



EUROPEAN COMMISSION  
Directorate-General for Health and Food Safety

ADVANCE PURCHASE AGREEMENT ("APA")<sup>1</sup> for the development, production,  
priority-purchasing options and supply of a successful COVID-19 vaccine for EU Member  
States

*SANTE/2020/C3/042 - SI2.834667*

1. The European Commission, acting on behalf and in the name of all the EU Member States (hereinafter referred to as "Member States")<sup>2</sup>:

being represented for the purposes of the signature of this APA by Ms Stella Kyriakides, Commissioner for Health and Food Safety,

on the one part and

2. SANOFI PASTEUR S.A, Société Anonyme (SA), a company existing and organised under the laws of France with its registered office located at 14 Espace Henry Vallée 69007 Lyon, France registered with the RCS number in LYON (France) B 349 505 370 under number VAT number: FR 54 349 505 370

(hereinafter referred to as "Sanofi Pasteur"), represented for the purposes of the signature of this APA which has the form of a framework contract by [REDACTED]

And

3. GLAXOSMITHKLINE BIOLOGICALS S.A., Société anonyme (SA), a company existing and organised under the laws of Belgium with its registered office located at Rue de l'Institut 89, B- 1330 Rixensart, Belgium, Registered with the Legal Entity Register (RPM Nivelles) under number VAT number 0440.72.918

(hereinafter referred to as "GSK"), registered with the Legal Entity Register (RPM Nivelles) under number VAT number 0440.72.918, represented for the purposes of the signature of this APA which has the form of a framework contract by [REDACTED]

(Sanofi Pasteur and GSK collectively 'the contractor')

on the other part,

<sup>1</sup> 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.

<sup>2</sup> 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.

HAVE AGREED

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

**Annex I** – Complement to the Advance Purchase Agreement (Appendixes A to I)

**Annex II** – Vaccine Order Form, to be entered into by the Member States

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

which form an integral part of this APA.

This APA sets out:

1. the procedure and conditions by which the Commission and the Participating Member State may pay the services and/or supplies from the contractor;
2. the provisions that apply to any Vaccine Order Form which the Participating Member States and the contractor may conclude under this APA; and
3. the obligations of the parties during and after the duration of this APA.

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## RECITALS

1. In the fight against the COVID- 19 pandemic crisis, Sanofi Pasteur and GSK are running an R&D project in order to develop and manufacture an adjuvanted COVID- 19 vaccine (hereafter the “**Adjuvanted Pandemic Vaccine**”) composed of Sanofi Pasteur’s recombinant COVID- 19 Spike protein antigen (“S Antigen”) and GSK’s squalene- based Adjuvant (the “Adjuvant”) both in multidose vials and to be reconstituted at bedside before injection. (as further described in Annex I Complement to the Advance Purchase Agreement, Appendix H).
2. The **Adjuvanted Pandemic Vaccine** is composed of an adjuvant and a protein expression system:
  - a. S Antigen expression system is FDA- approved and under EMA review for the flu vaccine (Supemtek) using the same technology;
  - b. GSK’s Adjuvant, AS03, is FDA/European Commission approved.
3. As such, Sanofi Pasteur and GSK are actively building/expanding their European production capacities for the Adjuvanted Pandemic Vaccine.
4. Sanofi Pasteur and GSK aim to make available hundreds of millions of the Adjuvanted Pandemic Vaccine doses (amount to be determined as the project develops) in 2021.
5. The European Commission (“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 (“APAs”) with vaccine manufacturers with the objective to procure vaccines for the purposes of combatting the COVID-19 pandemic at Union level.
6. The Commission wishes to secure supply of the Adjuvanted Pandemic Vaccine for human use for the Member States adhering to this APA during the COVID- 19 Pandemic as promptly as possible.
7. 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.
8. According to the Agreement between the Commission and the Member States and in particular Article 3 thereof, where the Commission concludes an Advance Purchase Agreement that provides for 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. The present Advance Purchase Agreement is such an agreement under which the European Commission makes a down payment to secure the right for the Member States to acquire

such vaccines doses. Thus, the Commission enters into the present APA on behalf and in the name of the Member States to which the vaccines will be ultimately supplied. The present APA will be complemented by a specific contract ("Vaccine Order Form") between each of the Member States and the contractor, if the respective Member State wishes to acquire the vaccine and to exercise the option to that effect. A template Vaccine Order Form for the agreement between each of the Member States and the contractor is attached in Annex II. Pursuant to these terms and conditions, access to vaccine 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.

9. The down payment, paid by the Commission, should be taken into account in equal terms per dose ordered by the Member States.
10. The contractor and the Commission have agreed to collaborate with the aim of achieving the above objective, implementing the principles described hereafter.

## **I. Special Conditions**

### **I.1. ORDER OF PRIORITY OF PROVISIONS**

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

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

### **I.2. SUBJECT MATTER**

The subject of this APA is financing the manufacturing and supply of a COVID-19 vaccine in accordance with the applicable legislation and securing the purchase of certain vaccine doses for the participating Member States.

By Decision C (2020) 4192 final of 18 June 2020, the Commission approved the agreement with Member States on procuring COVID-19 vaccines on behalf of the Member States ("the Decision", see Annex III). This 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<sup>3</sup> ("the ESI Regulation") which provides that the Commission may grant emergency support in the form of procurement on behalf of the Member States based on an agreement between the Commission and Member States. In order to implement such action, the Commission has offered to run a single central procurement procedure on behalf of the Member States, with a view to signing

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<sup>3</sup> 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.

EU-level APAs with vaccine manufacturers. In view of its importance in the implementation of the Vaccine Instrument, this APA will be approved for signature on behalf and in the name of the Member States by a separate individual Commission decision.

### **I.3. ENTRY INTO FORCE AND DURATION OF THE APA**

**I.3.1** The APA enters into force on the date on which the last party signs it.

**I.3.2** The APA is concluded for a period of 24 months with effect from the date of its entry into force. The APA, including its provisions relating to liability and indemnification (Articles II.6), continues to apply to the Order Forms after its expiry. The services relating to such Order Forms must be performed no later than six months after the expiry of the APA.

**I.3.3** The parties may not sign any Vaccines Order Forms after the APA expires.

### **I.4. IMPLEMENTATION OF THE APA**

The APA shall be implemented following the signature between the Commission and the contractor as follows:

#### **I.4.1. Volume of Adjuvanted Pandemic Vaccine available for EU Member States**

Sanofi Pasteur and GSK aim to make available up to three hundred (300) million doses of the Adjuvanted Pandemic Vaccine for the Member States of the European Union in 2021. Additional orders are subject to separate discussions.

This volume is at the time of execution of the contract indicative only and is based on current assumptions around manufacturing and release timelines as well as antigen yield assumptions.

The above-mentioned three hundred (300) million doses are based [REDACTED]

Taking into account the uncertainties of the situation and the specific conditions under which the supply of the Adjuvanted Pandemic Vaccine is envisaged, Sanofi and GSK will use their best reasonable efforts to adhere to the supply of the volumes indicated and the time-line of such delivery schedule.

The target product profile is currently based on a 2- dose regimen per vaccine, with the doses being administered 3- 4 weeks apart. However, in Phase I/II clinical trial, a 1-dose regimen will also be tested to assess all options and fully inform choice for the Phase III clinical trial design. The three hundred (300) million doses of the Adjuvanted Pandemic Vaccine for the Member States would be predominantly manufactured at GSK and Sanofi Pasteur sites in the European territory and additional manufacturing sites (internal & Contract Manufacturing Organisations (CMOs)) could be leveraged to accelerate production and/or to provide a back- up solution for supply security and expansion. (cf. Annex I, **Appendix A and Appendix I**).

Sanofi Pasteur and GSK shall be entitled to direct part of the activities contemplated in this APA to their respective Affiliates. It being understood that Sanofi Pasteur and GSK shall remain solely liable towards the Commission or the Participating Member States, as the case may be, for actions of their Affiliates as per article II.2.

#### **I.4.2. Timeline**

Timeline for availability of Adjuvanted Pandemic Vaccine is anticipated as follows:

- Start full scale S Antigen Drug Substance production early Q1 2021
- First doses of Adjuvanted Pandemic Vaccine shipped as early as Q2 2021 (pending Union marketing authorisation)
- Union marketing authorisation anticipated June 2021

Consequently, it is anticipated that up to three hundred (300) million doses of the Adjuvanted Pandemic Vaccine for Relevant Member States will be available as follows:

- 150 million doses in Q3- 2021
- 150 million doses in Q4- 2021

Taking into account the timelines agreed in these special conditions, Sanofi and GSK will use their best reasonable efforts to adhere to such delivery schedule.

The Adjuvanted Pandemic Vaccine is a refrigerator- stable product, i.e. stored between 2 and 8 degrees Celsius which permits leveraging standard vaccine distribution and delivery infrastructure.

These anticipated volumes and delivery timelines are indicative only and are based on current assumptions around manufacturing, yield, and release and under the provision of free movement of raw materials, intermediates and finished goods. The contractor will specify the volumes available at the end of Phase I/II anticipated in December 2020/January 2021 in the steps as provided for under Articles I.5., I.6.2.

#### **I.5. PRICES**

**Maximum amount of the APA, maximum prices and mechanism to determine a final price**

Sanofi Pasteur and GSK commit that the price for the Adjuvanted Pandemic Vaccine will in any case not be more than [REDACTED] per dose (exclusive of VAT). This is a ceiling price. This [REDACTED] Ceiling Price includes [REDACTED] corresponding to transportation and related insurance costs per dose of Adjuvanted Pandemic Vaccine.

The final price will depend upon a number of parameters, in particular the antigen amount per dose and manufacturing yield. Once the parameters are confirmed, which is anticipated to occur from December 2020/ January 2021 (end of phase I/II), Sanofi Pasteur and GSK will communicate to the Commission the final price (the "Final Price") and will inform the Commission on the parameters related to the drug substance dosage. The Final Price will be communicated through Formal Notification as per Article II.5.2.

