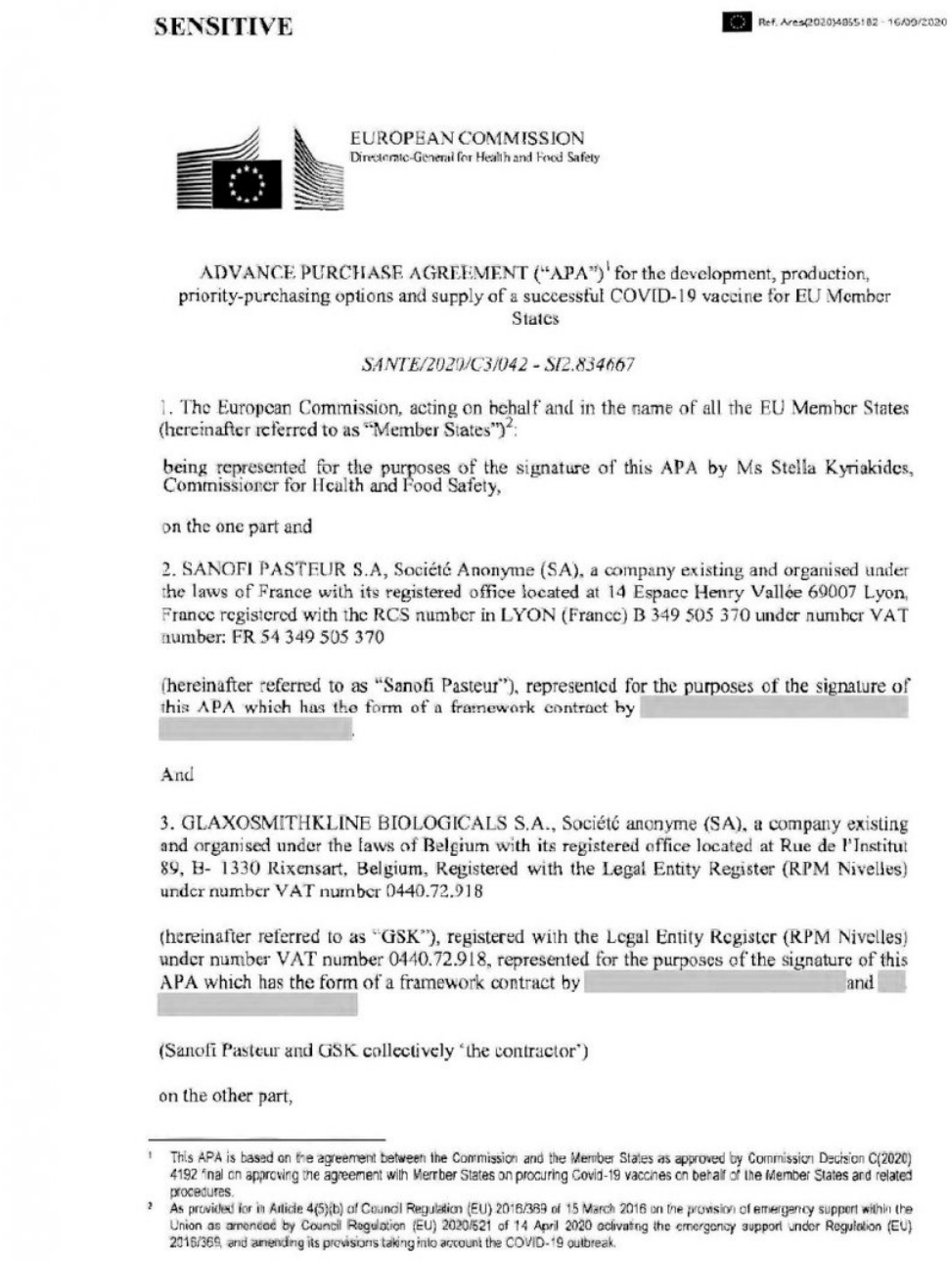
Fac-similé du contrat signé entre Sanofi-GSK et l'Union européenne

Mercredi 17 Février 2021

Pour l'heure, seuls trois contrats de préachat de vaccins, sur huit au total, signés par l'UE avec des multinationales engagées dans la course aux vaccins, sont officiellement accessibles au grand public : CureVac, AstraZeneca et Sanofi-GSK. Ces pages sont extraites du contrat signé entre Sanofi-GSK et l'Union européenne.



