FWC number: HERA/2022/NP/0002

EUROPEAN COMMISSION

EUROPEAN HEALTH EMERGENCY PREPAREDNESS AND RESPONSE AUTHORITY

FRAMEWORK CONTRACT FOR SUPPLIES

NUMBER – HERA/2022/NP/0002

The European Union ('the Union'), represented by the European Commission ('the lead *contracting authority*'), and the following *contracting authorities* ('the *contracting authority*' or 'the *contracting authorities*')

Contracting authority	Representative of the participating country for the purpose of signing the framework contract
Kingdom of Belgium (BE)	
Kingdom of Denmark (DK)	
Republic of Ireland (IE)	
Kingdom of Spain (ES)	
French Republic (FR)	
Italian Republic (IT)	
Republic of Cyprus (CY)	

Republic of Latvia (LV)	[redacted]
Grand Duchy of Luxembourg (LU)	[redacted]
Kingdom of the Netherlands (NL)	[redacted]
Republic of Austria (AT)	[redacted]
Portuguese Republic (PT)	[redacted]
Kingdom of Sweden (SE)	[redacted]
Kingdom of Norway (NO)	[redacted]

(collectively, 'the *contracting authority*' or '*contracting authorities*') represented for the purposes of signing this framework *contract* for supplies (hereinafter, "the *contract*" or the "*FWC*") by [redacted] *Director-General of the Health Emergency Preparedness and Response Authority,*

on the one part, and

HIPRA HUMAN HEALTH
HIPRA HUMAN HEALTH, S.L.
Limited Company (*Spanish Sociedad Limitada*)
EUID: ES17010.000261436
Av. La Selva 135 (Girona), Spain
VAT No.: B04998092,

appointed as the leader of the group by the members of the group that submitted the joint tender;

and

LABORATORIOS HIPRA
LABORATORIOS HIPRA, S.A.
Stock Corporation (*Spanish Sociedad Anónima)*
EUID: ES17010.000002911
Av. La Selva 135 (Girona), Spain
VAT No.: A28063675

identified as the manufacturing company of the HIPRA's group.

(collectively 'the *contractor*' or "HIPRA"), represented for the purposes of the signature of this *FWC* by [redacted] HIPRA HUMAN HEALTH,

on the other part,

HAVE AGREED

to the special conditions, the general conditions for supply *contracts* and the following annexes:

- Annex I Tender specifications (reference No Ares (2022)3451440 of 5th of May 2022)
  - Part 1 (Administrative specifications).
  - Part 2 (Technical specification).
- Annex II *contractor*'s tender (reference No Ares(2022)4993536
- Annex III Model for *Vaccine Order form*.
- Annex IV *Delivery schedule* (initial quantities).
- Annex V Reporting template.

which form an integral part of this *FWC*.

This *FWC* sets out:

1. the procedure under which the *contracting authority* may order the supplies of *Vaccine* from the *contractor*;

2. provisions that apply to any *Vaccine Order form* which the *contracting authorities* and *contractor* may conclude under this *contract*;

3. the obligations of the parties during and after the duration of this *contract*.

TABLE OF CONTENT

I. SPECIAL CONDITIONS

I.1. ORDER OF PRIORITY OF PROVISIONS

If there is any conflict between different provisions in this *contract,* 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 *contract*.

b) The provisions set out in the general conditions take precedence over those in the other annexes.

c) The provisions set out in the tender specifications (Annex I) take precedence over those in the tender (Annex II).

d) The provisions set out in the *vaccines order form* (Annex III) take precedence over those in the other annexes.

e) The provisions set out in the *FWC* take precedence over those in the *vaccines order form*.

All documents issued by the *contractor* (end-user agreements, general terms and conditions, etc.) except its tender are held inapplicable, unless explicitly mentioned in the special conditions of this *contract*. In all circumstances, in the event of contradiction between this *FWC* and documents issued by the *contractor*, this *FWC* prevails, regardless of any provision to the contrary in the *contractor*'s documents.

I.2. SUBJECT MATTER

The subject matter of the *FWC* is the supply of up to 250.000.000 (two hundred and fifty million) doses of the *vaccine* once it has received the EU wide (conditional) *marketing authorisation* or national emergency use authorisation.

The total of 250.000.000 doses (maximum quantity) will be distributed to the *contracting authorities* as follows:

a) The initial [redacted] doses (*initial doses*) are to be allocated among the *participating authorities* as determined by the *delivery schedule* in Annex IV;

b) Additionally, this *FWC* gives the opportunity to *contracting authorities* to order, and to the *contractor* to supply, during the term of the *contract,* up to a further [redacted] doses of the vaccine in several additional tranches as determined by the *delivery schedule* attached to each *vaccine order form* (the '*additional doses*').

The *vaccine* supplied under this *FWC* will be labelled in accordance with the applicable EU legislation for *contracting authorities* within EEA and with the *marketing authorisation*.

I.3. ENTRY INTO FORCE AND DURATION

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

I.3.2 The *implementation of the FWC* cannot start before its entry into force.

I.3.3 The *FWC* is concluded for a period starting on the date of the entry into force until

31 December 2023 (the "expiry date"). *Implementation of the FWC* starts from the date of entry into force of the *FWC*.

I.3.4 All *vaccine order forms* must be signed before the date of the expiry of the *contract*. The *FWC* continues to apply to the signed *vaccines order forms* after its expiry. All deliveries must be made no later than 6 months of the *FWC* expiry or extended expiry date.

Notwithstanding any other term of the *contract,* the provisions of the *FWC* which need to survive the expiry of the *FWC* and of the *Vaccines Order forms* (in particular Articles I.4.9, I.11, I.12, II.1, II.3-6, II.13, II.23) will remain in force and effect after the expiry of the *FWC* and of *Vaccines Order forms*.

I.3.5 The *FWC* is renewed automatically once for six (6) months (until 30 June 2024, the "extended expiry date"), unless one of the parties receives *formal notification* to the contrary at least two months before the end of the ongoing duration. Renewal does not change or postpone any existing obligations. The renewal will automatically apply to all parties.

I.3.6 The period of implementation of the *FWC* may be extended, beyond the period of extension or renewal, only with the express written agreement of the parties before the expiration of such period.

I.4. APPOINTMENT OF THE *CONTRACTOR* AND *IMPLEMENTATION OF THE CONTRACT*

I.4.1 The *contracting authority* appoints the *contractor* for a single *FWC*.

I.4.2 This *FWC* is signed by the lead *contracting authority* in the name and on behalf of all the other *contracting authorities*, and it constitutes a bilateral legal commitment between each *contracting authority* and the *contractor*. Each *contracting authority* is responsible, on the terms and conditions agreed in the *FWC*, for *the implementation of the FWC*, through the signature of *vaccines order forms* (see definition under article II.1 and following the model in Annex III).

Either the *contractor*, or its relevant local affiliate on its behalf, may be the party to any such specific *contract*.

I.4.3 If the *contractor* has a complaint about the conclusion, performance or termination of a specific *vaccine order form*, the *contractor* remains bound by its obligations under the *FWC* and other *vaccine order forms*. After receiving, by the *contractor*, EU wide (conditional) *marketing authorisation* or national emergency use authorisation, applicable to the relevant *contracting authority*, the *initial doses* are ordered by *participating authorities*, by sending the *contractor* a *vaccine order form* following the model available in Annex III, corresponding to the amount determined in Annex IV, by e-mail. For *initial doses*, each *contracting authority* shall send the *contractor* the *vaccine order form* within 10 working days from the date the *contractor* received the marketing authorization applicable to this *contracting authority*.

Within 5 calendar days, unless agreed differently by the *contract*ing parties in writing, following the reception of the signed *vaccine order form* by email, the *contractor* must either send back to the *participating authorities* the *vaccine order form* duly signed and dated in paper format and an advanced scanned copy by e-mail or send an explanation of why it cannot accept the order.

Within 10 calendar days following *the reception* of the signed *vaccines order form* in paper format, unless the parties agree differently in writing, the *participating authority* shall sign it and return one copy to the *contractor* or send an explanation of why it cannot sign it.

A repetitive refusal to sign the *vaccine order form* by the *contractor* or to send them back on time may be considered as a breach of the obligations under this *contract,* as referred to in Article II.18.1.b).

If the (conditional) marketing authorisation is delayed beyond [redacted], contracting authorities are entitled to revise the quantities of initial doses they would like to order, as indicated in the delivery schedule (annex IV).

I.4.4 In order to order *additional doses*, the Commission, at the request of one or more of the *contracting authorities*, will determine the demand for *additional doses*.