In case there should be material differences to the anticipated volume of the Adjuvanted Pandemic Vaccine and the time-lines in which it is anticipated to be available, as set out in Articles I.4.1 and I.4.2, Sanofi Pasteur and GSK will duly inform the Commission and provide the rationale of such differences.

In any event, the Final Price shall not exceed the [REDACTED] per dose ceiling (exclusive of VAT).

#### **I.6. PAYMENT ARRANGEMENTS**

It is the common intention of the Parties to make the Adjuvanted Pandemic Vaccine available to the Member States of the European Union as soon as possible, which requires production to start as soon as possible while the Adjuvanted Pandemic Vaccine is still under development.

The acceleration of the at- risk production of the three hundred (300) million doses of the Adjuvanted Pandemic Vaccine for the EU Market would require Sanofi Pasteur and GSK not only to invest in fixed assets in upstream & downstream manufacturing infrastructures but also to support substantial additional operating expenditures (including significant opportunity cost) related to the manufacturing and supply preparedness of such doses during 2020.

Considering this, the Parties agree to share the risks induced as follows:

- Sanofi Pasteur and GSK will deploy a large network of industrial assets and a broad workforce, and support associated costs:
  - Sanofi Pasteur and GSK own industrial assets: [REDACTED]
  - [REDACTED] experts contributing to the project across Sanofi Pasteur and GSK supporting delivery for Europe: [REDACTED]

- The European Commission will support Sanofi Pasteur and GSK for expenditures related to the manufacturing preparedness of these doses and through possibility to purchase doses in advance according to the evolution of the clinical development of the Adjuvanted Pandemic Vaccine as described hereunder.

The cost sharing consists of two separate payment mechanisms. The payment mechanisms are meant to structure financial commitments in a way that supports scale up of production of the full estimated volume of 300 million doses, while providing flexibility to the European Commission and the Member States (further detailed in Annex I, **Appendix B**).

- The first mechanism is a down payment intended to support Sanofi Pasteur and GSK's manufacturing preparedness, to enable to initiate full scale production of the Adjuvanted Pandemic Vaccine as soon as possible. This down payment is set at [REDACTED]
- The second mechanism relates to the Vaccines Order Forms (as defined hereunder) with three separate financial milestones, whereby the first financial milestone will be split into two instalments.

#### **I.6.1. Down Payment for manufacturing preparedness**

I.6.1.1 In order to enable Sanofi Pasteur and GSK to initiate full scale production of the Adjuvanted Pandemic Vaccine for the EU Market in early Quarter 1 (Q1) 2021, the Commission agrees to support Sanofi Pasteur and GSK for expenditures related to the manufacturing preparedness of these doses and incurred and/or committed (insofar they can no longer be avoided) until the preliminary results of Phase I/II of the clinical trial of the Adjuvanted Pandemic Vaccine which are anticipated in December 2020 / January 2021 (see Annex I, **Appendix G**) for an amount limited to the Down Payment.

Such expenditures will allow Sanofi Pasteur and GSK to be in a position to prepare production in 2020 and start full scale manufacturing in early Q1-2021 while simultaneously conducting Phase III (further detailed in Annex I, **Appendices C&D**.)

The Commission will support these costs through a financial contribution of [REDACTED] (the "Down Payment") according to the following types of expenditures:

- Project costs, including technology transfers to industrial sites / CMOs, qualification batches, and development / scale up
- Raw materials and primary components (vials, stoppers, proprietary media for cell culture, chromatography gel, raw materials for adjuvant bulk production). These raw materials and primary components are mostly specific to the Adjuvanted Pandemic Vaccine and are thus mostly non reusable by Sanofi Pasteur and GSK;
- Direct costs, including hiring and training of additional skilled work force in Europe;

- CMO costs including take or pay contracts to expand manufacturing capacity;
- Costs actually incurred by Sanofi Pasteur and GSK in relation to deferred commercial agreements, in particular for any trade-offs resulting from the prioritization of the Adjuvanted Pandemic Vaccine production over the production of the existing vaccine portfolio.

In full transparency, Sanofi Pasteur and GSK shall provide to the Commission regular reports that will substantiate the activities performed and progresses made regarding the manufacturing preparedness supported by the Down payment (hereafter “the Down Payment Progress Report”).

The Down Payment Progress Report shall indicate the status of manufacturing preparedness in relation to the following elements: Technology Transfer, qualification batches, development/scale-up, raw material & primary component procurement, hiring and training execution of additional skilled work force, and CMO’s contracting status to expand manufacturing capacity. Such elements are further detailed in Annex I, **Appendices C&D**.

Such Down Payment Progress Reports shall be provided by each of Sanofi Pasteur and GSK for the first one not later than end of October 2020 and for the second by end of December 2020.

I.6.1.2 This Down Payment is 100% deductible from the Vaccines Order Forms provided that the Total Purchase Amount is superior or equal to the Down Payment (see illustrative examples under Article I.6.4). The Down Payment by the Commission shall be taken into account in equal terms per dose purchased by the Member States and the price per dose to be paid by each Member State shall be the same.

The Down Payment will not be otherwise refundable except in the following situations:

- The contractor has not transmitted the Down Payment Progress Reports
- The contractor has evaluated that the results of Phase I/II clinical studies (which are anticipated to occur in December 2020/January 2021) do not permit to proceed to Phase III clinical trial (“the Phase I/II Development Failure”). In this case, the contractor will inform at the earliest and in written the Commission (“the “Notification”) and

(i) the APA shall be terminated automatically as per article II.15.1(a)

(ii) each of Sanofi Pasteur and GSK shall respectively send to the Commission within 60 days from the receipt of the Notification, a financial statement (the “Financial Statement”) that the Down Payment has been used for the purposes as set out in the APA (namely the manufacturing preparedness) and will notify the unspent amount of the Down Payment not incurred nor committed (the “Non-Committed Portion”) at the date the Notification. Such Non-Committed Portion will be reimbursed within 30 days from the receipt of the Financial Statement by respectively Sanofi and GSK.

For the sake of clarity, in the event of a Phase I/II Vaccine Development Failure and the relevant expenditure calculation, the Down Payment shall also cover any costs for suspending and/or terminating relevant manufacturing activities (including costs related to laying off workforce and write-off of intermediate goods) Sanofi Pasteur and GSK will actually incur following the Phase I/II Vaccine Development Failure.

Sanofi Pasteur and GSK will, upon the Commission's request to be provided within 45 days after the receipt of the Financial Statement, transfer to the Commission or a third party named by the Commission any raw materials and primary components not used until that date and paid for with the Down Payment (the "Refundable Items"). GSK and Sanofi Pasteur will also facilitate the discussion of a transfer of reserved capacity with CMOs paid for with the Down Payment 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.

I.6.1.3 The Down Payment of [REDACTED] [REDACTED] shall be paid within 30 days following a payment request by the contractor after the execution of the agreement.

#### **I.6.2 Vaccine Order Form - Milestone 1, Upon Availability of Phase I/II results anticipated in December 2020/January 2021**

Upon the availability of positive Phase I/II clinical trials results as defined in section I.6.1.2, which are anticipated to occur in December 2020/January 2021, Sanofi Pasteur and GSK will be able to confirm to the Commission the total volume of the Adjuvanted Pandemic Vaccine available for the EU market.

Sanofi Pasteur and GSK commit to provide the Commission, as soon as available, the following data (hereafter the Data of Milestone 1) described in more detail in Annex I, **Appendices E&F**:

- Preclinical studies results
- Key Phase I/II clinical study results
- Phase III clinical study final design and protocol
- Anticipated delivery schedule

#### **(i) Purchase of the vaccine**

Should the Commission confirm the interest of the Member States in purchasing in advance the Adjuvanted Pandemic Vaccine, the Commission shall provide an overall volume intended to be purchased by the Member States ("Purchase Total Amount") with a breakdown by Member State (the "Allocation"). This communication by the Commission shall occur within 4 weeks after

- (i) the communication of the phase I/ II results;
- (ii) the communication of material differences, if any, to the anticipated volume of the Adjuvanted Pandemic Vaccine and the timelines in which it is anticipated to be available and

- (iii) the communication on the Final Price as set out in point I.5.1, whichever is later.

Upon such communication by the Commission of the Purchase Total Amount and the Allocation, Sanofi Pasteur and GSK shall sign the vaccine order forms with each Participating Member State.

To facilitate the contractual process, a template agreement for the Member State that agrees to buy the Adjuvanted Pandemic Vaccine (“Participating Member State”) is agreed in Annex II (the “Vaccine Order Form”). The Final Price will be included in the Vaccine Order Form. The Vaccine Order Form to be entered by Participating Member States shall be substantially conform to the template in Annex II.

Such Vaccine Order Form will formalize the agreement of the parties thereto on the Final Price, agreed volume, anticipated delivery schedule and the unique point of delivery to be chosen by the Participating Member State within the Member State Territory with respect to the doses to the doses purchased by the Participating Member State.

The Vaccine Order Form defines principles such as

- minimum volume for delivery [REDACTED]
- number and frequency of delivery,
- designation of a unique delivery location per Participating Member State.

The signature of the Vaccine Order Form by the Participating Member States should occur within 2 weeks after the communication by the Commission of the Purchase Total Amount and the Allocation. Delay in signature of a Vaccine Order Form may result in a delay in the delivery of the Adjuvanted Pandemic Vaccine. For the avoidance of doubt, Member States will not be obliged to enter into any Vaccine Order Forms or to purchase the Adjuvanted Pandemic Vaccine under the APA if they do not wish to do so.

The signature of the Vaccine Order Forms will allow Sanofi Pasteur and GSK to launch at risk full- scale production of the Adjuvanted Pandemic Vaccine for the EU Market simultaneously with conduct of the phase III clinical study.

Participating Member States agree to pay to Sanofi Pasteur and GSK Milestone 1 in two equal instalments **after signature of their respective Vaccine Order Forms** and upon receipt of the following elements:

- *Instalment 1:* In full transparency, Sanofi Pasteur and GSK will provide to the Commission prior to the payment of instalment 1 of Milestone 1:
  - Phase III clinical trial authorization submission proof and Phase III clinical trial approvals by regulatory authority in relevant countries
  - Sanofi Pasteur- GSK progress report showing “first visit first subject”

- *Instalment 2:* Thereafter, Sanofi Pasteur and GSK shall provide to the Commission a report on the Phase III clinical trial progress showing “first visit last subject” (the “Milestone 1 Progress Report”). Such Milestone 1 Progress Report will substantiate the activities performed and progress made regarding Phase III clinical trial shall be provided by Sanofi Pasteur and GSK not later than by the end of March 2021. This will be the basis for the payment of instalment 2 of Milestone 1.

