SIGNATURES

For the Contractor,	For the Commission, on behalf and in the name of the Participating Member States,
Nanette Cocero	Stella Kyriakides
Global President, Vaccines, Pfizer Biopharmaceuticals Group, Pfizer Inc.	Commissioner of Health and Food Safety
Signature: 	Signature: 
Done at 20 of November, 2020	Done at ,

In duplicate in English.

II. GENERAL CONDITIONS FOR THE FRAMEWORK CONTRACT FOR SERVICES

II.1 DEFINITIONS

All definitions are contained in Article I.2

II.2 ROLES AND RESPONSIBILITIES IN THE EVENT OF A JOINT TENDER

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

II.3 SEVERABILITY

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

II.4 PROVISION OF SERVICES AND SUPPLIES

II.4.1 All periods specified in the APA are calculated in calendar days, unless otherwise specified.

II.4.2 The Contractor must immediately inform the Commission of any changes in the exclusion situations as declared, according to Article 137 (1) of Regulation (EU) 2018/1046.

II.5 COMMUNICATION BETWEEN THE PARTIES

II.5.1 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.9; and

(d) be sent by mail or email.

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

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

II.5.2 Date of communications by mail and email

Any communication is deemed to have been made when the receiving party receives it, unless this APA refers to the date when the communication was sent.

E-mail is deemed to have been received by the receiving party on the day of dispatch of that e-mail, provided that it is sent to the e-mail address indicated in Article I.9. 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 email or mail. In such a case, the sending party is not held in breach of its obligation to send such communication within a specified deadline.

Mail sent to the Commission or the Participating Member State is deemed to have been received on the date on which the department responsible referred to in Article I.9 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.6 LIABILITY

II.6.1 During the term of this APA, the Contractor or its Affiliates shall self-insure or procure and maintain such types and amounts of insurance to cover liabilities related to its activities under this APA as is normal and customary in the pharmaceutical industry generally for companies that are similarly situated and providing similar manufacturing and supply services. For absolute clarity, this shall not include, nor constitute, product liability insurance to cover any third party/patients claims and such general insurance shall be without prejudice to the Participating Member States' indemnification obligation as set out in this APA.

II.6.2 Pfizer and BioNTech are jointly and severally liable to the Commission or the Participating Member State for the Implementation of the APA.

II.6.3 The Commission and the Participating Member States shall use commercially reasonable efforts to mitigate both (1) the damages that would otherwise be recoverable from the other pursuant to this APA and the Vaccine Order Forms, and (2) any costs, fees, expenses or losses that may be incurred by the Commission or the Participating Member State, or for which the Contractor may be responsible, under this APA and/or any Vaccine Order Form, by taking appropriate and reasonable actions to reduce or limit the amount of such damages, costs, fees, expenses or losses.

II.6.4 Limits on liability

(i) Taking into account the unprecedented nature of the current COVID-19 situation and the exceptional circumstances under which the Vaccine shall be delivered, the parties explicitly agree that the Contractor and its Affiliates cannot be held liable for any damages except for proven damages which are

suffered by the Commission or the Participating Member States as a direct consequence of a breach by the Contractor or its Affiliates of its obligations under this APA or a Vaccine Order Form, and that the Contractor and its Affiliates shall in any case not be liable for late deliveries (subject to the Contractor's obligation to use Best Reasonable Efforts as contained in Article I.6.3), loss of revenue, loss of anticipated savings, loss of business, loss of profit, loss of goodwill, reputational damages, loses from economic disruption or cost of alternative supply.

(ii) Taking into account the Participating Member States' indemnification obligation as set out in this APA, the parties also explicitly agree that the Contractor shall have no liability to the Commission or the Participating Member States in respect of losses or damages suffered by the Commission or the Participating Member States as a result of any claim by a third party relating to the distribution or use of the Vaccine, save in circumstances where the Contractor would not have been entitled to indemnification under Article I.12, had such claim by a third party been made against the Contractor.

(iii) The aggregate liability of the Contractor and its Affiliates towards the Commission arising out of or relating to this APA and/or the Vaccine Order Forms (whether arising contractually or extracontractually), shall not exceed a sum equivalent to the Advance Payment actually received by the Contractor.