By the first working day of the last month of each quarter, starting on September 2022, the Commission will communicate to the *contractor* through a notice the willingness to execute the option and indicate the estimated demand for *additional doses* (initial notice) in the following quarter.

Within 10 working days of the Commission's initial notice, the *contractor* shall respond by providing an estimate of available amounts of *vaccine* and indicate *the Delivery schedule* for these doses.

The Commission will communicate to the *contractor* the execution of an option through a formal notice indicating the amount and allocation of *additional doses*, within 10 working days of the receipt of the *contractor*'s reply to the initial notice (final notice).

The *contractor* shall formally confirm the receipt of the final notice immediately after receiving it.

The *additional doses* may be ordered by the *contracting authorities* as of this moment, in accordance with the procedure described in Article I.4.2 and Article I.4.3 of this *FWC*, respecting the amounts and allocation determined in the final notice.

I.4.5 Before the signature of the *vaccine order form*, the *contracting authority* may, fully or partially, withdraw from the ordering of *additional doses*. Each *contracting authority*, shall, within 10 working days after the confirmation by the *contractor* of the final notice, send the *contractor* a *vaccine order form* for the *additional doses* and/or a *notification* on the withdrawal from ordering of the *additional doses.*

I.4.6 The doses must be delivered to the *contracting authorities* at the delivery locations – no more than 5 in total for one *contracting authority*, as indicated in the *vaccine order forms*, according to [redacted] (The place of delivery will be in a JPA country and will be defined for each delivery instalment in the *vaccine order form*).

The deadline for delivery for *initial doses* is determined in Annex IV. For *additional doses*, it is defined in accordance with the *delivery schedule* indicated by the *contractor* under I.4.4.

The *contractor* must notify the *contracting authority* of the exact date of delivery at least 10 working days in advance. Deliveries may be made on any working day during normal working hours at the agreed place of delivery.

I.4.7 The *contracting authority* shall be entitled to re-sell and/or donate any of the doses

of *Vaccine* supplied on a basis of this *FWC* to any other country, not party to this *contract,* this including for donations directly or indirectly via NGOs or the World Health Organisation, or any international public organisation. No resale shall take place at the price higher that the purchase price as agreed in the *contract*.

Any resale of doses of *vaccine* supplied under this *FWC* will be made pursuant to a written agreement among the relevant *contracting authority*, the *contractor* and the recipient country or organisation. This written agreement shall include, in relation to the product concerned by the resale, liability of each party, the assumption of costs between the parties, and conditions of transportation according to the *EU GDP*.

I.4.8 After communication to the *contractor*, the *contracting authorities* will be entitled to donate the purchased doses (including for clinical trials, pre-clinical trials or other studies conducted within the EU territory). The *contractor* is not responsible for the delivery of donation doses, unless agreed differently with the *contracting authority* (e.g.: delivery in the territory of another JPA country).

I.4.9 During the duration of this *FWC*, including the renewal, if applicable, within 30 days after the end of each Quarter, the *contractor* will report to the lead *Contracting authority* on the specific *contract*s signed per each *contracting authority* for the previous Quarter (including on the pricing tier applicable in that given moment), using a template provided in Annex V. The reports are considered as *confidential information* between the *contractor* and the lead *Contracting authority*, in the meaning of Article II.8 of this *FWC*, and this referred Article will apply to such reports.

I.5. PRICE AND MAXIMUM AMOUNT OF THE *FWC*

I.5.1 The maximum amount covering all purchases under the *FWC* [redacted] However, this does not bound the *contracting authorities* to purchase for the maximum amount.

The price of one *vaccine* dose under this *FWC* [redacted] for vials of 10 doses and purchases from 0 to 100.000.000 doses purchased among all *contracting authorities* (discount on prices will apply based on purchased volumes by all *contracting authorities* as indicated in the following table):

[redacted]

The price per dose varies according to the aggregate volume pricing tier described in the table above. When *contracting authorities* will make the first orders under this *FWC* according to the *delivery schedule* in Annex IV, the price will be determined according to the quantities initially requested. If additional orders by any *contracting authority* will result in volumes that fall within a different pricing tier, the new price per dose will be applicable to all *contracting authorities*. The total volume of doses will be an aggregate of all *order forms* signed during the entire implementation of the *FWC* by all *contracting authorities*.

If *contracting authorities* initially order 99.000.000 doses (10 DS vial), the price per dose [redacted] If there is an additional order for 49.000.000 *additional doses* (10 DS vial), the price per dose [redacted], as the aggregate of both *order forms* equals to 148.000.000 doses.

Accordingly, new invoices issued by *contractor* to *the contracting authorities* shall reflect the price per dose of the new volume pricing tier; in addition, for previously paid and outstanding invoices, *the contractor* shall issue to each *contracting authority* a credit reflecting an amount equal to the difference between the price per dose of the new volume pricing tier and the price per dose previously paid or invoiced, multiplied by the number of doses for which such *contracting authority* previously paid or has been invoiced.

If by the end of the *FWC*, the amount of credit owed to a *contracting authority* exceeds the amount due to the *contractor*, the *contractor* will issue a refund to such *contracting authority* in an amount equal to such excess.

For the avoidance of doubt, at the end of the *FWC*, prices per dose and presentation to the different *contracting authorities* will be the same and each *contracting authority* shall have paid the same price per dose and presentation equivalent to the tier corresponding to the total volume of purchased doses by all *contracting authorities* during the period of validity of the *FWC*.

I.5.2 The VAT conditions applicable to the *vaccine orders* will be agreed between *contractor* and the relevant *contracting authorities* in accordance with the applicable law.

I.5.3 Price revision is not applicable to this *contract*.

I.6. PAYMENT ARRANGEMENTS

I.6.1 Pre-financing is not applicable to this *contract*

I.6.2 Interim payment is not applicable to this *contract*.

I.6.3 Payments for delivery instalments.

a) The *contractor* may claim the payment for each delivery instalment, in accordance with Article II.21.

The *contractor* must send an invoice in paper format or by electronic mail, depending on the requirements of the *contracting authority*, for payment due under the *FWC*, as provided for in the tender specifications and accompanied by the proof of delivery of supplies to the delivery place mentioned in the *vaccine order form*.

Each invoice must contain the following information:
- Name of *contracting authority*;

- *Vaccine Order form* reference;
- Product delivered;
- Quantity delivered;
- Delivery reference and date;
- *Contractor* name and bank account.

b) The *contracting authority* must approve the submitted documents or supplies and pay within 60 days from receipt of the invoice.

c) The *contracting authority* may suspend the time limit for payment specified in point b) in accordance with Article II.17.3. Once the suspension is lifted, the *contracting authority* shall give its approval and pay within the remainder of the time-limit indicated in point b) unless it rejects partially or fully the submitted documents or deliverables.

I.7. WARRANTIES

The *contractor* warrants to the Commission and the *contracting authorities* that:

a) all *vaccine* doses supplied under this *FWC* shall at the time of delivery conform with the final specifications for the product as approved in the *marketing authorisation*';

b) all *vaccine* doses supplied under this *FWC* are manufactured in accordance with *EU GMP* and all applicable laws and delivered according to *EU GDP*;

c) all *vaccine* doses under this *FWC* will have, upon delivery:

(i) for deliveries in Q3 and Q4 2022: shelf life of at least [redacted] as per the tender specifications; or

(ii) for any subsequent order, a shelf life of at least [redacted] of the shelf life according to the updated/valid *marketing authorisation* or, when the authorised shelf life is equal or longer than [redacted], the shelf life of the delivered doses shall be at least of [redacted]. As soon as sufficient stability data are generated, the *contractor* will submit several variations to extend the initial shelf life of the *vaccine.* The Contractor shall maintain stability studies until data shows that no extension is possible anymore

I.8. BANK ACCOUNT

Payments must be made to the *contractor*'s back account denominated in euro identified in the invoice.

I.9. COMMUNICATION DETAILS

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

Contracting authority:

Directorate-General Health Emergency Preparedness and Response Authority Unit HERA.3
B-1049 Brussels
Email : [redacted]

Contracting authority	Contact person of the participating country for the purpose of signing the framework contract
Kingdom of Belgium (BE)	
Kingdom of Denmark (DK)	
Republic of Ireland (IE)	
Kingdom of Spain (ES)	
French Republic (FR)	

	[redacted]
Italian Republic (IT)	[redacted]
Republic of Cyprus (CY)	[redacted]
Republic of Latvia (LV)	[redacted]
Grand Duchy of Luxembourg (LU)	[redacted]
Kingdom of the Netherlands (NL)	[redacted]
Republic of Austria (AT)	[redacted]
Portuguese Republic (PT)	[redacted]

	[redacted]
Kingdom of Sweden (SE)	[redacted]
Kingdom of Norway (NO)	[redacted]

Contractor:

HIPRA HUMAN HEALTH
[redacted]
Av. La Selva 135, 17170 Amer (Girona) Spain
[redacted]

I.10. PROCESSING OF PERSONAL DATA

I.10.1 Processing of personal data by the *contracting authority*. For the purpose of Article II.9.1:

a) the data controller is Head of Unit HERA.3 of the European Commission's Directorate-General Health Emergency Preparedness and Response authority;

b) the data protection notice is available at https://ec.europa.eu/info/data-protection-public-procurement-procedures_en.