The purchase amount of each Participating Member State (“Each MS Purchase Amount”) is the result of the volume ordered by each Participating Member State multiplied by Final Price (per unit) agreed by the Parties.

The overall Milestone 1 payment of Participating Member State shall be equal to: (Each MS Purchase Amount minus Each MS Prorated Down Payment) multiplied by [REDACTED] Each MS Prorated Down Payment is equal to Down Payment multiplied by the percentage of Each MS Purchase Amount in the Purchase Total Amount.

- *The instalment 1* ([REDACTED]) of the Milestone 1 payment shall be paid by each of the Participating Member States to Sanofi Pasteur and GSK following an invoice and within 30 days after the signature of each Vaccines Order Form. The signature of the Vaccines Order Form should occur within 2 weeks after the communication by the Commission of the Purchase Total Amount and the Allocation. Delay in signature of a Vaccines Order Form may result in a delay in the delivery of the adjuvanted vaccine.
- *The instalment 2* ([REDACTED]) of the Milestone 1 payment shall be paid, following an invoice and within 60 days after the confirmation by Sanofi Pasteur and GSK that Phase III targeted enrolment is completed (as defined per Data of Milestone 1) (currently targeted by end of March 2021).

These two instalments of Milestone 1 will not be refundable, except as set out in Article II.15.5 (a).

### ***Redistribution***

Regarding the pandemic situation, the Commission or the Participating Member States are allowed to donate or redistribute doses between Member States or other countries or other international entities (see example under point I.10 in the Advance Purchase Agreement) that have concluded a Vaccines Order Form with Sanofi Pasteur and GSK.

Such redistribution to countries, which are part of the EEA is allowed if those countries agree to be bound by equivalent liability protection as set out in this Agreement. Should such redistribution take place, the Participating Member States concerned shall reimburse the Commission the part corresponding to the Commission’s Down Payment for the number of doses concerned.

Redistribution or donation to other countries or international entities will be subject to prior notification to and approval of Sanofi Pasteur and GSK, not to be unreasonably withheld, as well as subject to an agreement by those other countries or international entities that appropriate

liability protection at least as protective as the terms of this Agreement is in place for such a redistribution or donation.

**(ii) No purchase of the vaccine**

Should through Formal Notification the Commission on behalf of the Member States decide not to confirm the Member States' interest in purchasing in advance the Adjuvanted Pandemic Vaccine or should Sanofi and GSK not enter into any Vaccine Order Form with any Member State within four (4) weeks after the communication by the Commission of the Purchase Total Amount and the Allocation as set out in point I.6.2 (i), the Advance Purchase Agreement between the Commission and GSK and Sanofi Pasteur will be automatically terminated.

Consequently, should no Vaccines Order Forms be entered into for the reasons hereabove, then Sanofi Pasteur and GSK will transfer, upon request within 30 days further Formal Notification, to the Commission any raw materials and primary components not used during this first period and paid for with the Down Payment (the "Refundable Items"). GSK and Sanofi Pasteur will also facilitate the discussion of a transfer of reserved capacity with CMOs paid for with the Down Payment 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.

**I.6.3 Vaccines Order Form – Milestone 2 – Upon European Union marketing authorization anticipated June 2021**

The overall Milestone 2 payment of Participating Member State shall be equal to: (Each MS Purchase Amount minus Each MS Prorated Down Payment) multiplied by [REDACTED] Each MS Prorated Down Payment is equal to Down Payment multiplied by the percentage of Each MS Purchase Amount in the Purchase Total Amount.

The Milestone 2 shall be due subject to obtaining the Union marketing authorization for the Adjuvanted Pandemic Vaccine. The Parties agree that should Union marketing authorization not be granted to the Adjuvanted Pandemic Vaccine, the Milestone 2 instalment shall not be due by the Participating Member States and the unused raw materials and primary components, including the Refundable Items, shall, upon request within 30 days further Formal Notification, be returned to the Commission. The provision in Article I.6.2 (ii) applies mutatis mutandis.


Milestone 2 shall be paid by the respective Participating Member State two (2) weeks after obtaining EU Market authorization and the submission of an invoice by the contractor.

**I.6.4 Vaccine Order Form – Milestone 3 – Delivery of doses and final instalment**

Once the Union marketing authorization estimated in June 2021 is granted to the Adjuvanted Pandemic Vaccine, Sanofi Pasteur and GSK will be in a position:

- to prepare shipments according to the volume provided by the Participating Member States to Sanofi Pasteur and GSK in the Vaccine Order Forms.
- for a release and delivery from Q3 2021.

The Participating Member States will pay the Milestone 3 instalment to Sanofi Pasteur and GSK equal to the remaining amount:

(Each MS Purchase Amount minus Each MS Prorated Down Payment) multiplied by   
Prorated Down Payment is equal to Down Payment multiplied by the percentage of Each MS Purchase Amount in the Purchase Total Amount.

Each Participating Member State will pay the Milestone 3 instalment to Sanofi Pasteur and GSK of the Adjuvanted Pandemic Vaccine following Union marketing authorization and following receipt of an invoice and within 30 days after each delivery in proportion to the value of each product delivery.

If Union marketing authorization is not granted for the Adjuvanted Pandemic Vaccine and/or should GSK and Sanofi Pasteur face a production issue that would prevent Sanofi Pasteur and GSK to deliver the Adjuvanted Pandemic Vaccine, the Milestone 3 instalment will not be made by the Participating Member States and the unused raw materials and primary components shall, upon request within 30 days further Formal Notification, be returned to the Commission. The provision in Article I.6.2 (ii) applies mutatis mutandis.

Should GSK and Sanofi Pasteur face production issues affecting its final volume or timing of delivery (linked to yield, quality deviations or third- party supplier issues), the payment under Milestone 3 for each of the Participating Member States will be reduced in proportion to reflect the final volume delivered and the Vaccines Order Forms with the Member States will be deemed to be amended to that effect.

First doses of the Adjuvanted Pandemic Vaccine may be available prior to the anticipated Union marketing authorization in June 2021 and therefore before Milestone 2 instalment. If Relevant Member States seek to use the Adjuvanted Pandemic Vaccine based on temporary authorization under Article 5(2) of Directive 2001/83, the parties will seek to agree on Milestone 2 payment and use conditions.





### **I.6.5 Abandonment of the project**



### **I.6.6 Post-Marketing Study Costs**

Per application of Articles 10a and 16 of the Regulation 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency as further amended, the European Regulatory Authority (the “EMA”) could require Sanofi Pasteur and GSK to perform Post Marketing Studies (“PMS”) on vaccine safety, efficacy and effectiveness. In the pandemic context, the accelerated development timelines for COVID-19 vaccines with short follow up periods in clinical trials will likely lead to PMS requests with a scope and size far beyond PMS requested for regular vaccine projects and may include longer term effectiveness studies, studies in special populations (e.g., studies in pregnant women, frail elderly people, HIV or cancer patients, patients with underlying autoimmune diseases) as well as additional studies addressing real or perceived safety signals. The last point is a likely consequence of products, which will be rapidly rolled out to very large populations in a pandemic setting resulting in higher frequencies of spurious signals which have to be formally studied. The costs for such PMS have been estimated at an amount of [REDACTED]. For clarity, regular expected post licensure activities, which come with any licensure of a new product (e.g. lowering age indication (pediatric populations), longer term follow up of a subset of the phase III cohort, regular pharmacovigilance etc.) are paid by Sanofi Pasteur and GSK and are not part of the above estimated additional amount.

These estimated costs have been agreed by the Parties to constitute a maximum lump sum that would be paid by the Participating Member States through the allocation of an additional amount of up to [REDACTED] (exclusive of VAT) per dose of the Adjuvanted Pandemic Vaccine, invoiced to the Participating Members States (the “Additional Costs”).

- In case the Total Purchase Amount is 150 million doses or less, the Additional Costs will be [REDACTED] (exclusive of VAT) per dose of Adjuvanted Pandemic Vaccine.
- In case the Total Purchase Amount is more than [REDACTED] the Additional Costs will be calculated by dividing the maximum lump sum of [REDACTED] by the Total Purchase Amount.

This Additional Costs per dose of Adjuvanted Pandemic Vaccine will be added, as part of the Milestone 3 payments, to the invoices sent to each Participating Member State with respect to the corresponding Vaccine Order Form.

#### **1.6.7 Delivery**

The contractor shall notify the Commission and the representative of each Participating Member State in good time prior to such time that the contractor expects doses of the Adjuvanted Pandemic Vaccine to be available. This should be done at least 6 weeks before the start of the first delivery and continue on a rolling basis. Such notification shall include an estimate of the total number of doses expected to be available for delivery and the expected dates that such doses will be available to be shipped to the delivery hub designated by each Participating Member State. The number of doses per quarter shall be allocated to the Participating Member States pro rata based on the Allocation.

The respective Member State will specify a unique delivery hub per Member State in the Vaccines Order Form. The contractor shall deliver the vaccine doses at the place indicated by the Participating Member State. The delivery at each delivery hub will occur CIP (INCOTERMS 2020). For the avoidance of doubt, the Participating Member State will bear the costs of setting up of the delivery hub and the distribution as of the delivery hub.

#### **1.6.8 Invoice**

The contractor must send an invoice in paper format or by electronic systems for payment due under the terms of the specific Vaccine Order Form to the respective Participating Member State, as the case may be.

Each invoice must contain the following information:

- Name of a concerned Member State
- APA and Vaccines Order Form number/reference
- Order reference
- Contractor name and bank account.
- VAT intracom number of Participating Member State

**I.7. BANK ACCOUNT**

Payments must be made to the contractor's (or leader's in the case of a joint tender) bank account denominated in [euro], identified as follows:



**I.8. COMMUNICATION DETAILS**

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

**(Down Payment):**

European Commission

Directorate-General for Health and Food Safety

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

**(Order forms):**

Participating Member State [Information regarding each Member State will be completed upon the signature of the contract.]