(iv) The aggregate liability of the Contractor and its Affiliates towards any of the Participating Member States arising out of or relating to this APA and/or the Vaccine Order Form concluded with that Participating Member State (whether arising contractually or extracontractually), shall not exceed a sum equivalent to 50% of the sums actually received by the Contractor under the Vaccine Order Form concluded with that Participating Member State.

(v) For the avoidance of doubt, this provision does not in any way affect the rights of an injured third party (excluding the Commission or any Participating Member State) to claim damages under the applicable Law.

II.6.5 No limitation of liability

(i) Nothing in this APA excludes or limits the liability of either party for:

(a) wilful intent, fraud or fraudulent misrepresentation;

(b) any breach of Article II.9 (Confidentiality);

(c) in the case of the Commission, failure to pay the Advance Payment;

(d) in the case of a Participating Member State, failure to pay the price for the Product or any other sums properly owing to the Contractor or a Participating Contractor Affiliate under this APA and Vaccine Order Form;

(e) in the case of a Participating Member State, the indemnity given by it under Article I.12;

(f) in the case of Contractor the circumstances in which the indemnity under Article I.12 is not available.

II.6.6 Waiver of sovereign immunity

Each Participating Member State represents that it has adequate statutory or regulatory authority and adequate funding appropriation to undertake and completely fulfil the indemnification obligations pursuant to Article I.12 of this APA.

II.6.7 Recall

In the event of a recall of the Vaccine, the Participating Member States shall be responsible for all costs of any recall or market withdrawal of the Vaccine, including reasonable costs incurred by or on behalf of the Contractor and its Affiliates, except to the extent that such recall or market withdrawal results from one of the situations described in points (i) and (ii) of Article I.12.1 of this APA, in which event the Contractor shall be responsible for all costs of any recall or market withdrawal of the Vaccine, including reasonable costs incurred by or on behalf of the Commission and Participating Member States.

II.7 CONFLICT OF INTEREST AND PROFESSIONAL CONFLICTING INTERESTS

II.7.1 The Contractor must take all the necessary measures to prevent any situation of *conflict of interest or professional conflicting interest*.

II.7.2 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 Implementation 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 not to award a Vaccine Order Form to the Contractor.

II.7.3 The Contractor must pass on all the relevant obligations in writing to:

(a) its personnel which is directly involved in the performance of this APA;

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

(c) third parties involved in the Implementation 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.8 Representations and warranties

II.8.1 Mutual representations and warranties

The parties each represent and warrant to each other the following:

(i) Organization and authority. They have full right, power and authority to enter into this APA and to perform their respective obligations under this APA;

(ii) No conflicts or violations. The execution and delivery of this APA by such party and the performance of such party's obligations hereunder (i) do not conflict with or violate any laws existing as of the date of entry into force of the APA and applicable to such party and (ii) do not conflict with, violate, breach or constitute a default under, and are not prohibited or materially restricted by, any contractual obligations of such party existing as of the date of entry into force of the APA; and

(iii) Valid execution. Such party is duly authorised to execute and deliver this APA, and the person executing this APA on behalf of such party is duly authorised to execute and bind such party to the terms set forth herein.

The above warranties shall also be given by the Participating Member States in respect of the Vaccine Orders Forms and their obligations contained therein.

II.8.2 Warranties of either party

The Contractor warrants to the Commission and the Participating Member States that:

(i) at the time of delivery, the Vaccine (except for any non-compliance or failure to meet the relevant standard or requirement that could not be reasonably discovered given the state of medical, scientific or technical knowledge at the time when the Contractor delivered the Vaccine):

(a) complies with the Specifications;

(b) has been manufactured in accordance with current Good Manufacturing Practice; and

(ii) subject to the Contractor's disclaimer of non-infringement of intellectual property rights of a third party, it has good title to the Contracted Doses delivered to the Participating Member States pursuant to this APA and shall pass such title to the Participating Member States free and clear of any security interests, liens, or other encumbrances.

In the event of any breach of the Contractor's warranties or undertakings relating to the Vaccine, the Commission's and the Participating Member States' sole and exclusive remedy will be for the Contractor to deliver replacement Vaccine in the circumstances provided in Article I.6.14.

The Commission warrants that the APA is awarded and each Vaccine Order Form is concluded in accordance with applicable Laws.