I.10.2 Processing of personal data by the *contractor*. This clause is not applicable to this *contract*.

I.11. APPLICABLE LAW AND SETTLEMENT OF DISPUTES

I.11.1. Provisions applicable for the *FWC* between the *contractor* and the Commission:

a) The *FWC* is governed by Union law, complemented, where necessary, by the law of Belgium.

b) The courts of Brussels have exclusive jurisdiction over any dispute regarding the interpretation, application or validity of the *vaccines order forms*.

I.11.2. Provisions applicable for the contractual relations between the *contractor* and each *contracting country*:

a) Without prejudice of the direct applicability of EU Regulations and decisions, the *Vaccine Order forms* are governed by the law of the country where the relevant *contracting authority* is established.

b) The courts of the capital city of the country where the relevant *contracting authority* is established have exclusive jurisdiction over any dispute regarding the interpretation, application or validity of the *vaccines order forms*.

I.12. OTHER SPECIAL CONDITIONS

I.12.1 Each Party will maintain records necessary to permit a *recall* of any *Vaccine* delivered under this *FWC*.

I.12.2 Either Party will notify other Party, promptly after notifying the European Medicines Agency of any information which might affect the safety, effectiveness of the *vaccine*, in particular in situation when such *notification* may justify a *recall* of the *vaccine* or any signal detected during the pharmacovigilance and product monitoring programmes.

I.12.3 The decision to initiate a *recall* or to take some other corrective action, if any, with respect to the Product on the territory of any of the *contracting authorities*, will be made by the competent authority(ies) concerned or by *contractor* in agreement with the competent authority(ies).

I.13. *VACCINE* DISTRIBUTE

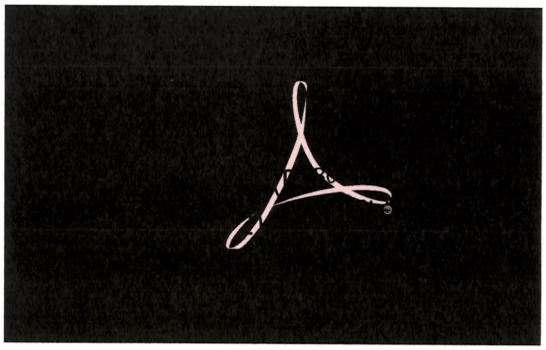
I.14. D PRIOR TO THE EU WIDE (CONDITIONAL) *MARKETING AUTHORISATION*

Pursuant to Articles I.2 and I.3.2, if a national emergency use authorisation to temporarily distribute the *vaccine* before the EU wide (conditional) *marketing authorisation* has been issued in accordance with Directive 2001/83/EC, the *vaccine* can be purchased and supplied prior to the EU wide (conditional) *marketing authorisation* by the European Commission in compliance with Directive 2001/83/EC, notwithstanding anything to the contrary under this *contract*. Specific national regulatory and other requirements may apply to such purchase and supply and to the extent such specific requirements impact the timeline for availability of the *vaccine*, this shall be taken into account under the specific *vaccines order form*.

SIGNATURES:

For the *contractor*,

HIPRA



For the *contracting authority*,

DG HERA

In duplicate in English.

II. GENERAL CONDITIONS FOR THE SUPPLIES *CONTRACT*

II.1. DEFINITIONS

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

'**Additional doses**' has the meaning set forth in Article I.2.;

'Back office': the internal system(s) used by the parties to process electronic invoices;

'Breach of obligations': failure by the *contractor* to fulfil one or more of its *contract*ual obligations.

'Confidential information or document': any information or document received by either party from the other or accessed by either party in the context of the *implementation of the Contract,* that any of the parties has identified in writing as confidential. The technical, scientific and commercial sections included in Annex II of this *Contract,* as well as the unit prices and any other pricing info included in Article I.5 of this *FWC*, or in any Annexes of this *FWC* (except the total value of this *FWC*) are considered confidential. *Confidential information* may not include information that its owner has made publicly available without any breach;

'Conflict of interest': a situation where the impartial and objective *implementation of the FWC* 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 *contracting authority* or any third party related to the subject matter of the *Contract*;

'*Delivery schedule*': the quantities and *delivery schedule* attached to each *Vaccine Order form* pursuant to the terms of the *FWC*, that specifies the quantities of *Vaccine* Doses to be delivered to the relevant *contracting authority* under such *Vaccine Order form*, including the dates of delivery, as may be updated from time to time by an agreement of the parties. The *Delivery schedule* for *initial doses*, as defined in Article I.2 of this *FWC*, forms Annex IV of the *FWC*

'EDI message' (electronic data interchange): a message created and exchanged through the electronic transfer, from computer to computer, of commercial and administrative data using an agreed standard;

'e-PRIOR': the service-oriented communication platform that provides a series of web services and allows the exchange of standardised electronic messages and documents between the parties. This is done either through web services, with a machine-to-machine connection between the parties' *back office* systems (*EDI messages*), or through a web application (the *supplier portal*). The Platform may be used to exchange electronic documents (e-documents) such as electronic *requests for supplies*, electronic specific *contracts*, and electronic delivery of the certificate of conformity or electronic invoices between the parties;

'Force majeure': any unforeseeable, exceptional situation or event beyond the control of the parties that prevents either of them from fulfilling any of their obligations under the *Contract*. The situation or event must not be attributable to error or negligence on the part of the parties or on the part of the sub*contractor*s and must prove to be inevitable despite their exercising due diligence. Defaults, defects in equipment or material or delays in making them available, labour disputes, strikes and financial difficulties may not be

invoked as *force majeure*, unless they stem directly from a relevant case 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;

'**Good Distribution Practice / EU GDP**': all applicable Good Distribution Practices, as determined in accordance with applicable provisions of Directive 2001/83/EC, current and in force at the applicable time, including: the Guidelines of 5 November 2013 on Good Distribution Practice of medicinal products for human use (2013/C 343/01); and Guidelines of 19 March 2015 on principles of Good Distribution Practice of active substances for medicinal products for human use (2015/C 95/01) and the relevant applicable laws in any relevant country, each as may be amended and applicable from time to time;

'**Good Manufacturing Practice / EU GMP**' means the current practices for manufacture medicinal products set up in the Directive 2001/83/EC, as last amended, Directive 2017/1572 and guidelines published on a basis of Article 47 of Directive 2001/83/EC in the EudraLex Volume 4 of the Rules Governing Medicinal Products of Human and Veterinary Use;

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

'**Gross negligence**' means "*faute lourde*" under Belgian law.

'Implementation of the *contract*': the execution of tasks and delivery of the purchased supplies by the *contractor* to the *contracting authority*;

'**Initial doses**' has the meaning set forth in Article I.2.

"Indirect Damages" or **"Consequential Damages"** are, but not limited to, financial or commercial losses, loss of profits, increase of general costs, loss of expected profits, capital or clients and similar non direct or unforeseeable consequences. Article 1150 of the Belgian Civil Code (BCC) says that a party can only be liable for "*dommages prévisibles*" and the Article 1151 BCC says that a party can only be liable for damages resulting directly "*qui est une suite immédiate et directe de l'inexécution*".

'Interface control document': the guideline document which lays down the technical specifications, message standards, security standards, checks of syntax and semantics, etc. to facilitate machine-to-machine connection. This document is updated on a regular basis;

'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.

'**Participating authorities**': *Contracting authorities* purchasing *initial doses.*

'**Marketing authorisation'**: the approval under the relevant provisions of Regulation (EC) 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, by the European Commission necessary for placing on the market of the *vaccine* in the territory of the European Union, including conditional *marketing authorisation* in accordance with Article 14a of Regulation (EC) 726/2004 and as amended.

'Non-indemnifiable Loss': Loss, which a *Contracting authority* is legally prohibited from indemnifying, pursuant to national or Union Law.

