.

II.8.2. In the case of subcontracting, the *contractor* remains bound by its contractual obligations and is solely responsible for the performance of the *APA*.

II.8.3. The *contractor* must ensure that the subcontract does not affect the rights of the *Commission* and the *participating Member States* under this *APA*.

II.8.4. The *Commission* may request the *contractor* to replace a subcontractor found to be in a situation provided for in Article II.14.2(d) and (e).

II.9. AMENDMENTS

II.9.1. Any amendment to the *APA* must be made in writing by the *contractor* and the *Commission*, (also) acting in the name and on behalf of all *participating Member States*, and any amendment to a *Vaccine Order Form* must be made in writing by the *contractor* and the relevant *participating Member State*. The conclusion of a *Vaccine Order Form* does not constitute an amendment to the *APA*.

II.9.2. No amendment can make changes to the *APA* or a *Vaccine Order Form* that might alter the initial conditions of the procurement procedure or result in unequal treatment of tenderers or contractors.

II.10. ASSIGNMENT

II.10.1. The *contractor* cannot assign any of the obligations arising from the *APA*, without prior written authorisation from the *Commission*. In such cases, the *contractor* must provide the *Commission* with the identity of the intended assignee.

II.10.2. Any obligation assigned by the *contractor* without authorisation is not enforceable against the *Commission*.

II.11. FORCE MAJEURE

II.11.1. If the *contractor*, or one of its subcontractors, is affected by *force majeure*, the *contractor* must immediately *notify* the *Commission* or, if only the performance of certain *Vaccine Order Forms* are affected, the relevant *participating Member State(s)*, stating the nature of the circumstances, their likely duration and foreseeable effects. If the *Commission* and/or a *participating Member State* is affected by *force majeure*, the *Commission* and/or the relevant *participating Member State(s)* must

immediately *notify* the *contractor*, stating the nature of the circumstances, their likely duration and foreseeable effects.

II.11.2. A *Party* is not liable for any delay or failure to perform its obligations under the *APA* if that delay or failure results from a *force majeure*. As long as the *contractor* is unable to fulfil its contractual obligations owing to *force majeure*, it has the right to remuneration only for the *doses* of the *Product* actually delivered.

II.11.3. The *Parties* must take all necessary measures to limit any damage due to *force majeure*.

II.12. REDUCTION IN PRICE

II.12.1. Quality standards

If the *contractor* fails to deliver the *Product* in accordance with the *APA*, the *participating Member State* in question may reduce or recover payments in accordance with Article I.14.4.

II.12.2. Procedure

The *participating Member State* in question must *formally notify* the *contractor* of its intention to reduce payment and the corresponding calculated amount.

The *contractor* has 30 days following the date of receipt to submit observations. Failing that, the decision becomes enforceable the day after the time limit for submitting observations has elapsed.

If the *contractor* submits observations, the *participating Member State* in question, taking into account the relevant observations, must *notify* the *contractor*:

(a) of the withdrawal of its intention to reduce payment; or

(b) of its final decision to reduce payment and the corresponding amount.

II.13. SUSPENSION OF THE APA

II.13.1. Suspension by the contractor

If and to the extent the *contractor*, including any of its subcontractors, is affected by *force majeure*, it may suspend the performance of the *APA* and/or the *Vaccine Order Forms*.

If the performance of the *APA* or both the performance of the *APA* and the performance of all *Vaccine Order Forms* are affected, the *contractor* must immediately *notify* the *Commission* of the suspension or, if only the performance of certain *Vaccine Order Forms* is affected, the *contractor* must immediately *notify* the relevant *participating Member State(s)* of the suspension. The *notification* must include a description of the *force majeure* and state when the *contractor* expects to resume the performance of the *APA* and/or the *Vaccine Order Forms*.

The *contractor* must *notify* the *Commission* or the relevant *participating Member State(s)* (as the case may be) as soon as it is able to resume performance of the *APA* and/or *Vaccine Order*

Form, unless the *APA* or the *Vaccine Order Form* has already been terminated.