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

1. For Sanofi Pasteur :

SANOFI PASTEUR



@sanofi.com ( [redacted] sanofi.com)

And

2. For GSK:

GLAXOSMITHKLINE BIOLOGICALS S.A



gsk.com



@gsk.com

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.9. EXPLOITATION OF THE RESULTS OF THE APA**

The European 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, including all Know-How (collectively, the “Vaccine IP Rights”). The contractor shall be entitled to exclusively exploit any such Vaccine IP Rights. Except as expressly set forth in this APA, the contractor does not grant to the European 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.10. GLOBAL ACCESS – ACT ACCELERATOR**

Sanofi Pasteur and GSK will endeavour to provide at least two- hundred (200) million doses of the Adjuvanted Pandemic Vaccine total worldwide available supply capacity to the global initiative “Access to COVID- 19 Tools (act) Accelerator” so as to ensure availability for all, especially vulnerable countries subject to the inclusion of satisfactory liability protection.

This APA does not cover specific details with regard to provision of doses to the COVID- 19 Tools (act) Accelerator to be concluded and agreed separately with the relevant parties involved.

### **I.11. APPLICABLE LAW AND SETTLEMENT OF DISPUTES**

**I.11.1.** This Agreement shall be governed by the laws of Belgium.

#### **I.11.2. Dispute Resolution**

- (a) In the event of a dispute arising under this APA 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 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.

**I.12. WARRANTIES**

Sanofi Pasteur and GSK warrant that the Adjuvanted Pandemic Vaccine will be released in compliance with the specification of Union marketing authorization and with the EU Good Manufacturing Practices in effect at the time of manufacture.

Sanofi Pasteur and GSK warrant that they will comply with all material terms of the Annex II of the Regulation 726/2004 and all material terms of the European pharmacovigilance legislation as Pharmaceutical companies, as such terms have been modified by the applicable regulatory agency for approval or use of a Covid- 19 pandemic vaccine.

Sanofi Pasteur and GSK warrant that to the best of their knowledge they will have all necessary Intellectual property rights for the supply of the Adjuvanted Pandemic Vaccine.

Sanofi Pasteur and GSK expressly disclaim and make no other warranties of any kind, express or implied, at the time of delivery, with respect to the Adjuvanted Pandemic Vaccine other than those expressly provided hereabove.

**I.13. OTHER SPECIAL CONDITIONS**

Per application of article 107h of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001, as amended by Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010, the contractor shall keep the Commission and the Participating Member States' regulatory body informed in the event of new risks or risks that have changed or changes to the risk-benefit balance being detected in relation to the Adjuvanted Pandemic Vaccine within 5 working days from notifying the European Medicines Agency.

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**SIGNATURES**

For SANOFI PASTEUR,

[Redacted]

Signature: [Redacted]

Done at Lyon, date Sep 16, 2020

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

Stella KYRIAKIDES  
Commissioner for Health and Food Safety.

Signature: [Redacted]

Done at [Redacted], date [Redacted]

For GLAXOSMITHKLINE  
BIOLOGICALS S.A.,

[Redacted]

Signature: [Redacted]

Done at [Redacted], date Sep 16, 2020

For GLAXOSMITHKLINE  
BIOLOGICALS S.A.,

[Redacted]

Signature: [Redacted]

Done at [Redacted], date Sep 16, 2020

## II. General conditions

### II.1. DEFINITIONS

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

**“Affiliate”** means any company which Controls, is Controlled by, or is under common Control with GSK or/and Sanofi Pasteur as applicable, and/or its respective ultimate parent company as applicable.

**“Breach of obligations”**: failure by the contractor to fulfil one or more of its contractual obligations.

**“Confidential information, material or document”**: any and all information of any kind (including know-how, software, algorithms, designs, plans, forecasts, analyses, evaluations, research, business information, financial information, business plans, strategies, customer lists, marketing plans or other information) and any physical items, compounds, components, samples or other materials disclosed directly or indirectly by one Party and/or any of its affiliates or representatives to the other Party and/or any of its affiliates or representatives, in written, oral, electronic or in any other form. For the avoidance of doubt and for the purpose of this definition, “Party” includes the Commission, the EU Member States and the contractor.

**“Conflict of interest”**: a situation where the impartial and objective *implementation of the APA* by the contractor is compromised for reasons involving family, emotional life, political or national affinity, economic interest, any other direct or indirect personal interest, or any other shared interest with the Commission, the Participating Member State or any third party related to the subject matter of the APA;

**“Control”** means the holding, directly or indirectly, of:

- A) equal to or more than fifty percent (50%) of the voting share capital of a company; or
- B) the power to appoint at least one half of the Board of Directors or similar body of a company; or
- C) the power, by virtue of the constitution of the company or other arrangements or documents regulating that company, to secure that the affairs of a company are conducted in accordance with the holder’s wishes.

**“Disclosing party”**: a Party or any of that Party’s affiliates or representatives disclosing confidential information, material or documents before, on or after the date of entry into force of the APA. For the avoidance of doubt and for the purpose of this definition “Party” includes the Commission, the EU Member States and the contractor.

**“Force majeure”**: any events or circumstances reasonably beyond the control of the Parties including, without limitation, war or other national emergency, riot, fire, explosion, pandemic other than Covid19 pandemic, flood or other Act of God, general and long- lasting strike affecting the activity of either Party, the inability of a Party to perform under this APA due to an injunction or blockade imposed by a jurisdiction acting further to a claim for infringement of

intellectual property rights by a third- party, any injunction, decree, order, law or regulation of any public authority or any decision by a government such as a constraint order or requisition or embargo, or any inability to obtain electricity, fuel or raw material (collectively, “*events of force Majeure*”).

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

**“Fraud”**: an 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;

**“Implementation of the APA”**: the purchase of services envisaged in the APA through the signature and *performance of Vaccine Order Forms* by Member States, on the terms and conditions set forth in this APA and the Vaccine Order Form;

**“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.

**“Notification”** (or ‘notify’): form of communication between the parties made in writing including by electronic means;

**“Performance of a Vaccine Order Form”**: the execution of tasks and delivery of the purchased services or supplies by the contractor to the Participating Member State;

**“Professional conflicting interest”**: a situation in which the contractor’s previous or ongoing professional activities affect its capacity to implement the APA or to perform a Vaccine Order Form to an appropriate quality standard.

**“Receiving party”**: a Party or any of that Party’s affiliates or representatives receiving confidential information, material or documents before, on or after the date of entry into force of the APA. For the avoidance of doubt and for the purpose of this definition, “Party” includes the Commission the EU Member States and the contractor.

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

**“Vaccine Order Form”**: a contract implementing the APA and specifying details of the delivery of the vaccine, a template of which is attached to the APA as Annex II;



## **II.2. ROLES AND RESPONSIBILITIES OF SANOFI PASTEUR AND GSK**

This is a joint APA of Sanofi Pasteur and GSK, both Sanofi Pasteur and GSK enter into direct, tri-partite contractual relations with the Commission, acting on behalf of the Member States, pursuant to the present APA.

In terms of liability, Sanofi Pasteur and GSK are jointly and severally liable for the performance of the APA, including with respect to any financial obligations or liabilities towards the Commission and the Participating Member States. The Adjuvanted Pandemic Vaccine is composed of Sanofi Pasteur's recombinant COVID- 19 Spike protein antigen and GSK's squalene- based Adjuvant, to be reconstituted at bedside before injection. The Adjuvanted Pandemic Vaccine therefore relies on essential contributions from each of Sanofi Pasteur and GSK which the respective other party does not and cannot deliver. As a consequence, it is agreed that if Sanofi Pasteur and GSK are unable to meet their supply obligation for a committed supply of Adjuvanted Pandemic Vaccine under this APA, any remedy imposed on Sanofi Pasteur and GSK to require performance and supply of the Adjuvanted Pandemic Vaccine will not require (1) GSK to manufacture or supply Sanofi Pasteur's recombinant COVID-19 Spike protein antigen, nor (2) Sanofi Pasteur to manufacture or supply GSK's squalene-based Adjuvant. This is due to the proprietary nature of these respective components and the specific expertise and unique contributions of each of Sanofi Pasteur and GSK for the supply of the Adjuvanted Pandemic Vaccine.

## **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 accordance with Article II.11. The APA must be interpreted as if it had contained the substitute provision as from its entry into force.

## **II.4. PROVISION OF SERVICES AND SUPPLIES**

**II.4.1.** The contractor must provide services and supplies of high-quality standards, in accordance with the state of the art in the industry and the provisions of this APA.

**II.4.2.** The contractor must comply with the minimum requirements provided for in this APA.

**II.4.3.** All periods specified in the APA are calculated in calendar days, unless otherwise specified.

**II.4.4.** The contractor must immediately inform the Commission of any changes in the exclusion situations as declared, according to Article 137 (1) of Regulation (EU) 2018/1046.

## **II.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 Vaccines Order Form number;
- (c) be made using the relevant communication details set out in Article I.8; 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 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 in Article I.8. 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.8 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 TOWARDS THIRD PARTIES AND INDEMNIFICATION**

**II.6.1.** If a third party brings any action against the Commission or a Participating Member State in connection with the *implementation of the APA*, including any action for alleged breach of intellectual property rights, the contractor must assist the Commission or the Participating Member State, including by intervening in support of the Commission or the Participating Member State upon request.

**II.6.2.** The use of the Adjuvanted Pandemic Vaccine will occur in conformity with EU and national legislation governing such use, and the administration of those vaccines will be conducted under the sole responsibility of the Participating Member States. Due to the specific circumstances surrounding the COVID- 19 pandemic, the use of the Adjuvanted Pandemic Vaccine, may occur in a situation where the efficacy and safety profiles of such Adjuvanted Pandemic Vaccine are not yet fully documented in an immunologically naïve population. In addition, the virus for which the Adjuvanted Pandemic Vaccine is intended to immunize is likely to be highly virulent.