'Notification' (or 'notify'): form of communication between the parties made in writing including by electronic means;

'Order form': a simplified form of specific contract by which the *contracting authority* orders supplies under this *FWC*. Once signed by both parties, the *Order form* can only be modified by a mutual agreement between the relevant contracting authority and the contractor on terms agreed in the *FWC*. An exception can be the case, where a unilateral modification by one Party, to the *Order form*, is foreseen in this *FWC*, e.g. such as a termination right(s). *Order form*s cannot contradict the terms of the *FWC*

'Personnel': persons employed directly or indirectly or *contract*ed by the *contractor* to perform the *Contract*;

'Professional conflicting interest': a situation in which the *contractor*'s previous or ongoing professional activities affect its capacity to perform the *FWC* to an appropriate quality standard.

'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*;

'Supplier portal': the *e-PRIOR* portal, which allows the *contractor* to exchange electronic business documents, such as invoices, through a graphical user interface;

'**Vaccine**' the finished package form of the *contractor vaccine* against COVID-19 as well as any changes to the products following the initial *marketing authorisation*, including any improved versions of that *vaccine* or any adapted version for the purpose of addressing mutations or variants of SARS-CoV-2 virus and/or any new formulations.

'**Recall**' has the meaning set forth in the *EU GMP.*

'**Wilful misconduct**' means conduct which (i) constitutes an intentional act aimed at achieving a wrongful purpose, (ii) occurs in the absence of a legal or factual justification, and (iii) occurs in disregard of a known or obvious risk of causing harm.

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

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

appointed as leader of the group.

II.3. SEVERABILITY

Each provision of this *FWC* 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 *contract*. This does not affect the legality, validity or enforceability of any other provisions of the *contract,* 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 *FWC* must be interpreted as if it had contained the substitute provision as from its entry into force.

II.4. DELIVERY OF SUPPLIES

II.4.1 The *contractor* must comply with the minimum requirements provided for in the tender specifications. This includes compliance with applicable obligations under environmental, social and labour law established by Union law, national law and collective agreements or by the international environmental, social and labour law provisions listed in Annex X to Directive 2014/24/EU, compliance with data protection obligations resulting from Regulation (EU) 2016/679 and Regulation (EU) 2018/1725; and Regulation (EU, Euratom) 2018/1046[1] 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.

II.4.2 All periods specified in the *FWC* are calculated in calendar days, unless otherwise specified.

II.4.3 Delivery:

a) Time allowed for delivery. The time allowed for delivery is calculated in accordance with Article I.4 and indicated in the *Delivery schedule*.

b) Date, time and place of delivery. The relevant *contracting authority* must be notified in writing of the exact date of delivery within the period indicated in Article I.4. All deliveries must be made at the agreed place of delivery during the hours indicated in Article I.4.

   The *contractor* must bear the costs and risks involved in delivering the supplies to the place of delivery as agreed in Article I.4.6.

c) Proof of delivery. Each delivery instalment must be accompanied by a consignment note in duplicate, duly signed and dated by the *contractor* or its carrier, giving the *FWC* number and particulars of the supplies delivered, and confirming the compliance with conditions required by good distribution practice, necessary to ensure the consistent quality of the *vaccine*. One copy of the consignment note must be countersigned by the *contracting authority* and returned to the *contractor* or to its carrier.

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1544791836334&uri=CELEX:32018R1046

Signature of the consignment note by the *contracting authorities* simply an acknowledgment of the fact that that the delivery took place and in no way implies conformity of the supplies with the *Contract*.

II.4.4 Conformity of the supplies delivered. The *vaccine* delivered by the *contractor* to the *contracting authority* must be in conformity in quantity, quality, price and packaging with the *FWC* and the relevant *vaccines order form*.

Contractor warrants that the *Vaccine* supplied under each *Vaccine Order form* shall:

a) meet the specifications of the relevant Authorisation in the jurisdiction of the relevant *contracting authority* who is the party to such specific *Contract,* as applicable;

b) be manufactured in accordance with *EU GMP*; and

c) be distributed in accordance with *EU GDP* until the point delivery to the relevant *contracting authority*.

Conformity of the supplies delivered must be evidenced by the signature of a certificate to this effect by the *contracting authority* no later than one month after the date of delivery, unless otherwise specified in the special conditions or in the tender specifications.

Conformity must be declared only where the conditions laid down in the *FWC* are satisfied and the supplies conform to the tender specifications.

If, for reasons attributable to the *contractor*, the *contracting authority* is unable to accept the supplies, the *contractor* must be notified in writing at the latest by the deadline for conformity.

II.4.5 Remedies. If a *contracting authority* considers that any delivery instalment supplied by *contractor* does not comply with the *Contract,* in particular with the Article I.7, and Article II.4.4, the following procedure applies:

a) such *contracting authority* will give *contractor* written notice of such alleged non-compliance including the reasons therefor, in reasonable detail including the nature and basis, and any other relevant information, and, if requested by *contractor*, will provide sufficient samples of such *Vaccine* to *contractor* for confirmatory testing:

   (i) in the case of non-compliance readily discoverable by a customary inspection of such *Vaccine* on delivery, within five (5) working days after delivery; or

   (ii) in the case of non-compliance which cannot be readily discoverable by a customary inspection of such *Vaccine* following delivery, within two (2) working days after such non-compliance becomes known, or might reasonably be expected to become known, to such *contracting authority*, but in any event not later than sixty (60) days after delivery;

b) *Contractor* will evaluate such *Vaccine* (including testing of samples provided by such *contracting authority*, if applicable) and notify such *contracting authority* within twenty (20) working days after receipt of such *contracting authority*'s written notice. If *contractor* notifies such *contracting authority* that it disagrees that there is a non-compliance and such *contracting authority* does not accept *contractor*'s position, *contractor* and such *contracting authority* will use their commercially reasonable efforts to resolve the issue amicably. If such disagreement

is not resolved within five (5) working days after one party notifies the other party in writing of the disagreement and requesting resolution, *contractor* and such *contracting authority* will refer the dispute for final settlement to an independent testing laboratory mutually acceptable to *contractor* and such *contracting authority*. The costs of the testing laboratory will be borne by such *contracting authority* or by *contractor*, depending upon whether a non-compliance is established, or not, by the independent testing laboratory, and in case of non-compliance which party is deemed responsible for the non-compliance as determined in the final written conclusion of the testing laboratory with respect to the root cause of the non-compliant *Vaccine*; and

c) if a non-compliance is deemed attributable to *contractor* (either upon agreement of the parties or final determination pursuant to subsection (b) above as applicable), *contractor* shall, at its sole discretion, within twenty (20) working days either (i) supply such *contracting authority* with an equivalent replacement quantity of conforming *vaccine*; or (ii) issue a credit note to refund such *contracting authority* the amounts paid by such *contracting authority* relating to the nonconforming Product in question.

In case of non-compliance by the *contractor* with a *Delivery schedule*, Article II.15 will apply.

II.4.6 The supplies must be packaged in a way that facilitates storage in the conditions required to maintain the quality of the products.

Each shipment must be clearly labelled with the following information:
- name of *contracting authority* and address for delivery;
- name of *contractor*;
- description of contents;
- date of delivery;
- number and date of *Contract*;
- EC code number of article, when applicable.

II.4.7 The *contractor* must immediately inform the *contracting authority* 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 FWC must:

a) be made in writing in paper or electronic format in the language of the *contract*;

b) bear the *FWC* number;

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

d) be sent by mail, email or, for the documents specified in the special conditions, via *e- PRIOR*.

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 *FWC* 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 *contracting authority* is deemed to have been received by the *contracting authority* 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.5.3 Submission of e-documents via *e-PRIOR*. If provided for in the special conditions, the exchange of electronic documents (e-documents) such as invoices between the parties is automated through the use of the *e-PRIOR* platform. This platform provides two possibilities for such exchanges: either through web services (machine-to-machine connection) or through a web application (the *supplier portal*).

The *contracting authority* takes the necessary measures to implement and maintain electronic systems that enable the *supplier portal* to be used effectively.

In the case of machine-to-machine connection, a direct connection is established between the parties' *back offices*. In this case, the parties take the measures necessary on their side to implement and maintain electronic systems that enable the machine-to-machine connection to be used effectively. The electronic systems are specified in the *interface control document*. The *contractor* (or leader in the case of a joint tender) must take the necessary technical measures to set up a machine-to-machine connection and at its own cost.

If communication via the *supplier portal* or via the web services (machine-to-machine connection) is hindered by factors beyond the control of one party, it must *notify* the other immediately and the parties must take the necessary measures to restore this communication.