SENSITIVE

Ref. Ares(2020)4855182 - 16/09/2020

EUROPEAN COMMISSION
Directorate-General for Health and Food Safety

ADVANCE PURCHASE AGREEMENT ("APA")[1] 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")[2]:

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] and [redacted]

(Sanofi Pasteur and GSK collectively 'the contractor')

on the other part,

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1 This APA is based on the agreement between the Commission and the Member States as approved by Commission Decision C(2020) 4192 final on approving the agreement with Member States on procuring Covid-19 vaccines on behalf of the Member States and related procedures.

2 As provided for in Article 4(5)(b) of Council Regulation (EU) 2016/369 of 15 March 2016 on the provision of emergency support within the Union as amended by Council Regulation (EU) 2020/521 of 14 April 2020 activating the emergency support under Regulation (EU) 2016/369, and amending its provisions taking into account the COVID-19 outbreak.

intention and the detailed terms. In case a Member State does not agree with the conclusion of an APA containing an obligation to acquire vaccine doses or its terms, it has the right to opt out by explicit notification to the ***Commission***. All ***participating Member States*** not having opted out in accordance with the Agreement between the ***Commission*** and the Member States are deemed to have authorised the ***Commission*** to negotiate and conclude an Advance Purchase Agreement with the vaccine manufacturer in their name and on their behalf.

H. This ***APA*** is such an agreement which the ***Commission*** enters into on behalf and in the name of the Member States which have not opted out of the agreement. These ***participating Member States*** will then have an obligation to acquire the ***Product*** and a right to be supplied with the respective ***Product*** doses. While the ***APA*** is legally binding upon those ***participating Member States***, it will be further implemented by means of the conclusion of contracts between the ***participating Member States*** and the ***contractor***. The present APA will be complemented by a ***Vaccine Order Form*** ("Vaccine Order Form") between each of the ***participating Member States*** and the ***contractor.*** A template ***Vaccine Order Form*** for the agreement between each of the ***participating Member States*** and the ***contractor*** is attached in Annex II.

I. The development, production, advance sale and supply of the ***Product*** as per this ***APA*** require significant investments by the ***contractor*** to increase the speed of vaccine research and development and clinical trials and the preparation of the at-scale production capacity along the entire production value chain in the EU required for a rapid deployment of the millions of ***doses*** of the ***Product***. The ***Commission*** as well as the ***participating Member States*** are willing to contribute to financing of those investments in the form of up-front payments.

J. Pursuant to these terms and conditions, access to ***Product doses*** will be allocated to Member States according to a population distribution key, unless a different allocation would be communicated by the ***Commission*** to the ***contractor.*** The up-front payments, paid by the ***Commission***, should be taken into account in equal terms per ***dose*** ordered by the Member States.

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

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

M. The ***participating Member States*** further acknowledge that the ***specification*** of the ***Product*** has not yet been fully determined and still contains target specifications, which are being refined as supporting data emerges. In particular, the vaccination regimen

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
- First doses of Adjuvanted Pandemic Vaccine shipped (pending Union marketing authorisation)
- Union marketing authorisation anticipated

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:

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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.

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 per dose (exclusive of VAT). This is a ceiling price.
This Euro Ceiling Price includes 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 (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 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:
  - ~ experts contributing to the project across Sanofi Pasteur and GSK supporting delivery for Europe:

- 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 , while providing flexibility to the European Commission and the Member States

- 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 Euros (exclusive of VAT).
- 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 , 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 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 while simultaneously conducting Phase III

The Commission will support these costs through a financial contribution of exclusive of VAT (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, propietary 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 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.