**II.6.3.** Under such circumstances, absent a specific indemnification clause, Sanofi Pasteur's and GSK's performance under this APA would subject Sanofi Pasteur and GSK to increased liability risks for which Sanofi Pasteur and GSK in all fairness should be held harmless.

**II.6.4.** Each Participating Member State shall, directly or through any of its agencies and/or existing indemnification funds indemnify and hold harmless each Sanofi Pasteur and GSK and their respective Affiliates (the "Sanofi Pasteur Indemnified Entities" and the "GSK Indemnified Entities", respectively) for any and all liability, and reasonable direct external legal costs necessary to the defense in Third Party Claims, (i.e. law firm's fees, external experts fees) incurred and normally borne by them relating to harm, damages and losses (together, the "Losses") associated with the death, physical, mental or emotional injury, illness, disability, property loss or damage or business interruption of a party injured as result ("the Injury") of the use or deployment of the Adjuvanted Pandemic Vaccine in the jurisdiction of the Participating Member State in question.

Such indemnification will be available to the Sanofi Pasteur Indemnified Entities and the GSK Indemnified Entities for the Losses arising from the use and administration of any Adjuvanted Pandemic Vaccine doses sold during the initial duration of the Down Payment and Advance Purchase Agreement which term will be of 24 months (the "Covered Doses") (even if delivered and/or used after) and will apply to Losses arising from vaccination with such Covered Doses regardless of when the Injury leading to the Losses occurs or is reported.

In the event the Parties mutually agree to extend the Advance Purchase Agreement after its initial duration and then mutually agree to supply additional doses of the Adjuvanted Pandemic Vaccine under such extended agreement, the Parties will discuss in good faith whether any amendment to the above indemnification provisions is warranted.

**II.6.5.** There shall be no obligation to indemnify and hold Sanofi Pasteur Indemnified Entities and GSK Indemnified Entities harmless where it is demonstrated [REDACTED]

(i)

(ii)

(iii)

(iv)

**II.6.6.** In case liability has been incurred by a Sanofi Pasteur Indemnified Entity or GSK Indemnified Entity for Losses defined in Article II.6.4, subparagraph 1, the Sanofi Pasteur Indemnified Entity or GSK Indemnified Entity shall give the Participating Member State in question, or an independent expert as referred to in Article II.6.7, reasonable access to information necessary for the Participating Member State to indemnify the Indemnified Entity and to verify whether the conditions pursuant to Articles II.6.4 and II.6.5 –are fulfilled. This information shall include clinical trial and other data generated to demonstrate the safety, efficacy and quality of the vaccines (including communications and correspondence with regulatory agencies and bodies to include all audit observations, inspection reports, meeting minutes, and all Sanofi Pasteur and GSK commitments and responses) as well as all data relevant to the manufacturing of the Adjuvanted Pandemic Vaccine including quality control data.

**II.6.7.** The Participating Member State shall be allowed to access the information as referred to in Article II.6.6 through an independent expert with expertise in the relevant field. In that case, the Participating Member State shall notify the Sanofi Pasteur Indemnified Entity or GSK Indemnified Entity (depending on which has requested indemnity) in advance of its intention to use an expert and the identity of such expert. The Sanofi Pasteur Indemnified Entity or GSK Indemnified Entity depending on which has requested indemnity) shall be permitted to object to the use of an expert within 10 calendar 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 Sanofi Pasteur Indemnified Entity or GSK Indemnified Entity that the above process can be reinitiated. In the event the independent expert would have access to confidential information of the Sanofi Pasteur Indemnified Entity and/or GSK Indemnified Entity (depending on which has requested indemnity), a specific procedure to protect such confidential information shall be agreed prior to granting such access.

**II.6.8.** Sanofi Pasteur and GSK (and their respective Affiliates) shall promptly inform the relevant Participating Member State of any claim brought against them before the courts of that Participating Member State (“**Third Party Claim**”), stating the nature and basis of the claim in question and the maximum estimated amount of damages. The Sanofi Pasteur Indemnified Entity and GSK Indemnified Entity (depending on which has requested indemnity) shall keep the Participating Member State informed of any developments relating to such Third-Party Claim, including updates in the estimated maximum amount of damages.

**II.6.9.** The Sanofi Pasteur Indemnified Entity and GSK Indemnified Entity (depending on which has requested indemnity shall (i) use commercially reasonable efforts to defend themselves against Third Party Claims and mitigate the liability incurred; and (ii) reasonably cooperate with the Participating Member States and their legal representatives in the investigation and defense of any matter which is the subject of indemnification. The Participating Member States shall have the right to assume and control the defense of Sanofi Pasteur Indemnified Entity and GSK Indemnified Entity against Third Party Claims, using legal

counsel reasonably chosen by the Participating Member States. In such situation, Sanofi Pasteur Indemnified Entity and GSK Indemnified Entity shall be obliged to support the Participating Member States in the defense against Third Party Claims, using their commercially reasonable efforts.

**II.6.10.** The payment of any indemnification required to be made to the Sanofi Pasteur Indemnified Entity and GSK Indemnified Entity (depending on which has requested indemnity) shall be made within sixty (60) calendar days following the date on which such indemnification becomes due as a result of an agreement between the Participating Member States and the Sanofi Pasteur Indemnified Entity and GSK Indemnified Entity, as the case may be, or its amount becomes final and binding upon the relevant indemnified Party and the Participated Member States as a result of an order of a court of competent jurisdiction or other Governmental Authority that will be attached with the request for payment; it being specified that the Participated Member States shall bear interest from this date through and including the date of actual payment at the rate applied by the European Central Bank for its main refinancing operations in euros (the reference rate) plus five points pursuant to the provisions of Article II.17.5 (Interest on late payment). The payment shall be made by wire transfer of immediately available funds to such bank accounts as the received indemnified Party shall designate in writing at least five (5) calendar days prior to the expiration of the sixty (60) day period referred to above.

## **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 Vaccines Order Form to the contractor.

**II.7.3.** 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 *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. CONFIDENTIALITY**

**II.8.1. Temporal scope.** The Commission, the EU Member States and the contractor must treat with confidentiality and in accordance with the provisions below, any *confidential information, material or documents*, prior to and during the term of the APA and for a period of five (5) years.

**II.8.2. Exclusions from Confidential Information or Material:** In this Agreement, Confidential Information or Material shall not include any information (or materials), for which the Receiving Party can prove:

- (a) is or becomes public knowledge through no improper conduct on the part of the Receiving Party, the Receiving Party's affiliates and/or their respective representatives;
- (b) is already lawfully possessed by the Receiving Party and/or the Receiving Party's affiliates or representatives without any obligations of confidentiality or restrictions on use prior to first receiving it from the Disclosing Party; /or
- (c) is obtained subsequently by the Receiving Party and/or the Receiving Party's affiliates or representatives from an unrelated third party without any obligations of confidentiality and such unrelated third party is in lawful possession of such information or materials and not in violation of any contractual or legal obligation to maintain the confidentiality of such information or materials;

Or

- (d) the Disclosing Party expressly agreed to release the Receiving Party from the confidentiality obligation earlier.

**II.8.3. Legally Required Disclosure of Confidential Information or Material.** The Receiving Party and/or the Receiving Party's Affiliates may disclose Confidential Information to the extent required by law or regulation or by legal, judicial, regulatory or administrative process or pursuant to an audit or examination by a regulator or self-regulatory organisation subject to compliance with this Section. If the Receiving Party is so compelled to disclose any Confidential Information, the Receiving Party will provide the Disclosing Party with prompt written notice thereof so that the Disclosing Party may seek a protective order or other appropriate remedy. Subject to its obligations to comply with such subpoenas, court processes or directions, the Receiving Party will reasonably cooperate with the Disclosing Party's counsel in their efforts to obtain a protective order or other similar remedy to accord some form of confidential treatment to any such Confidential Information of the Disclosing Party.

**II.8.4. Limitations on Use of Confidential Information or Material.** The Receiving Party shall treat all Confidential Information as secret and confidential and shall not use, copy or disclose to any third party any Confidential Information of the Disclosing Party (whether before, on or after the date of this Agreement) except as set out in Section **II. 8.5** below.

**II.8.5. Use and disclosures of Confidential Information or Material.** The Receiving Party shall:

- (a) ensure the protection of confidential information or documents with the same level of protection as its own confidential information or documents and in any case with due diligence;

- (b) use and disclose Confidential Information or Material of the Disclosing Party solely to the extent necessary to enable the Receiving Party to exploit the rights granted under this Agreement and/or to perform its obligations under this Agreement; provided, that where any disclosure is required to third parties the Receiving Party shall: (1) only disclose Confidential Information or Material to third parties that have entered into appropriate and legally binding confidentiality and non-use obligations in respect of the Confidential Information or Material disclosed; (2) procure that such third parties do not further disclose or use Confidential Information or Material; and (3) obtain the prior written approval of the other Party (such approval not to be unreasonably withheld or delayed). For the avoidance of doubt, the Receiving Party shall not use the Confidential Information or Material with respect to or for any other program or project other than the Vaccine and the express objectives set forth herein.
- (c) disclose Confidential Information or Material of the Disclosing Party to those of the Receiving Party's Affiliates, officers and employees to whom such disclosure is necessary (and only disclose that part of the Confidential Information or Material which is necessary) to enable the Receiving Party to exploit the rights granted under this Agreement and/or to perform its obligations under this Agreement and provided that the Receiving Party shall remain responsible for procuring that the Receiving Party's Affiliates, officers and employees do not further disclose and/or use the Confidential Information or Material for any other purpose; and
- (d) after giving written notice to the Disclosing Party, disclose any part of the Confidential Information or Material of the Disclosing Party solely to the extent that it is legally required to do so pursuant to an order of a court of competent jurisdiction or other Governmental Authority or otherwise as required by Applicable Law including the laws and regulations applying to any public listing authority, provided that the Receiving Party shall use reasonable endeavors to limit such disclosure and to provide the Disclosing Party with an opportunity to make representations to the relevant court or other Governmental Authority, Regulatory Authority, or allied authority or listing authority.