If it is impossible to restore the communication within two working days, one party must *notify* the other that alternative means of communication specified in Article II.5.1 will be used until the *supplier portal* or the machine-to-machine connection is restored.

When a change in the *interface control document* requires adaptations, the *contractor* (or leader in the case of a joint tender) has up to six months from receipt of the *notification* to implement this change. This period can be shortened by mutual agreement of the parties. This period does not apply to urgent measures required by the security policy of the *contracting authority* to ensure integrity, confidentiality and non-repudiation of information and the availability of *e-PRIOR*, which must be applied immediately.

II.5.4 Validity and date of e-documents. The parties agree that any e-document, including related attachments exchanged via *e-PRIOR*:

a) is considered as equivalent to a paper document;

b) is deemed to be the original of the document;

c) is legally binding on the parties once an *e-PRIOR* authorised person has performed the 'sign' action in *e-PRIOR* and has full legal effect; and

d) constitutes evidence of the information contained in it and is admissible as evidence in judicial proceedings.

The parties expressly waive any rights to contest the validity of such a document solely on the grounds that communications between the parties occurred through *e-PRIOR* or that the document has been signed through *e-PRIOR*. If a direct connection is established between the parties' *back offices* to allow electronic transfer of documents, the parties agree that an e- document, sent as mentioned in the *interface control document*, qualifies as an *EDI message*.

If the e-document is dispatched through the *supplier portal*, it is deemed to have been legally issued or sent when the *contractor* (or leader in the case of a joint tender) is able to successfully submit the e-document without any error messages. The generated PDF and XML document for the e-document are considered as a proof of receipt by the *contracting authority*.

In the event that an e-document is dispatched using a direct connection established between the parties' *back offices*, the e-document is deemed to have been legally issued or sent when its status is 'received' as defined in the *interface control document*.

When using the *supplier portal*, the *contractor* (or leader in the case of a joint tender) can download the PDF or XML message for each e-document for one year after submission. After this period, copies of the e-documents are no longer available for automatic download from the *supplier portal*.

II.5.5 Authorised persons in *e-PRIOR*. The *contractor* submits a request for each person who needs to be assigned the role of 'user' in *e-PRIOR*. These persons are identified by means of the European Communication Authentication Service (ECAS) and authorised to access and perform actions in *e-PRIOR* within the permissions of the user roles that the *contracting authority* has assigned to them.

User roles enabling these *e-PRIOR* authorised persons to sign legally binding documents such as specific tenders or specific *contracts* are granted only upon submission of supporting documents proving that the authorised person is empowered to act as a legal representative of the *contractor*.

II.6 LIABILITY

II.6.1 General liability clauses Without prejudice to the terms of Articles II.6.6 - Article II.6.11 of this *FWC*, the *contracting authority* is not liable for any other damage or loss caused by the *contractor*, including any damage or loss to third parties, during or as a consequence of i*mplementation of the contract FWC.*

If required by the relevant applicable legislation, the *contractor* must take out an insurance policy against risks and damage or loss relating to the *implementation of the contract*. It must also take out supplementary insurance as reasonably required by

standard practice in the industry. Upon request, the *contractor* must provide evidence of insurance coverage to the *contracting authority*.

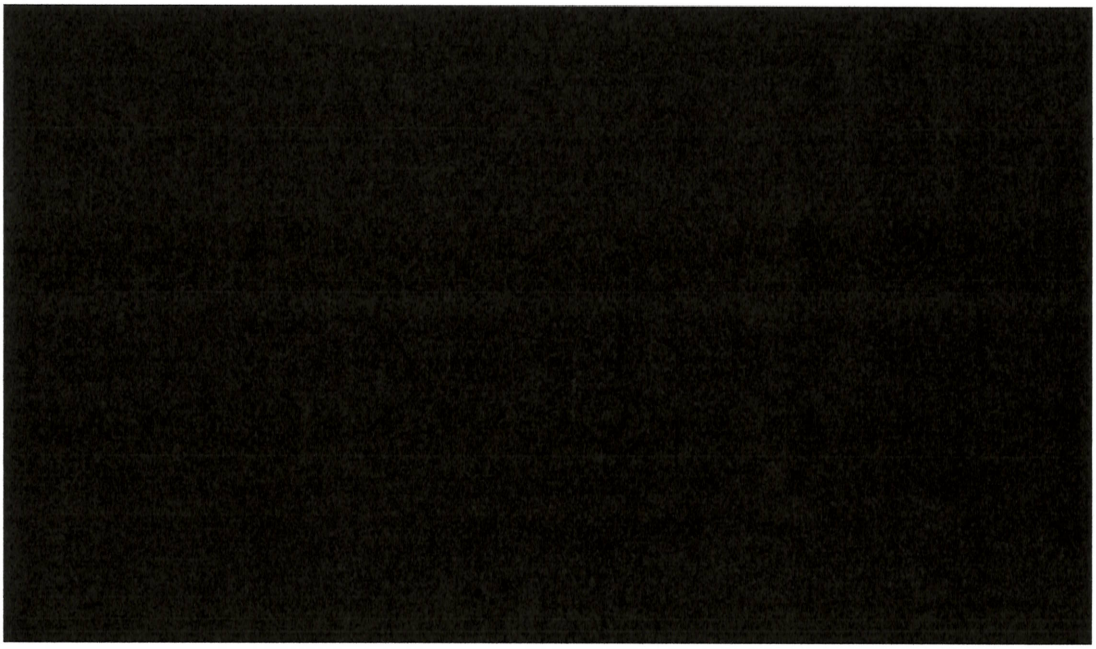
II.6.2 Including in the cases as stated in the Article II.4.5 above (*remedies*), the *contractor* is liable for any loss or damage (excluding *indirect or consequential damages*) caused to the *contracting authority* during or as a consequence of *implementation of the contract,* including in the event of subcontracting, but, towards each *contracting authority*, only to an amount not exceeding the total amount of the specific *contract*s (*vaccine* orders), signed between the *contractor*, and this *contracting authority*. However, if the damage or loss is caused by the *gross negligence* or *wilful misconduct* of the *contractor* or of its *personnel* or sub*contractor*s, as well as in the case of an action brought against the *contracting authority* by a third party for breach of its intellectual property rights, the *contractor* is liable for the whole amount of the damage or loss.

II.6.3 If a third party brings any action against the *contracting authority* in connection with the *implementation of the contract,* the *contractor* must reasonably assist the *contracting authority* in the legal proceedings, including by intervening in support of the *contracting authority* upon request.

If the *contracting authority*'s liability towards the third party is established and that such liability is caused by the *contractor* during or as a consequence of the *implementation of the contract,* Article II.6.2 and Article II.6.4 will apply.

II.6.4 If the *contractor* is composed of two or more economic operators (i.e. who submitted a joint tender), they are all jointly and severally liable to the *contracting authority* for the *implementation of the contract*.

II.6.5 The *contracting authority* is not liable for any loss or damage caused to the *contractor* during or as a consequence of *implementation of the contract,* unless: (a) the loss or damage was caused by *wilful misconduct* or *gross negligence* of the *contracting authority*; and (b) the loss or damage was caused by a breach by the *contracting authority* of the terms of a *vaccine* order accepted by both signatory parties.



II.6.7 Such indemnification will only be available to the *Indemnified Persons* if such *Losses* arise with respect to the *initial doses* and *additional doses* supplied during the

duration of this Framework *contract* as laid down in Article I.3. Indemnification will not be available to the extent that (i) the *Losses* result from the *wilful misconduct* or *gross negligence,* as defined in Art. I.1 of the General Conditions of this *FWC*, of such *Indemnified Persons*; or (ii) the *Losses* result from a defect in the *Product* which occurred because of the *Indemnified Persons* failure to comply with the terms of the (both conditional and definitive) *Marketing authorisation*, applicable EU GMP, or with the obligations listed in Annex II of Regulation 726/2004, pharmacovigilance activities; or (iii) the *Losses* qualify as *Non-Indemnifiable Loss*.

II.6.8 Assistance. In case liability has been incurred by the *Indemnified Persons* for *Losses* defined in Article II.6.6, the *contractor* shall give the *Participating Contracting authority* in question, or an independent expert as referred to in Article II.6.9, access to all information reasonably necessary for the *Participating Contracting authority* to indemnify the *Indemnified Persons* and to verify whether the conditions pursuant to Articles II.6.6 and II.6.7 are fulfilled.