II.13.2. Suspension by the *Commission* or the *Participating Member State*

The *Commission* or the *participating Member State* with respect to its *Vaccine Order Form* may suspend the performance of the *APA* or performance of a *Vaccine Order Form*, respectively, or any part of it:

(a) if the procedure for awarding the *APA* or a *Vaccine Order Form* or the performance of the *APA* proves to have been subject to *irregularities* or *fraud* on the part of the *contractor*;

(b) in order to verify whether the presumed *irregularities* or *fraud* on the part of the *contractor* 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 *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 a *Vaccine Order Form* under Article II.14.2 e).

The *contractor* is entitled to compensation for suspension of any part of the *APA* or a *Vaccine Order Form* if the verification comes to the result that the presumed *irregularities* or *fraud* on the part of the *contractor* did not occur.

The *Commission* may in addition suspend the time allowed for payments in accordance with Article II.16.4.

II.14. TERMINATION OF THE APA

II.14.1. Grounds for automatic termination of the APA

The APA will be automatically terminated if and when the *contractor* notifies the *Commission* of its inability to provide the *Product* because of, and only because of, the following reasons: (i) the clinical trial results not being satisfactory, (ii) the clinical trial results not meeting their end point in terms of efficacy or safety or (iii) the *EU marketing authorisation* not being granted. The *notification* of the *contractor* shall set out in detail the underlying reasons for automatic termination of the *APA*. The termination will be effective unless the *Commission* objects in writing within thirty (30) calendar days following the notification by the *contractor*, such objection may only be issued based on reasonable grounds given the evidence of one the three reasons (points (i) through (iii)) stated above and taking into account the severity of the impact that the continuation of the *APA* would have on the *contractor*'s business. If and once the termination becomes effective the *contractor* may not sell and/or deliver the *Product* to any third party.

II.14.2. Grounds for termination by the Commission or the participating Member States

The *Commission*, acting on behalf and in the name of the *participating Member States*, may terminate the *APA* in the following circumstances (a) through (h), and the *participating Member States* may terminate their respective *Vaccine Order Forms* in the following circumstances (b) through (h). Except for the termination right in case of (a) below, a right of termination only exists if the reason giving rise of the right to terminate is not cured, removed or otherwise no longer existent within ninety (90) calendar days of receipt by the *contractor* of *formal notification* from the *Commission* of the intention to terminate the APA or *participating Member States* to terminate the respective *Vaccine Order Forms*, which *formal notification* shall include a reasonably detailed description of the alleged breach.

(a) If no *EU marketing authorisation* is granted by 31 December 2021, or any other day mutually agreed upon by the *Commission* and the *contractor* in writing or if by that date no *doses* of the *Initial European Doses* have been supplied to any of the *participating Member States*. If the *contractor* expects that such a situation may occur, it will inform the *Commission* well in advance of such possibility, explain the reasons behind such delays and, if possible, propose a remedy for the situation, including a revised delivery schedule.

(b) If the *contractor* is in material *breach of obligations* (i) in relation to the main performance obligations such as the obligations under the second paragraph of Article I.3 and/or Article I.7.1, (ii) in relation to the obligations under Article I.9.4, Article I.14.1(a) and/or Article I.14.1(b) or (iii), in the case of a *participating Member State*, in relation to the obligations under a *Vaccine Order Form*, or if the *contractor* repeatedly refuses to sign one or several *Vaccine Order Form(s)*.

(c) If the *contractor* is in one of the situations provided for in points (a) and (b) of Article 136(1) of the Financial Regulation[4].

(d) If the *contractor*, any of the members of its management board or any of its key employees involved in the performance of this *APA* 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* or the performance of the *APA* prove to have been subject to *irregularities* or *fraud* on the part of the *contractor*.

(f) If the *contractor* is in a situation that constitutes a *conflict of interest* or a *professional conflicting interest* and such situation is not resolved by the *contractor* in accordance with Article II.5.2.