**II.8.6. Protection of Confidential Information or Material.** The Receiving Party shall at all times maintain documents, materials and other items (including items in electronic form) containing Confidential Information or Material of the Disclosing Party and any copies thereof, in a secure fashion by taking reasonable measures to protect them from theft and unauthorised use and disclosure. Without prejudice to the foregoing, the Receiving Party shall exercise at least the same degree of care to prevent theft and unauthorised disclosure and/or use of the Disclosing Party's Confidential Information or Material as the Receiving Party exercises in respect of its own confidential material of like importance.

**II.8.7. Losses of Confidential Information or Material.** The Receiving Party shall notify the Disclosing Party immediately if the Receiving Party becomes aware of any unauthorised use or disclosure of, or any unauthorised access to or of any theft or loss of any copies of any Confidential Information or Material of the Disclosing Party.

**II.8.8. Survival.** The provisions of this Article II.8 shall continue for so long as either Party has knowledge of any Confidential Information or Material received or derived from the other Party

and shall survive termination or expiry of this Agreement for a period of five (5) years in respect of all Confidential Information.

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## **II.9. PROCESSING OF PERSONAL DATA**

### **II.9.1. Processing of personal data by the Commission**

The sharing of personal data is necessary to support contact with employees and subcontractors in order to collaborate under this Agreement (“In-Scope Personal Data”). The Party receiving the personal data from the other Party shall not process the In-Scope Personal Data for longer than necessary to fulfil the agreed purposes of this Agreement.

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](https://ec.europa.eu/info/data-protection-public-procurement-procedures_en).

The Parties 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 Parties 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.9.2. Processing of personal data by the Parties**

The processing of personal data by the contractor shall meet the requirements of Regulation (EU) 2018/1725 and be processed solely for the following purposes: contact with employees and subcontractors in order to collaborate under the Agreement. Both Parties agree each act as Data Controllers with regards to the Processing of Personal Data they each undertake.

Each Party represents and warrants that it has provided an appropriate data privacy notice and obtained appropriate consent (if legally required) from the data subjects whose In-Scope Personal Data is being shared with the other Party and that such notice and consent is in accordance with Applicable Laws regarding data protection and allows for the desired use of such In-Scope Personal Data. Should a Party learn that it has provided In-Scope Personal Data that may not be shared pursuant to a consent or notice, such Party is responsible for promptly notifying the other Party so that the affected In-Scope Personal Data can be deleted as required.

The Parties agree that the responsibility for complying with any communication addressed to one or both Parties under this Agreement made by a Data Subject exercising one or several of his/her data protection rights under Applicable Laws regarding Data Protection (“Data Subjects Requests”) falls to the Party receiving the Data Subject Request in respect of the personal data

held and under the responsibility of that Party as data controller. The Parties agree to cooperate and provide reasonable assistance as is necessary to each other to enable them to (1) comply with Applicable Laws regarding Data Protection, (2) comply with Subject Requests and (3) respond to any other queries or complaints from data subjects.

In the event a Party suffers a personal data breach, such Party shall ensure it complies with Applicable Laws regarding Data Protection and, if applicable, complies with any obligations to notify Data Protection Supervisory Authority, data subjects or other regulatory bodies as required by Applicable Law regarding the Personal Data Breach.

To the extent the Commission or a Participating Member State suffers a personal data breach that (1) has an impact on the services provided under this Agreement or (2) relates to In-Scope Personal Data the contractor shared with the Commission or EU Member State, the Commission or EU Member State shall promptly notify the contractor about such personal data breach.

## **II.10. SUBCONTRACTING**

**II.10.1.** The contractor may not subcontract and have the APA implemented by third parties beyond the third parties already mentioned in its tender without prior written authorisation.

**II.10.2.** In the case of subcontracting, the contractor remains bound by its contractual obligations and is solely responsible for the *implementation of the APA*.

**II.10.3.** The contractor must ensure that the subcontract does not affect the rights of the Commission and the Participating Member States under this APA.

**II.10.4.** The Commission may request the contractor to replace a subcontractor found to be in a situation provided for in points (d) and (e) of Article II.15.2.

## **II.11. AMENDMENTS**

**II.11.1.** Any amendment to the APA or a Vaccines Order Form must be made in writing before all contractual obligations have been fulfilled. A Vaccines Order Form does not constitute an amendment to the APA.

**II.11.2.** No amendment can make changes to the APA or a Vaccines Order Form that might alter the initial conditions of the procurement procedure or result in unequal treatment of tenderers or contractors.

## **II.12. ASSIGNMENT**

**II.12.1.** The contractor cannot assign any of the rights and obligations arising from the APA, including claims for payments or factoring, without prior written authorisation from the

Commission. In such cases, the contractor must provide the Commission with the identity of the intended assignee.

**II.12.2.** Any right or obligation assigned by the contractor without authorisation is not enforceable against the Commission.

### **II.13. FORCE MAJEURE**

**II.13.1.** A party is not liable for any delay or failure to perform any of its covenants or its obligations under this APA if that delay or failure is a *result events of force Majeure*. If the contractor is unable to fulfil its contractual obligations owing to *events of force majeure*, it has the right to remuneration only for the services actually provided.

**II.13.2.** The affected Party (including the Member States) shall (i) forthwith inform the other Party in writing of the occurrence of the event of *force majeure* and (ii) exert reasonable efforts to eliminate, cure or overcome any such event of *force majeure* and to resume performance hereunder with all possible speed; provided, however, that nothing herein shall require the Party to settle on terms unsatisfactory to such Party any strike or dispute. To the extent that an event of *force majeure* continues for a period in excess of six (6) months, the parties agree to negotiate in good faith either (i) to resolve the event of *force majeure*, if possible, (ii) to extend the time period to resolve, eliminate or overcome such event or (iii) to terminate the APA.

### **II.14. SUSPENSION OF THE IMPLEMENTATION OF THE APA**

#### **II.14.1. Suspension by the contractor**

If the contractor is affected by *force majeure* event, it may suspend the implementation of the APA or performance of a *Vaccines Order Form* for the duration of such *force majeure* event under the terms as set out in Article II.13; it being understood that the time for performance of such obligations shall be extended for a period equal to the duration of such *force majeure* event.

#### **II.14.2. Suspension by the Commission or the Participating Member State**

The Commission or the Participating Member State may suspend the *implementation of the APA* or *performance of a Vaccines Order Form* or any part of it:

- (a) if the procedure for awarding the APA or a Vaccines Order Form or the *implementation of the APA* proves to have been subject to *irregularities or fraud*;
- (b) in order to verify whether the presumed *irregularities or fraud* have actually occurred.

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

The Commission or the Participating Member State in question must *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 Vaccines Order Form under Article II.15.2, e).

The contractor is not entitled to compensation for suspension of any part of the APA or a specific contract.

## **II.15. TERMINATION OF THE APA**

### **II.15.1. Grounds for automatic termination of the APA**

The APA will be automatically terminated in the following circumstances:

- (a) if the Phase I/II clinical trials results are non-satisfactory and do not meet their primary end point in terms of efficacy and safety as defined in section I.6.1.2 or if the regulatory authorization process would prevent the project to be successful; in that case, the contractor notifies the Commission its inability to provide the Adjuvanted Pandemic Vaccine;
- (b) if no Member State enters into a Vaccine Order Form within four (4) weeks after the communication by the Commission of the Purchase Total Amount and the Allocation (see Article I.6.2(ii));
- (c) if the Commission on behalf of the Participating Member States decides not to confirm the Member States interest in purchasing in advance the Adjuvanted Pandemic Vaccine (see Article I.6.2(ii)).

### **II.15.2. Grounds for termination by the Commission**

The Commission may terminate the APA or the Participating Member State any on-going Vaccine Order Form in the following circumstances:

- (a) if the contractor is unable, through its own fault, to obtain any permit, licence or marketing authorisation required for *implementation of the APA*; failure to obtain such permit, licence or marketing authorization because of the non-satisfactory clinical trial results does not qualify as a contractor's fault, but may lead to the automatic termination of the APA (see Article II.15.1 a);
- (b) if the contractor does not implement the APA or perform the Vaccines Order Form in accordance with the terms set out in the APA or the Vaccine Order Forms or is in material breach of another substantial contractual obligation;
- (c) if the contractor or any person that assumes unlimited liability for the debts of the contractor is in one of the situations provided for in points (a) and (b) of Article 136(1) of the Financial Regulation<sup>4</sup>;

<sup>4</sup> 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=>

- (d) if the contractor or any *related person* is in one of the situations provided for in points (c) to (h) of Article 136(1) or to Article 136(2) of the Financial Regulation;
- (e) if the procedure for awarding the APA or the *implementation of the APA* prove to have been subject to *irregularities* or *fraud*;
- (f) if a change to the contractor's legal, financial, technical, organisational or ownership situation is likely to substantially affect the *implementation of the APA* or substantially modify the conditions under which the APA was initially awarded or a change regarding the exclusion situations listed in Article 136 of Regulation (EU) 2018/1046 that calls into question the decision to award the contract;
- (g) in the event of *force majeure* under the conditions as provided in Article II.13.

#### II.15.3. Grounds for termination by the contractor

- (a) The contractor may terminate the APA or any on-going Vaccines Order Form if the Commission or the Participating Member State fail to comply with its obligations, in particular the obligation to provide the information needed for the contractor to implement the APA or a Vaccine Order Form.

(b) .

- (c) The contractor may terminate the APA or any on-going Vaccines Order Form in the event of *force majeure* under the conditions as provided in Article II.13.

#### II.15.4. Procedure for termination

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

The other party has 30 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* its final decision to terminate the APA within 15 days following the date of receipt of the observations. Failing that, the APA will not be terminated.

#### II.15.5. Effects of termination

- (a) *in case of automatic termination of the APA under Article II.15.1*

No liability is incurred by either party in case of automatic termination. As provided for in Articles I.6.1 and I.6.2 (ii), those payments by the Commission or the Participating Member States shall not be refundable except in the situations defined in Articles I.6.1.2. In accordance with terms and conditions defined in Article I.6.1.2. the Non-Committed Portion will be reimbursed within 30 days from the receipt of the Formal Notification by respectively Sanofi and GSK.