II.6.9 Access to Information. The *Participating Contracting authority* shall be allowed to access the information as referred to in Article II.6.8 through an independent expert in the field of damages claims, in particular in the field of public health; provided that such independent expert is bound by a confidentiality agreement reasonably acceptable to the *contractor*. In that case, the *Participating Contracting authority* 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 ten (10) 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 Contracting authority* shall be allowed to appoint a new independent expert and notify that expert to the *contractor.* If the *contractor* also refuses that expert, the *Participating Contracting authority* is entitled to seek a court appointed expert, in accordance with Article I.11.2.

II.6.10 Procedure. The *contractor* shall promptly inform the relevant *Participating Contracting authority* of any damages claim brought against any of the *Indemnified Persons* before the courts of that *Participating Contracting authority* or other forum ("***Third Party Claim***"), stating the nature and basis of the damages claim in question and the maximum estimated amount of damages; provided that any failure or delay in providing such written notice will not relieve the *Participating Contracting authority* of its indemnification obligations except to the extent the *Participating Contracting authority* can demonstrate actual prejudice due to such delay or lack of notice. The *contractor* shall keep the *Participating Contracting authority* informed of any material developments relating to such *Third Party Claim*, including updates in the estimated maximum amount of damages.

II.6.11 Obligations. The *contractor* shall ensure that the *Indemnified Persons (i)* use commercially reasonable efforts to defend themselves against *Third Party Claims* and mitigate the liability incurred; and (ii) fully reasonably cooperate with the *Participating Contracting authority* and their legal representatives in the investigation and defence of any matter which is the subject of indemnification. The *Indemnified Persons* shall only be allowed to settle any *Third Party Claim* with the prior written consent of the *Participating Member State* in question, such consent not being unreasonably withheld. Upon written notice to the *Indemnified Persons,* the *Participating Contracting authority* shall have the right to assume and control the defence of the *Indemnified Persons* against *Third Party Claims*, using legal counsel reasonably chosen by the *Participating Contracting authority*. The *contractor* shall be obliged to support the *Participating Contracting authority* in the defence against *Third Party Claims*, using its reasonable efforts. If the *Participating Contracting authority* assumes the defence of a *Third Party Claim*, the *Participating Contracting authority* shall ensure that any settlement does not include a statement as to or an admission of fault, culpability or a failure to act by or on behalf of the *Indemnified Persons* or require that that the *Indemnified Persons* take or refrain from taking any action.

II.7 *CONFLICT OF INTERESTS* 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 *contracting authority* in writing as soon as possible of any situation that could constitute a *conflict of interest* or a *professional conflicting interest* during the *performance of the contract*. The *contractor* must immediately take action to rectify the situation.

The *contracting authority* 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;

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 *performance of the contract,* including sub*contractor*s.

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 Each *contracting authority* and the *contractor* must treat with confidentiality any information or documents, in any format, disclosed in writing or orally relating to the *implementation of the FWC* and identified in writing as confidential.

II.8.2 Each party must:

a) not use *confidential information or documents* for any purpose other than to perform its obligations under the *FWC* without the prior written agreement of the other party;

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

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

II.8.3 The confidentiality obligation set out in this Article are binding on the *contracting authority* and the *contractor* during the performance of the *FWC* and for as long as the information or documents remain confidential unless:

a) the disclosing party agrees to release the receiving party from the confidentiality obligation earlier;

b) the *confidential information or documents* become public through other means than in breach of the confidentiality obligation

c) the applicable law requires the disclosure of the *confidential information or documents*.

II.8.4 The *contractor* must obtain from any natural person with the power to represent it

or take decisions on its behalf, as well as from third parties involved in the performance of the *contract,* a commitment that they will comply with this Article .At the request of the *contracting authority*, the *contractor* must provide a document providing evidence of this commitment.

II.9 PROCESSING OF PERSONAL DATA

II.9.1 Processing of personal data by the *contracting authority*. Any personal data included in or relating to the *contract,* 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 *FWC* by the data controller.

The contractor or any other person whose personal data is processed by the data controller in relation to this FWC has specific rights as a data subject under Chapter III (Articles 14-25) of Regulation (EU) 2018/1725, in particular the right to access, rectify or erase their personal data and the right to restrict or, where applicable, the right to object to processing or the right to data portability.

Should the contractor or any other person whose personal data is processed in relation to this FWC 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.

Details concerning the processing of personal data are available in the data protection notice referred to in Article I.9.

II.9.2 Processing of personal data by the *contractor*. The processing of personal data by the *contractor* shall meet the requirements of Regulation (EU) 2018/1725 and be processed solely for the purposes set out by the controller.

The *contractor* shall assist the data controller for the fulfilment of the controller's obligation to respond to requests for exercising rights of person whose personal data is processed in relation to this *FWC* as laid down in Chapter III (Articles 14-25) of Regulation (EU) 2018/1725. The *contractor* shall inform without delay the controller about such requests.

The *contractor* may act only on documented written instructions and under the supervision of the data controller, in particular with regard to the purposes of the processing, the categories of data that may be processed, the recipients of the data and the means by which the data subject may exercise its rights.

The *contractor* shall grant *personnel* access to the data to the extent strictly necessary for the implementation, management and monitoring of the *contract*. The *contractor* must ensure that *personnel* authorised to process personal data has committed itself to confidentiality or is under appropriate statutory obligation of confidentiality in accordance with the provisions of Article II.8.

The *contractor* shall adopt appropriate technical and organisational security measures, giving due regard to the risks inherent in the processing and to the nature, scope, context and purposes of processing, in order to ensure, in particular, as appropriate:

a) the pseudonymisation and encryption of personal data;

b) the ability to ensure the ongoing confidentiality, integrity, availability and resilience of processing systems and services;

c) the ability to restore the availability and access to personal data in a timely manner in the event of a physical or technical incident;

d) a process for regularly testing, assessing and evaluating the effectiveness of technical and organisational measures for ensuring the security of the processing;

e) measures to protect personal data from accidental or unlawful destruction, loss, alteration, unauthorised disclosure of or access to personal data transmitted, stored or otherwise processed.

The *contractor* shall notify relevant personal data breaches to the controller without undue delay and at the latest within 48 hours after the *contractor* becomes aware of the breach. In such cases, the *contractor* shall provide the controller with at least the following information:

a) nature of the personal data breach including where possible, the categories and approximate number of data subjects concerned, and the categories and approximate number of personal data records concerned;

b) likely consequences of the breach;

c) measures taken or proposed to be taken to address the breach, including, where appropriate, measures to mitigate its possible adverse effects.

The *contractor* shall immediately inform the data controller if, in its opinion, an instruction infringes Regulation (EU) 2018/1725, Regulation (EU) 2016/679, or other Union or Member State data protection provisions as referred to in the tender specifications.

The *contractor* shall assist the controller for the fulfilment of its obligations pursuant to Article 33 to 41 under Regulation (EU) 2018/1725 to:

a) ensure compliance with its data protection obligations regarding the security of the processing, and the confidentiality of electronic communications and directories of users;

b) notify a personal data breach to the European Data Protection Supervisor;

c) communicate a personal data breach without undue delay to the data subject, where applicable;

d) carry out data protection impact assessments and prior consultations as necessary.

The *contractor* shall maintain a record of all data processing operations carried on behalf of the controller, transfers of personal data, security breaches, responses to requests for exercising rights of people whose personal data is processed and requests for access to personal data by third parties.

The *contracting authority* is subject to Protocol 7 of the Treaty on the Functioning of the European Union on the privileges and immunities of the European Union, particularly as regards the inviolability of archives (including the physical location of data and services as set out in Article I.9.2) and data security, which includes personal data held on behalf of the *contracting authority* in the premises of the *contractor* or sub*contractor*.

The *contractor* shall notify the *contracting authority* without delay of any legally binding request for disclosure of the personal data processed on behalf of the *contracting authority* made by any national public authority, including an authority from a third country. The *contractor* may not give such access without the prior written authorisation of the *contracting authority*.

The duration of processing of personal data by the *contractor* will not exceed the period referred to in Article II.22.2. Upon expiry of this period, the *contractor* shall, at the choice of the controller, return, without any undue delay in a commonly agreed format, all personal data processed on behalf of the controller and the copies thereof or shall effectively delete all personal data unless Union or national law requires a longer storage of personal data.

For the purpose of Article II.10, if part or all of the processing of personal data is sub*contract*ed to a third party, the *contractor* shall pass on the obligations referred to in Articles I.9.2 and II.9.2 in writing to those parties, including sub*contractor*s. At the request of the *contracting authority*, the *contractor* shall provide a document providing evidence of this commitment.

