

I.9 COMMUNICATION DETAILS

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

If to the Commission:

European Commission

Directorate-General for Health and Food Safety

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

If to a Participating Member State – See details in Vaccine Order Form

If to Pfizer:

Janine Small

IDM Vaccines Regional President

Pfizer Inc.

E-mail: Janine.small@pfizer.com

By derogation from this Article I.9, different contact details for the Commission, the Participating Member States or the Contractor may be provided in Vaccine Order Form.

I.10 PROJECT MANAGEMENT

Pfizer, BioNTech and the Commission will each nominate a project manager that will be the sole contact point for and responsible for managing the overall relationship between the parties. Each Participating Member State shall in addition appoint an expert to work on APA implementation at Participating Member State level. Project meetings with the Commission and Participating Member State experts will be held regularly on a timeframe to be determined following execution of the APA to report, amongst other things, on progress of clinical studies, licensing activities, manufacturing status, forecast and deliveries. Details specific to each Participating Member State such as logistics and payments shall be handled directly by the respective Participating Member State experts.

I.11 EXPLOITATION OF THE RESULTS OF THE APA⁴

The Commission acknowledges and agrees that the Contractor shall be the sole owner of all intellectual property rights generated during the development, manufacture, and supply of the Vaccine or otherwise related to the Vaccine, including all know-how (collectively, the “**Vaccine IP Rights**”). The Contractor shall be entitled to exclusively exploit any such Vaccine

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This article must be adapted with care. In particular where the FWC is in essence only a licence on pre-existing materials (with no actual production of new materials specifically for the Union), as is the case for instance for a subscription contract to a database service provider, this article must be adapted accordingly. All information is in the Explanatory note on IPR on: <http://myintracomm.ec.testa.eu/budgweb/EN/imp/procurement/Documents/ipr-note-en.pdf>.

IP Rights. Except as expressly set forth in this APA, the Contractor does not grant to the Commission by implication, estoppel or otherwise, any right, title, license or interest in the Vaccine IP Rights. All rights not expressly granted by the Contractor hereunder are reserved by the Contractor.

I.12 INDEMNIFICATION

I.12.1 The Commission, on behalf of the Participating Member States, declares that the use of Vaccines produced under this APA will happen under epidemic conditions requiring such use, and that the administration of Vaccines will therefore be conducted under the sole responsibility of the Participating Member States. Hence, each Participating Member State shall indemnify and hold harmless the Contractor, their Affiliates, sub-contractors, licensors and sub-licensees, and officers, directors, employees and other agents and representatives of each (together, the **"Indemnified Persons"**) from and against any and all liabilities incurred, settlements as per Article I.12.6, and reasonable direct external legal costs incurred in the defence of Third Party Claims (including reasonable attorney's fees and other expenses) relating to harm, damages and losses as defined in Article I.12.2 (together, the **"Losses"**) arising from or relating to the use and deployment of the Vaccines in the jurisdiction of the Participating Member State in question. This Article I.12 applies to Losses which arise from or relate to the Vaccines supplied in accordance with this APA during the initial duration of this APA of 24 months (for the avoidance of doubt, regardless whether the Use of the Vaccine or Losses occur within or after such initial duration). In the event that additional doses of the Vaccine are supplied under this APA following its renewal, the parties will discuss in good faith whether the grounds justifying the existence of this clause are still present. If this is not the case, the indemnification provisions will cease to apply to doses supplied pursuant to and after that renewal agreement. If those grounds are still (partially) present, the parties will discuss in good faith whether any amendment to this clause is warranted. Such indemnification will not be available to the Indemnified Persons to the extent that (i) the Losses were caused by the Wilful Misconduct, as defined in Article I.12.3, of such Indemnified Person; or (ii) the Losses were caused by a material breach of Good Manufacturing Practice (as applied at the time of manufacture) before certification of batch-release of the Vaccine according to the requirements set out in Title IV of Directive 2001/83/EC, leading to a Quality Defect in the Vaccine at the time of each delivery and resulting in a determination by the competent regulatory authority to recall or suspend the supply of the Vaccine, or in a withdrawal or suspension of the Authorisation by the European Commission. The Participating Member State shall, notwithstanding the competency and responsibility of the competent regulatory authority, involve the CHMP of the European Medicines Agency (the "EMA") in any case of a recall or suspension of supply of the Vaccine because of suspected GMP failure, and shall seek without delay a scientific opinion of the CHMP whether a recall or suspension of supply of the Vaccine by the competent regulatory authority was justified, and shall submit all necessary information to the CHMP. The Contractor shall be involved in the process in accordance with the applicable procedures. For the purposes of applying the provisions under point (ii) above, regard shall be had to the CHMP opinion. For the avoidance of doubt, indemnification under the conditions laid down in this Article I.12 includes Losses arising from or related to actions or omissions of any person receiving the Vaccine directly or indirectly after Indemnified Persons deliver the Vaccine to Participating

Member States or their designated carriers, including, but not limited to, any transport, storage, distribution, handling, use, administration, or change in the condition of the Vaccine.