(g) If a change to the *contractor*'s legal, financial, technical, organisational or ownership situation substantially affects the performance of the *APA* or substantially modify the conditions under which the *APA* was initially awarded or a change regarding the

[4] 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

exclusion situations listed in Article 136 of Regulation (EU) 2018/1046 that calls into question the decision to award the contract.

(h) 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 or result in unequal treatment of tenderers or contractors.

II.14.3. 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* materially fail to comply with their respective obligations.

(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 or result in unequal treatment of tenderers or contractors.

II.14.4. Procedure for termination

The *contractor* or the *Commission* (as the case may be) must *formally notify* the *Commission* or the *contractor* (as the case may be) of its intention to terminate the *APA*. The foregoing sentence shall apply mutatis mutandis to the *Vaccine Order Forms*, it being understood, however, that *formal notification* shall be issued by or to (as the case may be) the relevant *participating Member State*.

The *Party* receiving a termination notice pursuant to the foregoing paragraph shall have thirty (30) calendar days 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.

If the other *Party* submits observations, the *Party* intending to terminate must formally notify it either of the withdrawal of its intention to terminate or of its final decision to terminate.

In the cases referred to in points (a) to (c), (f) and (g) of Article II.14.2 and in Article II.14.3, the date on which the termination takes effect must be specified in the *formal notification*.

In the cases referred to in points (d), (e) and (h) of Article II.14.2, the termination takes effect on the day following the date on which the *contractor* receives *formal notification* of termination.

II.14.5. Effects of termination

(a) in case of an automatic termination pursuant to Article II.14.1

No liability is incurred by any *Party* in case of an automatic termination according to Article II.14.1.

The *up-front payment* and the *second up-front payments* shall not be refundable except in the

following way:

The *contractor* shall send to the *Commission* within sixty (60) days from notifying the *Commission* about the automatic termination of the *APA*, a financial statement (the "**Financial Statement**"), detailing for which expenses the *up-front payments* have been used in relation to the purposes as set out in the *APA*. Expenses to be taken into account include the full amount of internal and/or external expenses which have been, or will be, incurred as well as such which have been committed by, or relate to commitments made by, the *contractor* at the time when the *contractor* notified the *Commission*, it being understood that such 'expenses' shall include, without limitation, costs, expenses and liabilities, write-offs and value adjustments in connection with research, development, ramp up, IP, real estate, construction, administration, manufacturing, production, packaging, delivery, preservation, transportation, personnel, redundancy, litigation, agreements, terminations of agreements, advice and services, penalties and fines, whether incurred directly or indirectly by the *contractor*, a provider, a contractor or a subcontractor of the *contractor*.

In the *Financial Statement*, the *contractor* will set out such amounts as well as those amounts of the *up-front payments* that have neither been incurred nor committed ("**unspent amounts**"). Such *unspent amounts* will be reimbursed by the *contractor* to the *Commission* and the *participating Member States* in proportion to their respective *up-front payments* within thirty (30) days from the receipt of the *Financial Statement* by the *Commission*, it being understood that the *Financial Statement* and the *unspent amounts* shall be final and binding upon all *Parties* to the extent the *Commission* and the *participating Member States* have not provided to the *contractor* a written statement of objections, specifying in reasonable detail the grounds of objections, within thirty (30) days from the receipt of the *Financial Statement* by the *Commission*.

In addition, the *contractor* will transfer, upon the *Commission*'s request to be provided within forty-five (45) days after the receipt of notification about the automatic termination, to the *Commission*, or a third party named by the *Commission*, any raw materials and primary components not used and paid for with the *up-front payments* (the "**Refundable Items**"). The *contractor* will also facilitate the discussion of a transfer of reserved capacity with *CMOs* paid for with the *up-front payments* to a third party selected by the *Commission*. Any such transfer is subject to the *CMOs* express agreement and any discussions about financial terms of such transfer will take place between such selected third party and the *CMO*.

(b) in case of termination pursuant to Article II.14.2

In case of a termination by the *Commission* according to Article II.14.2(a), the provisions on the effect of the termination and refunding of the *unspent amounts* and the *Refundable Items* as set out in Article II.14.5(a) apply mutatis mutandis.