II.10 SUBCONTRACTING

II.10.1 The *contractor* must not sub*contract* and have the *FWC* performed by third parties beyond the third parties already mentioned in its tender without prior written authorisation from the *contracting authority*. The *contractor* shall be responsible for, and liable to the Commission and *contracting authorities* for the acts or omissions of any sub*contractor* it engages to supply the *vaccine*s. Any sub*contract*ing of manufacturing activities should be compliant with EU GMP.

II.10.2 In the case of sub*contract*ing, the *contractor* remains bound by its *contract*ual obligations and solely responsible for the *implementation of this contract.*

II.10.3 The *contractor* must ensure that the sub*contract*ing does not affect the rights of the *contracting authority* under this *contract*.

II.10.4 The *contracting authority* may request the *contractor* to replace a sub*contractor* found to be in a situation provided for Article 136(1) and (2) of the Financial Regulation.

II.11 AMENDMENTS

II.11.1 Any amendment to this *FWC* or *Vaccine Order form* must be made in writing.

II.11.2 Any amendment must not make changes to the *FWC* or to the *Vaccine Order form* that might alter the initial conditions of the procurement procedure or result in unequal treatment of tenderers.

II.12 ASSIGNMENT

II.12.1 The *contractor* must not assign any of the rights and obligations arising from the *contract,* including claims for payments or factoring, without prior written authorisation from the *contracting authority*. In such cases, the *contractor* must provide the *contracting authority* 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 *contracting authority*.

II.13 INTELLECTUAL PROPERTY RIGHTS

Upon reasonable request by the Commission, the *contractor* will provide evidence of its ownership of license to the *Vaccine* IP Rights. The Commission may request this evidence after the end of this *contract*.

This evidence may include, as appropriate:

a) The title and number of the patent or patent application; or

b) A redacted copy of the license or of the agreement granting the relevant rights to the *contractor* or a reference to this license.

The provision of evidence does not release the *contractor* from its responsibilities if it is found that it does not hold necessary rights, regardless of when and by whom this fact is revealed.

II.14 FORCE MAJEURE

II.14.1 If a party is affected by *force majeure,* it must immediately *notify* the other party, stating the nature of the circumstances, their likely duration and foreseeable effects.

II.14.2 A party is not liable for any delay or failure to perform its obligations under the *FWC* if that delay or failure is a result of *force majeure*. If the *contractor* is unable to fulfil its *contract*ual obligations owing to *force majeure*, it has the right to remuneration only for the supplies actually delivered and which obtain a certificate of conformity.

II.14.3 The parties must take all necessary measures to limit any damage due to *force majeure*.

II.15 LIQUIDATED DAMAGES

II.15.1 If *contractor* does not deliver any *Vaccine* doses by the dates provided for in the applicable *Delivery schedule*, the *contractor* shall promptly notify the impacted *contracting authority* giving the reasons for such delay and may request the *contracting authority* to approve a revised *Delivery schedule.* The *contracting authority* shall not unreasonably withhold approval for the revised *Delivery schedule* if the proposed date for the full delivery of the concerned delivery instalment, is less than 30 days later than the original date for delivery.

II.15.2 If 10% or less of a given delivery instalment are not delivered pursuant to the agreed delivery dates, such delivery instalment shall not be considered delayed.

II.15.3 For the purposes of this Article II.15, 'Late Delivery Time' means the time, in weeks, between (i) the sixth calendar day following the end of the Quarter in which delivery of a given delivery instalment of *vaccine* doses was due to be made pursuant to the relevant *Vaccine Order form* and (ii) the actual date of delivery of such *vaccine* doses.

If the Late Delivery Time exceeds:

a) four (4) weeks, the *contractor* shall be obliged to give each affected *contracting authority* a price reduction [redacted] on the purchase price set out in Article I.5 in relation to such *vaccine* doses for which the late delivery time exceeds four (4) weeks;

b) eight (8) weeks, the *contractor* shall be obliged to give each affected *contracting*

authority a price reduction [redacted] on the purchase price set out in Article I.5 in relation to such *vaccine* doses for which the late delivery time exceeds eight (8) weeks; or

c) twelve (12) weeks, the *contractor* shall be obliged to give each affected *contracting authority* a price reduction [redacted] on the purchase price set out in Article I.5 in relation to such *vaccine* doses for which the late delivery time exceeds twelve (12) weeks.

The parties expressly acknowledge and agree that any price reduction applicable under this Article is not a penalty and represents a reasonable estimate of fair compensation for the damage incurred due to failure to provide the supplies within the applicable time limits set out in this *Contract*.

II.15.4 Claims and liability. Any claim for liquidated damages does not affect the *contractor*'s actual or potential liability or the *contracting authority*'s rights under Article II.18.

II.16 REDUCTION IN PRICE

See Article II.15.

II.17 SUSPENSION OF THE *IMPLEMENTATION OF THE CONTRACT*

II.17.1 Suspension by the *contractor* in the case of *force* majeure. If the *contractor* is affected by *force majeure,* it may suspend the *performance of the contract.*

The *contractor* must immediately notify the *contracting authority* about the suspension. The *notification* must include a description of the force majeure and state when the *contractor* expects to resume the performance of the *contract.*

The *contractor* must *notify* the *contracting authority* as soon as it is able to resume performance of the *contract,* unless the *contracting authority* has already terminated the *contract.*

II.17.1[1] Suspension by the *contractor* in other cases. The *contractor* may suspend the *implementation of the FWC* vis-à-vis any *contracting authority*, with the exception of the lead *contracting authority*, if this *contracting authority* fails to comply with its obligations, in particular, the obligation to provide the information needed for the *contractor* to perform the *FWC* as provided for in the tender specifications, or fails to comply with their *contract*ual obligations in a substantial or material manner.

The *contractor* must *formally notify* the concerned *contracting authority* of the suspension, and of the reasons for it. Suspension takes effect on the date of *formal notification*, or at a later date if the *formal notification* so provides.

Within 5 working days after receiving the *formal notification* from the concerned *contracting authority* in response to the suspension *notification*, the *contractor* shall assess the measures that the *contracting authority* has taken, in order to remedy the reasons for the suspension of the *implementation of the FWC,* and will resume *the implementation of the FWC* vis-à-vis the concerned *contracting authority* immediately, or send a second *formal notification*.

If, within 30 days after a the second *formal notification*, sent by the *contractor* to the *contracting authority* under this Article II.17.1[1], concerning the same failure, the *contracting authority* has not taken proportionate measures to rectify the situation, the *contractor* is entitled to terminate the Framework *contract* and/or *Vaccine Order forms* with this *contracting authority*, in accordance with Article II.18.3 and Article II.18.4 of

this *FWC*.

In the meaning of this Article II.17.1[1], not ordering by the *contracting authorities* any additional *Vaccine* Doses, as referred to in Article I.2, does not constitute a ground for the *contractor* to suspend or terminate the *FWC*.

II.17.2 Suspension by the *contracting authority*. The *contracting authority* may suspend the *implementation of the FWC* or any part of it:

a) if the procedure for awarding the *FWC* or the *implementation of the FWC* proves to have been subject to *irregularities, fraud or breach of obligations*;

b) in order to verify whether the presumed *irregularities, fraud* or *breach of obligations* have actually occurred.

The *contracting authority* 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 *contracting authority* 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 *FWC* under Article II.18.1(e) or (i).

The *contractor* is not entitled to compensation for suspension of any part of the *contract*.

The *contracting authority* may in addition suspend the time allowed for payments in accordance with Article II.21.

II.18 TERMINATION OF THE *CONTRACT*

II.18.1 Grounds for termination by the *contracting authority*. The *contracting authority* may terminate the *FWC* in the following circumstances:

a) If the *contractor* fails to receive (conditional) *Marketing authorisation* for the *Vaccine* the [redacted] then, as a remedy, the Commission and *contracting authorities* may terminate this *FWC* with immediate effect upon written notice to the *contractor*.

b) if the *contractor* does not implement the *FWC* in accordance with the tender specifications (as implemented through the *FWC* and, for the avoidance of doubt, subject to Article I.1) or is in material breach of another substantial *contract*ual obligation.;

c) if the needs of the contracting authority change and it no longer requires new supplies under the FWC; in such cases ongoing specific contracts remain unaffected;

d) 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[4];

e) 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.

f) if the procedure for awarding the *FWC* or the performance of the *FWC* prove to have been subject to irregularities, *fraud* or *breach of obligations*;

g) if the *contractor* does not comply with applicable obligations under environmental, social and labour law established by Union law, national law, collective agreements or by the international environmental, social and labour law provisions listed in Annex X to Directive 2014/24/EU; 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[2]

h) if the *contractor* is in a situation that constitutes a *conflict of interest* or a *professional conflicting interest* as referred to in Article II.7;

i) if a change to the *contractor*'s legal, financial, technical, organisational or ownership situation is likely to substantially affect the performance of the *FWC* or substantially modify the conditions under which the *FWC* was initially awarded or a change regarding the exclusion situations listed in Art 136 of Regulation (EU) 2018/1046 that calls into question the decision to award the *Contract*;

j) in the event of *force majeure*, where either resuming implementation is impossible or the necessary ensuing amendments to the *FWC* would mean that the tender specifications are no longer fulfilled or result in unequal treatment of tenderers or *contractor*s;

k) if the *contractor* is in breach of the data protection obligations resulting from Article II.9.2;

l) if the *contractor* does not comply with the applicable data protection obligations resulting from Regulation (EU) 2016/679.