The contractor will transfer, upon the Commission's request to be provided within 45 days after the receipt of the Formal Notification, to the Commission, or a third party named by the Commission, any raw materials and primary components not used during this first period and paid for with the Down Payment as well as those raw materials and primary components paid for with the Milestone 1 or Milestone 2 payments (the "Refundable Items"), as provided for in Articles I.6.1.2, I.6.2 (i), I.6.3 and I.6.4. The contractor will also facilitate the discussion of a transfer of reserved capacity with CMOs paid for with the Down Payment 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 by the Commission under Article II.15.2*

The contractor may be liable for damage incurred by the Commission or the Participating Member State as a result of the termination of the APA or a Vaccines Order Form if the damage is a result of a termination in accordance with Article II.15.2 (a) – (f), but not in case of Article II.15.2 (g). The Commission or the Participating Member State may claim compensation for such damage, as allowed by applicable laws.

*(c) in case of termination by the contractor under Article II.15.3*

The Commission or the Participating Member State may be liable for damage incurred by the contractor as a result of the termination of the APA or a Vaccines Order Form if the damage is a result of a termination in accordance with Article II.15.3 (a), [REDACTED]

[REDACTED] The contractor may claim compensation for such damage, as allowed by applicable laws.

The contractor must take all appropriate measures to minimise costs, prevent damage and cancel or reduce its commitments.

Within 60 days of the date of termination, the contractor must submit any report, deliverable or result and any invoice required for services that were provided before the date of termination.

The effects of termination due to the abandonment of the Project by the contractor are set out under Article II.15.3 (b).

## **II.16. INVOICES, VALUE ADDED TAX AND E-INVOICING**

### **II.16.1. Invoices and value added tax**

Invoices must contain the contractor's (or leader's in the case of a joint tender) identification data, the amount, the currency and the date, as well as the APA reference and reference to the Vaccines Order Form.

Invoices must indicate the place of taxation of the contractor (or leader in the case of a joint tender) 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.

For the avoidance of doubt, where legally required, VAT may be charged on doses of the Adjuvanted Pandemic Vaccine under the conditions of national legislation. In such cases, the taxable amount may include the amount paid by the Member State as well as the respective portion of the Down Payment paid by the Commission, as set out in I.6.1.

## **II.17. PAYMENTS AND GUARANTEES**

### **II.17.1. 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.17.2. Currency**

Payments are made in euros.

### **II.17.3. 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.17.4. 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.6 at any time by *notifying* the contractor (or leader in the case of a joint tender) that its invoice cannot be processed. The reasons the Commission or the

Participating Member State in question may cite for not being able to process an invoice are because it does not substantially comply with the invoicing process in the APA.

The Commission or the Participating Member State in question must *notify* the contractor (or leader in the case of joint tender) as soon as possible of any such suspension, giving the reasons for it. In cases b) and c) referred above, the Commission or the Participating Member State in question shall notify the contractor (or leader in case of a joint tender) the time limits to submit additional information or corrections or a new version of the documents or deliverables.

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, including on-the-spot checks, is carried out. Where the suspension period exceeds two months, the contractor (or leader in the case of a joint tender) may request the Commission or the Participating Member State in question to justify the continued suspension.

#### **II.17.5. Interest on late payment**

On expiry of the payment periods specified in Article I.6, 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 as provided for in Article II.17.4 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.17.1.

### **II.18. RECOVERY**

#### **II.18.1. Recovery procedure**

Before recovery, the Commission or the Participating Member State in question must *formally notify* the contractor of its intention to recover the amount it claims, specifying the amount due and the reasons for recovery and inviting the contractor to make any observations within 30 days of receipt.

If no observations have been submitted or if, despite the observations submitted, the Commission or the Participating Member State in question decides to pursue the recovery procedure, it must confirm recovery by formally notifying a debit note to the contractor, specifying the date of payment. The contractor must pay in accordance with the provisions specified in the debit note.

If the contractor does not pay by the due date, the Commission or the Participating Member State in question may, after informing the contractor in writing, recover the amounts due:

- (a) by offsetting them against any amounts owed to the contractor by the Commission or the Participating Member State in question;
- (b) by taking legal action.

#### **II.18.2. Interest on late payment**

If the contractor does not honour the obligation to pay the amount due by the date set by the Commission or the Participating Member State in question, the amount due bears interest at the rate indicated in Article II.17.5. 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.19. CHECKS AND AUDITS**

**II.19.1.** The Commission and the European Anti-Fraud Office may check or require an audit on the *implementation of the APA*. This may be carried out either by OLAF's own staff or by any outside body authorised to do so on its behalf.

Such checks and audits may be initiated at any moment during the provision of the services and up to five years starting from the payment of the balance of the last Vaccines 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.

Audit missions scope applies to the contractor's compliance with applicable regulatory standards insofar as relevant for the implementation of the contract. Audit missions may not be extended to a broader audit of the contractor's activities or the contractors' contractual relations, which do not involve the Commission or the Participating States regarding the purpose of this APA or the Vaccines Order Forms.

**II.19.2.** 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 Vaccines Order Form issued under this APA.

**II.19.3.** 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.19.4.** On the basis of the findings made during the audit, a provisional report is drawn up.

The Commission or its authorised representative must send it to the contractor, who has 30 days following the date of receipt to submit observations. The contractor must receive the final report within 60 days following the expiry of the deadline to submit observations.

On the basis of the final audit findings, the Commission or the Participating Member State in question may recover all or part of the payments made in accordance with Article II.18 and may take any other measures which it considers necessary.

**II.19.5.** 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 services and up to five years starting from the payment of the balance of the last Vaccines Order Form issued under this APA.

**II.19.6.** The Court of Auditors and the European Public Prosecutor's Office established by Council Regulation (EU) 2017/1939<sup>5</sup> ('the EPPO') have the same rights as the Commission, particularly right of access, for the purpose of checks, audits and investigations.

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

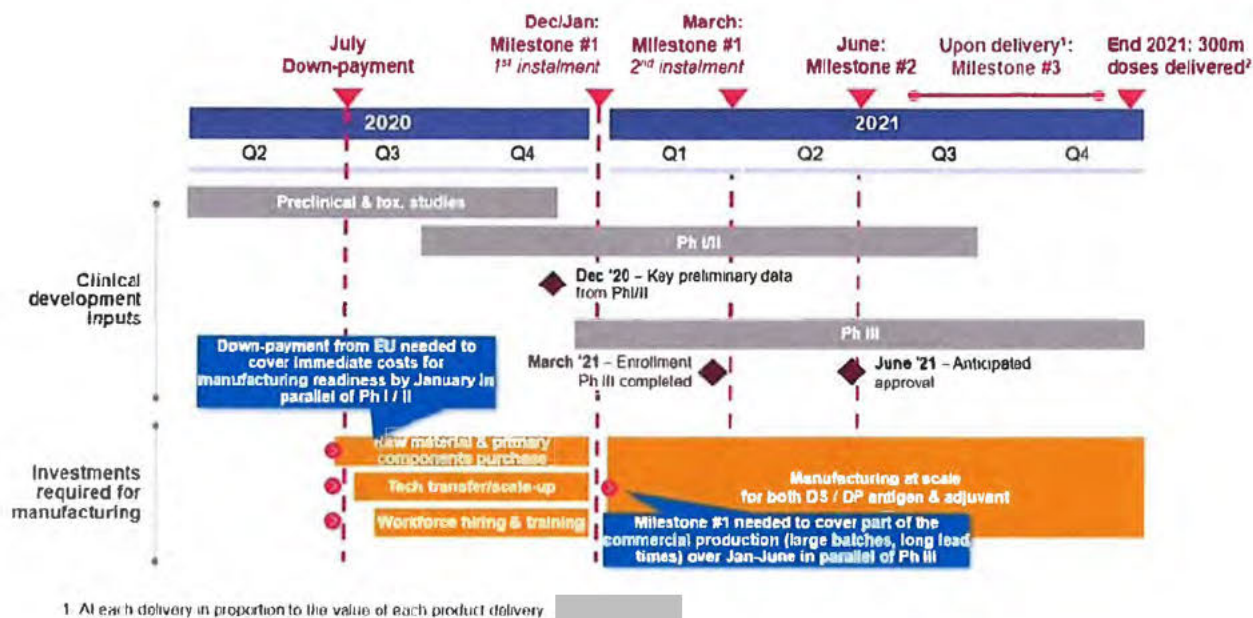


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## Appendix B

### Overview of the overall timeline



pages 45-54 have been deleted as they are fully protected by Article 4(2) first indent of Regulation (EC) No 1049/2001

## Annex II

## VACCINE ORDER FORM

1. [Name of Member State] (the **“Participating Member State”**),

represented for the purposes of signing this specific order form by [*forename, surname, function, department of authorising officer*],

[*VAT intra com registration number*]

And

2. Sanofi and GSK

[*Full official address*]

[*VAT registration number*]

(**“the contractor”**), represented for the purposes of signing this specific order form by

[*forename, surname and function of legal representative,*]

WHEREAS, Sanofi/GSK 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 the ChAdOx1 nCov-19 vaccine in the European Union dated [ ] September, 2020 (the **“APA”**).

WHEREAS, the APA provides that each Member State can execute an Order Form with the information filled in (a **“Vaccines Order Form”**);

WHEREAS, the Participating Member State wishes to order Doses 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 Adjuvanted Pandemic Vaccine allocated to each Participating Member State in a given timeframe, should it manage to develop a safe and effective vaccine.

HAVE AGREED

## Article 1

## Subject matter

1.1 This Order Form is entered into as contemplated by the APA **for the production and purchase of a successful COVID-19 vaccine in the European Union**, signed by the European Commission on behalf and in the name of the Member States and Sanofi and GSK on [*complete date*]. This Order Form is an integral part of the APA and the terms

and conditions of the APA and in particular Article 2.6 thereof are incorporated into this Order Form by reference.

- 1.2 By execution of this Order Form, the undersigned Participating Member State hereby exercises the option to purchase [insert the number of doses] Doses of the Vaccine in accordance with Article I.6.2 of the APA and to perform all obligations imposed on the Participating Member State by the APA with respect to such purchase.