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 . 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 exclusive of VAT) per dose of the Adjuvanted Pandemic Vaccine, invoiced to the Participating Members States (the "Additional Costs").

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

I.23.6.

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

I.23.8. The ***participating Member State*** shall be allowed to access the information through an independent expert in the field of damage claims, in particular in the field of public health, subject to an obligation of strict confidentiality. In that case, the ***participating Member State*** shall notify the ***contractor*** in advance of its intention to use an expert and the identity of such expert. The ***contractor*** shall be allowed to object to the use of an expert within 30 days counted from such notification, if it puts forward reasonable grounds on the basis of which the specific expert in question should not be permitted access to such information, such as ***conflict of interest.*** In such case, the ***participating Member State*** shall be allowed to appoint a new independent expert and notify that expert to the ***contractor.***

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

I.23.10. The ***contractor*** shall ensure that the ***Indemnified Persons*** take such commercially reasonable actions to avoid, defend or settle the ***Third Party Claim*** and to mitigate the liability incurred. Within calendar days of the submission by the ***contractor*** of an invoice for such actually incurred Losses (also when they arise during the course of legal proceedings or settlement discussions), the ***participating Member State*** shall provide written confirmation to the ***contractor*** that it will indemnify such losses, subject to the conditions set out in the present indemnification clause, in particular the conditions set above. The ***contractor*** shall keep the ***participating Member State*** reasonably informed in relation to the ***Third Party Claim*** and the ***contractor*** may settle the ***Third Party Claim*** only with the prior consent of the ***participating Member State*** (such consent not to be unreasonably conditioned, withheld or delayed).

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

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 [redacted] 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]

[redacted]

for any Participating Member State to conclude such a contract on the basis of the APA. The APA shall contain a clause to this end.

Article 4: APAs containing an obligation to acquire vaccine doses

Where the Commission intends to conclude, in conformity with the present agreement, an APA containing an obligation to acquire vaccine doses, it shall inform the Participating Member States of such intention and the detailed terms. In case a Participating Member State does not agree with the conclusion of an APA containing an obligation to acquire vaccine doses or its terms, it has the right to opt out by explicit notification to the Commission within 5 working days after the Commission has communicated its intention to conclude the APA. All Participating Member States not having opted out within the period of 5 working days are deemed to have authorised the Commission to negotiate and conclude the APA with the vaccine manufacturer in their name and on their behalf.

Article 5: The legally binding nature of APAs

Once concluded, the terms of the APA shall be legally binding on the Participating Member States, except for those who have exercised their right to opt out.

Article 6: Responsibility and liability

The present Agreement regulates only the division of potential liability and indemnification between the Commission and the Participating Member States. It does not regulate the extent to or the conditions under which potential liability of the vaccine manufacturer may b e taken over or indemnified under the APAs.

The Commission shall be exclusively responsible for the procurement process and the conclusion of APAs including any liability arising out of the conduct of the negotiations.

Participating Member States acquiring a vaccine shall be responsible for the deployment and use of the vaccines under their national vaccination strategies, and shall bear any liability associated with such use and deployment. This shall extend to and include any indemnification of vaccine manufacturers under the terms and conditions of the relevant APA for liability related to the use and deployment of vaccines normally borne by such manufacturer.

Article 7: Obligation not to negotiate separately

By signing the present Agreement, the Participating Member States confirm their participation in the procedure and agree not to launch their own procedures for advance pinchase ofthat vaccine with the same manufacturers.

In case an APA containing an obligation to acquire vaccine doses has been concluded with a specific manufacturer, the Member States having made use of the opt-out provided under the present Agreement can enter into separate negotiations with the same manufacturer after the APA under the present Agreement has been signed.

Annex

2

Initial considerations