In case of a termination of the *APA* by the *Commission* or a *Vaccine Order Form* by a *participating Member State* according to Article II.14.2(b) to (g), the *contractor* may be liable for damage incurred by the *Commission* or the *participating Member State* [redacted]. The *Commission* or the *participating Member State* may claim compensation for such damage, as allowed by

[redacted]

applicable laws.

(c) *in case of termination pursuant to Article II.14.3*

The *contractor* is not entitled to compensation for any damage resulting from the termination of the *APA* or a *Vaccine Order Form*, including loss of anticipated profits, if the *contractor* terminated the *APA* or the relevant *Vaccine Order Form* in accordance with Article II.14.3(b).

The *Commission* and the *participating Member State* are liable for damage incurred by the *contractor* as a result of the termination of the *APA* or a *Vaccine Order Form* by the *contractor* on the basis of Article II.14.3(a). The *contractor* may claim compensation for such damage against the *Commission* and/or the *participating Member State(s)*, as allowed by applicable laws.

The *Parties* must take all appropriate measures to minimise costs, prevent damage and cancel or reduce their commitments.

Within sixty (60) calendar days of the date of termination, the *contractor* must submit any report and any invoice required for *Products* that were provided before the date of termination.

Articles I.10.3, I.10.4, I.10.5, I.23, II.6, II.7 and II.17 shall survive any termination of this *APA* and/or the *Vaccine Order Forms*.

II.15. PAYMENT REQUESTS, INVOICES, VALUE ADDED TAX AND E-INVOICING

II.15.1. 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* (to the extent already concluded), (iii) the full name and address of the recipient, (iv) the name of the *participating Member State* concerned, (v) the invoiced amount, (vi) the currency, (vii) the quantity of *Product doses* delivered (or offered to be delivered if the *participating Member State* illegitimately refuses acceptance of delivery), or, with respect to the *up-front payment*, the *second up-front payment* and the *Additional Doses up-front payment*, the quantity of *Product doses* allocated to the relevant *participating Member State* pursuant to Articles I.8.1 through I.8.3, (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.

The *Commission* is exempt from all taxes and duties, including VAT, in accordance with Articles 3 and 4 of the Protocol 7 of the Treaty on the Functioning of the European Union on the privileges and immunities of the European Union. The *Parties* shall cooperate in good faith to ensure the tax exemption of the *Commission* at all steps of the *APA* and take all necessary actions to ultimately ensure such exemption in connection with the execution of the *APA*.

Notwithstanding the preceding paragraph, for the avoidance of doubt, 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 *up-front 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*.

II.15.2. E-invoicing

Receipt of invoices by standard format (pdf) or e-mail is accepted.

II.16. PAYMENTS

II.16.1. 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.16.2. Currency

Payments are made in euros.

II.16.3. Costs of transfer

The costs of the transfer are borne as follows:

(a) the *Commission* or the *participating Member State* in question bears the costs of dispatch charged by its bank;

(b) the *contractor* bears the costs of receipt charged by its bank;

(c) the *Party* causing repetition of the transfer bears the costs for repeated transfer.

II.16.4. Suspension of the time allowed for payment

The *Commission* or the *participating Member State* in question may suspend the payment periods specified in Article I.17 at any time by *notifying* the *contractor* that its payment request or invoice (as the case may be) cannot be processed if the *Commission* or the *participating Member State* in question is not able to process a payment request or invoice (as the case may be):

(a) because the payment request or invoice (as the case may be) does not comply with the *APA*; or

(b) because the *Commission* or the *participating Member State* in question has legitimate objections against the documents submitted with the payment request or invoice (as the case may be).

The *Commission* or the *participating Member State* in question must *notify* the *contractor* as soon as possible of any such suspension, giving the reasons for it.

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 requested information or revised documents are received or the necessary further verification is carried out. Where the suspension period exceeds two months, the *contractor* may request the *Commission* or the *participating Member State* in question to justify the continued suspension.