## **Article 2**

### **Price, Additional Costs, method of payment and invoicing**

- 2.1 The Price per dose shall equal the Final Price as determined in Article 1.5.1 and Article I.6.2 of the APA.
- 2.2 The Additional Cost per dose of Adjuvanted Pandemic related post Marketing Studies will be added (with applicable VAT) to the invoices sent to the Participating Member States as determined in section I.6.6 of the APA.
- 2.3 All payments to the contractor under this Order Form 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 1.7 of the APA. Payments for shipments of Doses shall be due and payable within thirty (30) days following invoicing for such Doses.
- 2.4 Invoice in paper format or by electronic systems for payments must contain the following information:
- (i) Name of the concerned Member State
  - (ii) APA and Vaccines Order Form number/reference
  - (iii) Order reference
  - (iv) VAT intracom number of the Member State
- 2.5 The undersigned Participating Member State hereby undertakes to comply with the payment obligations referred to in the APA, including but not limited to the Milestones payments as set forth in Article I.6. of the APA, with respect to the quantities of doses purchased by the undersigned Participating Member State.

## **Article 3**

### **Distribution**

- 3.1 The delivery hub for the Participating Member State is as follows:

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

- 3.2 The contractor shall notify the representative of each Participating Member State in good time prior to such time that the contractor expects doses of the Adjuvanted Pandemic Vaccine to be available. This should be done at least 6 weeks before the start of the first delivery and continue on a rolling basis. Such notification shall include an estimate of the number of doses expected to be available for delivery and the expected dates that such

doses will be available to be shipped to the delivery hub designated by the Participating Member State.

- 3.3** The contractor shall deliver the vaccine doses at the unique point of delivery indicated by the Participating Member State. The delivery will occur CIP (INCOTERMS 2020). For the avoidance of doubt, the Participating Member State will bear the costs of setting up of the delivery hub and the distribution as of the delivery hub.

#### **Article 4**

##### **Communication details; Notices**

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

Participating Member State:

*[Full name]*

*[Function]*

*[Name of Participating Member State]*

*[Full official address]*

E-mail: *[complete]*

The contractor

*[Full name]*

*[Function]*

*[Full official address]*

E-mail: *[complete]*

#### **Article 5**

##### **Liability of Sanofi and GSK**

This is a joint agreement with Sanofi Pasteur and GSK. Both Sanofi Pasteur and GSK enter into direct, tri-partite contractual relations with the Participating Member State within the framework of the APA concluded between the Commission and Sanofi Pasteur and GSK.

In terms of liability, Sanofi Pasteur and GSK are jointly and severally liable for the performance of the APA, including with respect to any financial obligations or liabilities towards the Commission and the Participating Member States. The Adjuvanted Pandemic

Vaccine is composed of Sanofi Pasteur's recombinant COVID- 19 Spike protein antigen and GSK's squalene- based Adjuvant, to be reconstituted at bedside before injection. The Adjuvanted Pandemic Vaccine therefore relies on essential contributions from each of Sanofi Pasteur and GSK which the respective other party does not and cannot deliver. As a consequence, it is agreed that if Sanofi Pasteur and GSK are unable to meet their supply obligation for a committed supply of Adjuvanted Pandemic Vaccine under this APA, any remedy imposed on Sanofi Pasteur and GSK to require performance and supply of the Adjuvanted Pandemic Vaccine will not require (1) GSK to manufacture or supply Sanofi Pasteur's recombinant COVID-19 Spike protein antigen, nor (2) Sanofi Pasteur to manufacture or supply GSK's squalene-based Adjuvant. This is due to the proprietary nature of these respective components and the specific expertise and unique contributions of each of Sanofi Pasteur and GSK for the supply of the Adjuvanted Pandemic Vaccine.

#### **Article 6**

##### **Indemnification**

The Participating Member State acknowledges and agrees to be bound by the provisions of Article II.6 of the APA, with regard to liability towards third parties and the indemnification of Sanofi Pasteur and GSK.

#### **Article 7**

##### **Termination**

This Vaccine Order Form shall terminate concurrent with the APA and with the same effects of termination as set forth in the APA.

#### **Signatures**

For the Member State authority,

*[forename/surname/function]*

signature:

*Done at [place], [date]*

In triplicate in English.

**Annex to the VACCINE ORDER FORM****SHIPMENT ACCEPTANCE PROCEDURE**

Immediately upon delivery of the Adjuvanted Pandemic Vaccine, the Participating Member State shall, through visual examination:

- (i) carefully inspect each shipment of Adjuvanted Pandemic Vaccine with respect to quantities, damages and defects, and, more generally, to the correspondence of the delivered Adjuvanted Pandemic Vaccine with the Vaccine Order Form, the invoice and the relevant documentation accompanying such shipment and;
- (ii) make sure that the cold chain was maintained during the shipment by downloading the temperature of the Adjuvanted Pandemic Vaccine and providing immediately such information to the contractor.

In the event of a major problem (damaged containers, leakage, improper tubing, alteration in the cold chain etc.) during transportation and prior to the delivery of the Adjuvanted Pandemic Vaccine to the Participating Member State, the Participating Member State shall notify immediately upon receipt of the Adjuvanted Pandemic Vaccine, the carrier with such damages, defects, cold chain break or discrepancies and have them specifically noted on the consignment pages of the carrier and have such papers signed by the carrier's driver. In such latter case, the Participating Member State shall within three (3) calendar days transmit a copy of the signed consignment pages to Sanofi Pasteur.

Any failure of the Participating Member State to duly and timely notify Sanofi Pasteur of any defect or damage in any delivery of Adjuvanted Pandemic Vaccine within the delay provided above shall be construed as an irrevocable acceptance of the said delivery of Adjuvanted Pandemic Vaccine. In such a case, the delivery of Adjuvanted Pandemic Vaccine shall be deemed to be of good condition and to conform to the relevant documentation, and the corresponding Vaccine Order Form.

If it is agreed between the Parties after the conduct of further investigation, that if the Adjuvanted Pandemic Vaccine is not in good condition, or does not conform to the relevant documentation or the Vaccine Order Form, Sanofi Pasteur shall replace the damaged or non-conforming Adjuvanted Pandemic Vaccine or shall credit to the Participating Member State an amount equal to the Final price of the Adjuvanted Pandemic Vaccine

**PHARMACEUTICAL REQUIREMENTS**

**Distribution and storage conditions:** The Participating Member State shall respect the European Good Distribution practices (EU GDPs) and have to take measures to avoid abnormal temperatures, humidity and light and to ensure the absence of microorganisms, parasites and worms and cross contamination.

The Participating Member State shall respect all the storage conditions as regard to moisture, temperature and light which are notified by Sanofi Pasteur and/or written on the packaging of the Adjuvanted Pandemic Vaccine or provided for in the Adjuvanted Pandemic Vaccine Union

Marketing Authorization for the Adjuvanted Pandemic Vaccine and in accordance with EU GDPs. The integrity of the initial labeling and packaging must be preserved.

**Product Technical complaints:** Each Product Technical complaint will be notified to Sanofi Pasteur or its Affiliate by the Participating Member State with the defective sample, name of the Adjuvanted Pandemic Vaccine, lot number, quantity, description of the defect. For the purpose of this section, Product Technical complaint shall mean any written electronic or oral communication that alleges deficiencies related to the appearance, labeling, identity, quality, and stability of the Adjuvanted Pandemic Vaccine.

## RECALL

**Recall due to manufacturing:** If at any time or from time to time any regulatory agency having jurisdiction in the country in which the Adjuvanted Pandemic Vaccine is supplied, requires the Participating Member State to recall the Adjuvanted Pandemic Vaccines due to a defect in the manufacture, processing, packaging or labeling of the Adjuvanted Pandemic Vaccines or any other matter whatsoever occurring prior to the transfer of risks in the Adjuvanted Pandemic Vaccines to the Participating Member State, the Participating Member State shall immediately notify Sanofi Pasteur and review with Sanofi Pasteur the proposed manner in which the recall is to be carried out. The recall shall be carried out by the Participating Member State wholly at the cost of Sanofi Pasteur in as expeditious manner as possible and in such a way as to comply with good public health practices and to attempt to cause the least disruption of distribution of the Adjuvanted Pandemic Vaccines in the country and to preserve the goodwill and reputation of the Adjuvanted Pandemic Vaccines and reputation of the Participating Member State and Sanofi Pasteur.

**Reimbursement:** With respect to any recall resulting from a defect in the manufacture of the Adjuvanted Pandemic Vaccines by Sanofi Pasteur or a defect in the packaging or labeling by Sanofi Pasteur of the Adjuvanted Pandemic Vaccines, Sanofi Pasteur shall credit to the Participating Member State an amount equal to the Final price (that shall exclude the costs of transportation and insurance as mentioned in section 1.5.1.) paid by the Participating Member State to Sanofi Pasteur for shipments of Adjuvanted Pandemic Vaccines so recalled. On the contrary, with respect to any recall resulting from handling, stocking or transportation faults by the Participating Member State, the Participating Member State shall not be exempt to its obligation to pay Sanofi Pasteur for the defective Adjuvanted Pandemic Vaccines.

**Recall due to the handling:** If at any time or from time to time any regulatory agency having jurisdiction in the Territory requires the Participating Member State to recall any Adjuvanted Pandemic Vaccines in respect of which risk have passed to the Participating Member State, due to a defect in the Adjuvanted Pandemic Vaccines resulting from the handling, storage or transportation or any other matter whatsoever occurring after delivery of such Adjuvanted Pandemic Vaccines to the Participating Member State, the Participating Member State shall immediately notify Sanofi Pasteur of such event and of the proposed manner in which such recall is to be carried out. The recall shall be carried out by the Participating Member State, wholly at the cost of the Participating Member State, in as expeditious a manner as possible and in such a way as to comply with good public health practices and to attempt to cause the least disruption of distribution of the Adjuvanted Pandemic Vaccines in the country and to preserve

the reputation of the Adjuvanted Pandemic Vaccines, of the Participating Member State and of the Contractor.

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

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