- I.12.2 Indemnification pursuant to Article I.12.1 will only be available for the following losses suffered by a third party: death, physical injury, mental or emotional injury, illness, disability, property loss or damage, economic losses or business interruption.
- I.12.3 For the purpose of this Article I.12, the following terms shall be defined as follows:
- (i) “Wilful Misconduct” shall mean: any wrongful act, willingly and knowingly committed, with the intent to cause harmful effects;
 - (ii) “Quality Defect” shall have the meaning defined in Volume 4 of the EU Rules governing medicinal products - EU Guidelines to Good Manufacturing Practice Medicinal Products for Human and Veterinary Use.
- I.12.4 If any Indemnified Person incurs any Losses as defined in Article I.12.1, the Indemnified Person(s) shall notify the Participating Member State in question promptly in writing, describing such Losses in reasonable detail, including the amount or estimated amount, if known or reasonably capable of estimation. If any action is instituted or claim is asserted by a third party with respect to which an Indemnified Person intends to seek indemnification for any Losses that may ultimately be incurred (“**Third Party Claim**”), the Contractor shall notify the Participating Member State in question promptly in writing, stating the nature and basis of such Third Party Claim. Any delay or deficiency of the Contractor in informing the Participating Member State of such Third Party Claim shall not limit the right to indemnification pursuant to Article I.12.1, unless such failure materially prejudiced the Participating Member State. Where permission from a third person is necessary to share certain information with the Participating Member States, the Contractor will use reasonable efforts to obtain such permission.
- I.12.5 The Participating Member State shall be allowed to utilize an independent expert to evaluate any notice or information provided under Article I.12.4. In that case, the Participating Member State shall notify the relevant Indemnified Person in advance of its intention to use an expert and the identity of such expert. The Indemnified Person shall be allowed to object to the use of an expert within thirty (30) business 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 shall provide the identity of that expert to the Indemnified Person who will have the right to object to the use of that expert in accordance with this Article I.12.5.
- I.12.6 The Contractor shall ensure that the Indemnified Person(s) control the defense against the Third Party Claim, using legal counsel chosen by the Indemnified Person(s) and approved by the Participating Member State(s), such consent not to be unreasonably withheld. For the avoidance of doubt, the Indemnified Person(s)’ control of the defense or the outcome of the claim shall not affect their right to indemnification for legal costs as provided in Article I.12.1. The Indemnified Person(s) may compromise or settle the

Third Party Claim, provided that the Indemnified Person(s) shall give the Participating Member State reasonable advance notice in writing of any proposed compromise or settlement and seek the Participating Member State's consent, such consent not to be unreasonably withheld. The Contractor shall ensure that the Indemnified Person(s) provide reasonable updates to the Participating Member State concerning the defense of the Third Party Claim either directly, or if the Participating Member State so chooses, through counsel chosen by the Participating Member State, provided that the fees and expenses of such counsel shall be borne by the Participating Member State. The Participating Member State shall cooperate with the Indemnified Person(s) for access to documents and other information required for the defense of any Third Party Claim, using reasonable efforts. The Participating Member State(s) may further cooperate in the defense of any Third Party Claim where appropriate, through its own counsel.

I.12.7 The parties explicitly and irrevocably agree that each of the Indemnified Persons, to the extent that such person is not a party, is a third-party beneficiary (within the meaning of Article 1121 of the Belgian Civil Code) of this Article I.12 and shall be entitled to invoke and exercise all rights, claims and waivers under this Article I.12 against any of the Participating Member States.

I.12.8 The parties explicitly agree that:

- (i) any warranties given by the Contractor, whether express or implied, under this APA as regards compliance with Good Manufacturing Practice or conformity of the Product with the Specifications shall be without prejudice to the provisions of this Article I.12, which shall apply independently of and prevail over such warranties, including any (claimed) breach of such warranty; and
- (ii) a Participating Member State does not have the right to suspend and/or otherwise not perform its obligations under this clause I.12 except where the Participating Member State puts forward reasonable evidence that one of the situations listed in this Article I.12.1(i) and (ii) is applicable and the matter is brought for dispute resolution under Article I.13, in which case the Participating Member State's obligation to make any indemnity payment which is the subject of such dispute resolution shall be suspended until the resolution of such dispute; and the amounts paid by a Participating Member State under this Article I.12 are not recoverable from the Contractor (irrespective of whether or not the Third Party Claim resulted from a contractual breach by the Contractor) based on a claim of breach by the Contractor of the provisions of this APA or of a Vaccine Order Form except where there is final adjudication by competent courts that no indemnification is available to the Contractor pursuant to this Article I.12, in which case any corresponding indemnification already paid by a Participating Member State shall be fully reimbursed by the Contractor.

I.13 APPLICABLE LAW AND SETTLEMENT OF DISPUTES

I.13.1 This APA shall be governed by the laws of Belgium.

I.13.2 Dispute Resolution

- (a) In the event of a dispute arising under this APA or the Vaccine Order Forms, as applicable, between the parties, the parties shall first refer such dispute to informal dispute resolution discussions between their respective representatives. The Contractor or the Commission on behalf of itself or of the Participating Member States may initiate such informal dispute resolution by sending written notice of the dispute to the other party, and, within twenty (20) days of such notice, the representatives shall meet and attempt to resolve the dispute by good faith negotiations.
- (b) The Commission, the Participating Member States and the Contractor each irrevocably submit to the exclusive jurisdiction of the courts located in Brussels, Belgium to settle any dispute or claim which may arise under or in connection with this APA or the legal relationships established by this APA or any Vaccine Order Form.

I.14 OTHER SPECIAL CONDITIONS

The Contractor shall keep the Commission and the Participating Member States informed about any significant safety signal detected during the pharmacovigilance or vaccine monitoring programmes in relation to the Vaccines which are the object of this APA within 5 business days from notifying the European Medicines Agency.

(Signature page follows)