II.16.5. Interest on late payments of the Commission and/or the participating Member States

On expiry of the payment periods specified in Article I.17, the *contractor* is entitled to interest on late payment at the rate applied by the European Central Bank for its main refinancing operations in euros (the reference rate) plus five points. The reference rate is the rate in force, as published in the C series of the *Official Journal of the European Union*, on the first day of the month in which the payment period ends.

Suspension of the payment period pursuant to Article II.16.4 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.16.1.

II.16.6. Interest on late payments of the contractor

If the *contractor* does not honour the obligation to pay the *unspent amount* when due, the amount due bears interest at the rate indicated in Article II.16.5. 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. Any partial payment is first entered against charges and interest on late payment and then against the principal amount.

II.17. CHECKS AND AUDITS

II.17.1. The *Commission* and the European Anti-Fraud Office ('the OLAF') may check or require an audit on the performance 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.

Such checks and audits may be initiated at any moment during the provision of the vaccines and up to five years starting from the payment of the balance of the last *Vaccine Order Form* 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.17.2. 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 *Vaccine Order Form* issued under this *APA*.

II.17.3. The *contractor* must grant the appropriate right of access to sites and premises where the *APA* is implemented and to all the 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.

II.17.4. 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.

II.17.5. 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 vaccines and up to five years starting from the payment of the balance of the last *Vaccine Order Form* issued under this *APA*.

II.17.6. The Court of Auditors and the European Public Prosecutor's Office established by Council Regulation (EU) 2017/1939[5] ('the EPPO') have the same rights as the *Commission*, particularly right of access, for the purpose of checks, audits and investigations.

II.17.7. The *Commission* and/or any *participating Member State* shall have the right to use, at their exclusive costs, an internationally recognised expert (not engaged on a contingent basis) to perform an audit in order to verify (a) any clinical trial data, and/or (b) the manufacturing conditions including by subcontractors. The *contractor* will enable such an audit and will make available to the third-party auditor, upon reasonable request, any documents or information for that purpose.

****** Signature page to follow ******

[5] Council Regulation (EU) 2017/1939 of 12 October 2017 implementing enhanced cooperation on the establishment of the European Public Prosecutor's Office

Sensitive*
RELEASABLE TO: Need to know basis

SIGNATURES

This *APA* has been executed on the place and dates mentioned hereunder, in two original copies, each of the *contractor* and the *Commission* acknowledging having received one original signed copy.

For the *contractor*,

[redacted]

Signature: [redacted]

Done at [redacted]

Pierre Kemula,
Chief Financial Officer

Signature:_ [redacted]

Done at [redacted]

For the *Commission*,

Stella Kyriakides,

Commissioner for Health and Food Safety

Signature:_ [redacted]

Done at Brussels, [redacted]

[redacted]

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RELEASABLE TO: Need to know basis

ANNEX I
LIST OF PARTICIPATING MEMBER STATES

Full name	Contact person	Full official address	Email address
Republic of Austria			
Kingdom of Belgium			
Republic of Bulgaria			
Republic of Croatia			
Republic of Cyprus			
Czech Republic			
Kingdom of Denmark			
Republic of Estonia			
Republic of Finland			
French Republic			
Federal Republic of Germany			
Hellenic Republic			
Hungary			
Ireland			
Italian Republic			
Republic of Latvia			
Republic of Lithuania			
Grand Duchy of Luxembourg			
Republic of Malta			
Kingdom of the Netherlands			
Republic of Poland			
Portuguese Republic			
Romania			
Slovak Republic			
Republic of Slovenia			
Kingdom of Spain			
Kingdom of Sweden			

ANNEX II
TEMPLATE VACCINE ORDER FORM

1. [Name of Member State] (the **"Member State"**), represented for the purposes of signing this specific order form by [*forename, surname, function, department of authorising officer*],

and

2. CureVac AG

   Friedrich-Miescher-Straße 15, 72076 Tübingen

   [*VAT registration number*]

(**"the contractor"**), represented for the purposes of signing this specific order form by [*forename, surname and function of legal representative,*]

WHEREAS, the *contractor* and the *Commission* acting on behalf of and in the name of the *participating Member States* entered into that Advance Purchase Agreement for the production, purchase and supply of Vaccine against *COVID-19* in the European Union dated [l] September 2020 (the **"APA"**).

WHEREAS, the *APA* provides that each *participating Member State* will execute an order form with the information filled in (a **"Vaccines Order Form"**);

WHEREAS, in line with the conditions set out in the *APA*, the *Member State* wishes to order *doses* of the *Product* from the *contractor* in accordance with the terms of the *APA*.

WHEREAS in accordance with the provisions set out in the APA, the *contractor* has agreed to supply the *doses* of the *Product* allocated to each *participating Member State* in a given timeframe, should it manage to obtain a (conditional) *EU marketing authorisation*.

WHEREAS defined terms used but not defined herein shall have the meaning ascribed to them in the *APA*.

HAVE AGREED

Article 1

Subject matter

1.1 This *Vaccine Order Form* is entered into as contemplated by the APA, signed by the *Commission*, acting on behalf and in the name of the *participating Member States* and the *contractor* on [*complete date*]. This *Vaccine Order Form* is an integral part of the APA and the terms and conditions of the APA are incorporated into this *Vaccine Order Form* by reference.

1.2 In line with the terms and conditions of the *APA*, the undersigned *Member State* hereby purchases [insert the number of doses] *doses* of the *Product* in accordance with Article I.8 of the *APA* and re-confirms to be obliged to perform all obligations imposed on the *Member State* by the *APA* with respect to such purchase.

Article 2

Price, method of payment and invoicing

2.1 The Price per does shall equal the price as determined in Article I.16 of the *APA*.

2.2 All payments to the *contractor* under this *Vaccine Order Form* shall be made in accordance with Article I.17 of the *APA* and they shall be made by deposit of Euros by wire transfer of immediately available funds in the requisite amount to the bank account referred to in Article I.18 of the APA.

2.3 Invoices shall be issued in accordance with Article II.15 of the APA.

2.4 The undersigned *Member State* hereby undertakes to comply with the payment obligations referred to in the APA, including but not limited to the payments as set forth in Article I.17.2 of the APA, with respect to the quantities of *doses* allocated to the undersigned *Member State*.

Article 3

Distribution

3.1 The delivery hub for the undersigned *Member State* is as follows:

[*Member State to enter unique location of the delivery hub*]

3.2 The *contractor* shall notify the representative of the undersigned *Member State* in good time prior to such time that the *contractor* expects *doses* of the *Product* to be delivered. The first notification should be done up to four (4) weeks before the start of the first delivery and continue on a rolling basis. Such notifications shall include an estimate of the number of *doses* expected to be delivered and the expected dates that such *doses* will be available to be shipped to the delivery hub designated by the undersigned *Member State*.

The *contractor* shall deliver the *doses* of *Product* at the unique point of delivery indicated by the undersigned *Member State*. For the avoidance of doubt, the undersigned *Member State* shall bear the costs of setting up of the delivery hub and the distribution of the *Product* as of the delivery hub.

Article 4

Communication details; Notices

Any notice given under this *Vaccine Order Form* shall be in writing in English, shall refer to the *APA* and this *Vaccine Order Form* and shall be sent by either pre-paid post/pre-paid airmail or courier to the principal office or registered office of the recipient or by electronic transmission (e-mail and/or pdf) to the addresses set forth below:

If to the *Member State* to:

[*Full name*]
[*Function*]
[*Name of Participating Member State*]
[*Full official address*]
E-mail: [*complete*]

If to the *contractor* to:

[redacted]c

CUREVAC AG

Friedrich-Miescher-Str. 15, 72076 Tübingen, Deutschland

[redacted]

Article 6

Indemnification

The undersigned *Member State* acknowledges and agrees to be bound by the provisions of Article I.23 of the APA.

Article 7

Termination

This *Vaccine Order Form* shall remain in full force and effect until all obligations under this *Vaccine Order Form* are duly fulfilled, unless and to the extent this *Vaccine Order Form* is terminated in accordance with the *APA*.

**** Signature page to follow ****

[redacted]

SIGNATURES

This *Vaccine Order Form* has been executed on the place and dates mentioned hereunder, in two original copies, each of the *contractor* and the *Member State* acknowledging having received one original signed copy.

For the *contractor*,

[*forename/surname/position*]

Signature:_____
Done at [*place*], [*date*]

For the *Member State*,

[*forename/surname/position*]

Signature:_____
Done at [*place*], [*date*]

[*forename/surname/position*]

Signature:_____
Done at [*place*], [*date*]

ANNEX III

ANNEX 7 TO COMMISSION DECISION C(2020) 4192 FINAL OF 18 JUNE 2020 - AGREEMENT BETWEEN THE COMMISSION AND MEMBER STATES ON PROCURING COVID-19 VACCINES ON BEHALF OF THE MEMBER STATES AND RELATED PROCEDURES

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EUROPEAN
COMMISSION

Brussels, 18.6.2020
C(2020) 4192 final

ANNEX

ANNEX

to the

Commission Decision

on approving the agreement with Member States on procuring Covid-19 vaccines on behalf of the Member States and related procedures

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16.06.2020

Agreement

Preamble

Having regard to Article 4(5)(b) of Council regulation (EU) 2016/369 on the provision of emergency support within the Union[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 (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

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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

2

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

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and Participating Member States. In order to launch negotiations with a specific manufacturer, there needs to be support from at least four Participating Member States. The joint negotiation team will make its best effort to take the advice of the steering board into account in the negotiations and will report back to the steering board on a regular basis on the progress made in negotiating with individual companies.

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

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

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

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

Advanced Purchase Agreements and conditions

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

As outlined in the present Agreement, the European Commission also has the possibility to conclude APAs including an obligation to procure the vaccine if it becomes available, where the conditions (notably the pricing) of those APAs make this worthwhile and in line with the conditions in the present Agreement. If in such a case the distinction between 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.

[6] Pages 57-70 have been deleted as they are fully protected by Article 4(2) first indent of Regulation (EC) No 1049/2001

ANNEX VI
GOODS RECEIVED FORM
(preliminary)

Receiver
XXX
Street
City
Country

Shipper
CureVac
Street
City
Country

Acknowledgment of goods received

Product and name: **[COMMERCIAL NAME] – CureVac Covid-19 Vaccine**
Shipment number: _____
Courier Services: _____

To whom it may concern

The undersigned hereby acknowledge receipt of goods (Covid-19 vaccine) of shipment referenced above and declare after visual inspection that (check one of the following)

☐ said goods **do not present apparent defects** upon initial visual inspection and **are complete**

☐ said goods **present some apparent defects** upon initial visual inspection (see description on next page)

☐ said goods **do not appear complete** (see description on next page)

Receiver

_____

Name (CAPITALS) Date
Signature

Please provide a copy of this completed form to the courier and send any other documentation of apparent defects such as photographs via E-Mail to CureVac Logistics logistics@curevac.com (shipment number in email title) as soon as possible and no later than four (4) calendar days after delivery.

Visual inspection checklist

1. **Quantity received**

   a. Concentrated vaccine _____ pallets / boxes (circle as appropriate)

   b. Diluent _____ pallets / boxes

   c. Package inserts (information leaflets) _____ pallets / boxes

2. **Temperature check**

   Temperature indicated on measurement device: _____°C

   Evidence of temperature excursion: (Yes/No): _____

3. **Apparent defects**

No apparent defect	**Some** apparent defect
☐ No apparent defect visible	☐ Broken or damaged boxes
	☐ Absence of labelling or mis-labelling
	☐ Leakage
	☐ Temperature of goods received
	☐ Other: _____

Comments or short description of apparent defects or of elements apparently missing

PLEASE PROVIDE PHOTOGRAPHS OF APPARENT ISSUE SEPARATELY IN EMAIL

Pages 73-75 have been deleted as they are fully protected by Article 4(2) first indent of Regulation (EC) No 1049/2001