II.18.2 Grounds for termination by the *contractor*. See Article II.17.1[1].

II.18.3 Procedure for termination. A party must *formally notify* the other party of its intention to terminate the *FWC* 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 *contract*ual obligations. Failing that, the decision to terminate becomes enforceable the day after the time limit for submitting observations has elapsed.

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

In the cases referred to in points (a) to (d) (g) to (i), (k) and (l) of Article II.18.1 and in Article II.17.2, the date on which the termination takes effect must be specified in the *formal notification.*

In the cases referred to in points (e), (f) and (j) of Article II.18.1, the termination takes effect on the day following the date on which the *contractor* receives *notification* of termination.

In addition, at the request of the *contracting authority* and regardless of the grounds for

[2] https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1544791836334&uri=CELEX:32018R1046

termination, the *contractor* must provide all necessary assistance, including information, documents and files, excluding the information protected by the *contractor*'s intellectual property rights, such as patents, to allow the *contracting authority* to complete, continue or transfer the delivery of the supplies to a new *contractor* or internally, without interruption or adverse effect on the quality or continuity of the delivery of the supplies. The parties may agree to draw up a transition plan detailing the *contractor*'s assistance unless such plan is already detailed in other *contract*ual documents or in the tender specifications. The *contractor* must provide such assistance at no additional cost, except if it can demonstrate that it requires substantial additional resources or means, in which case it must provide an estimate of the costs involved and the parties will negotiate an arrangement in good faith.

II.18.4 Effects of termination. The *contractor* is liable for damage incurred by the *contracting authority* as a result of the termination of the *FWC* as agreed in Article II.6, except if the damage is a result of a termination in accordance with Article II.18.1 (i) and (j) or Article II.18.2. The *contracting authority* may claim compensation for such damage as agreed in Article II.6.

The *contractor* is not entitled to compensation for any loss resulting from the termination of the *Contract,* including loss of anticipated profits, unless the loss was caused by the situation specified in Article II.18.2 or in Article II.6.6.

Both parties 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 and any invoice required for supplies that were provided before the date of termination.

In the case of joint tenders, the *contracting authority* may terminate the *FWC* with each member of the group separately on the basis of points (d), (e), (g), (k) or (l) of Article II.18.1, under the conditions set out in Article II.11.2.

II.19 INVOICES, VALUE ADDED TAX AND E-INVOICING

II.19.1 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 *FWC* reference.

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 *contracting authority* 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 *contractor* (or leader in the case of a joint tender) must complete the necessary formalities with the relevant authorities to ensure that the supplies and services required for *implementation of the FWC* are exempt from taxes and duties. The VAT conditions applicable to the *Vaccine* Orders will be agreed between *contractor* and the relevant *contracting authorities* in accordance with the applicable law.

II.19.2 E-invoicing. If provided for in the special conditions, the *contractor* (or leader in the case of a joint tender) submits invoices in electronic format if the conditions regarding electronic signature specified by Directive 2006/112/EC on VAT are fulfilled,

i.e. using a qualified electronic signature or through electronic data interchange.

Reception of invoices by standard format (pdf) or email is not accepted.

II.20 PRICE REVISION

If a price revision index is provided in Article I.5.4, this Article applies to it. Prices are fixed and not subject to revision during the first year of the *Contract*.

At the beginning of the second and every following year of the *Contract,* each price may be revised upwards or downwards at the request of one of the parties.

A party may request a price revision in writing no later than three months before the anniversary date of entry into force of the *Contract*. The other party must acknowledge the request within 14 days of receipt.

At the anniversary date, the *contracting authority* must communicate the final index for the month in which the request was received, or failing that, the last provisional index available for that month. The *contractor* establishes the new price on this basis and communicates it as soon as possible to the *contracting authority* for verification.

The price revision is calculated using the following formula:

$$Pr = Po \times \left(\frac{Ir}{Io}\right)$$

where: Pr = revised price;
Po = price in the tender;
Io = index for the month in which the *FWC* enters into force;
Ir = index for the month in which the request to revise prices is received.

II.21 PAYMENTS AND GUARANTEES

II.21.1 Date of payment. The date of payment is deemed to be the date on which the contracting authority's account is debited.

II.21.2 Currency. Payments are made in euros, unless another currency is provided for in Article I.7.

II.21.3 Conversion. The contracting authority makes any conversion between the euro and another currency at the daily euro exchange rate published in the Official Journal of the European Union, or failing that, at the monthly accounting exchange rate, as established by the European Commission and published on the website indicated below, applicable on the day when it issues the payment order.

The *contractor* makes any conversion between the euro and another currency at the monthly accounting exchange rate, established by the Commission and published on the website indicated below[3], applicable on the date of the invoice.

II.21.4 Cost of transfer. The costs of the transfer are borne as follows:

[3] http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm

a) the *contracting authority* 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.21.5 Pre-financing, performance and money retention guarantees. If, as provided for in Article I.6, a financial guarantee is required for the payment of pre- financing, as performance guarantee or as retention money guarantee, it must fulfil the following conditions:

a) the financial guarantee is provided by a bank or a financial institution approved by the *contracting authority* or, at the request of the *contractor* and with the agreement of the *contracting authority*, by a third party; and

b) the guarantee shall have the effect of making the bank or financial institution or the third party provide irrevocable collateral security or stand as first-call guarantor of the *contractor*'s obligations without requiring that the *contracting authority* has recourse against the principal debtor (the *contractor*).

The *contractor* bears the cost of providing such guarantee.

Pre-financing guarantees must remain in force until the pre-financing is cleared against interim payments or payment of the balance. Where the payment of the balance takes the form of a debit note, the pre-financing guarantee must remain in force for three months after the debit note is sent to the *contractor*. The *contracting authority* must release the guarantee within the following month.

Performance guarantees cover compliance with substantial *contract*ual obligations until the *contracting authority* has given its final approval for the supply. The performance guarantee must not exceed 10 % of the total *Vaccine* Order. The *contracting authority* must release the guarantee fully after final approval of the supply, as provided for in the *Contract*.

Retention money guarantees cover full delivery of the supplies in accordance with the *FWC* including during the *FWC* liability period and until their final approval by the *contracting authority*. The retention money guarantee must not exceed 10 % of the total price of the *Vaccine* Order. The *contracting authority* must release the guarantee after the expiry of the *FWC* liability period as provided for in the *Contract*.

The *contracting authority* must not request a retention money guarantee where it has requested a performance guarantee.

II.21.6 Payment of the balance. The *contractor* (or leader in the case of a joint tender) must send an invoice for payment of the balance within 60 days of the end of the period of provision of the supplies, as provided for in Article I.5 or in the tender specifications.

Payment of the invoice and approval of documents does not imply recognition of the regularity, authenticity, completeness and correctness of the declarations and information they contain.

Payment of the balance may take the form of recovery.

II.21.7 Suspension of the time allowed for payment. The *contracting authority* may suspend the payment period 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 and the reasons to suspend the payment. The reasons the *contracting authority* may cite for not being able

to process an invoice are:

a) because it does not comply with the *Contract*;

b) because the *contractor* has not produced the appropriate supplies or documents.

The *contracting authority* must *notify* the *contractor* (or leader in the case of a joint tender) as soon as possible of any such suspension, giving the reasons for it. In case b) referred above, the *contracting authority* 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 if the *contracting authority* requires it.

Suspension takes effect on the date the *contracting authority* 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 *contracting authority* to justify the continued suspension.

Where the payment periods have been suspended following rejection of a document referred to in the first paragraph of this Article and the new document produced is also rejected, the *contracting authority* reserves the right to terminate the *FWC* in accordance with Article II.18.1(b).

II.21.8 Interest on late payment. On expiry of the payment period specified in Article I.6, the *contractor* (or leader in the case of a joint tender) 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 eight 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.21.7 is not considered as a 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.21.1.

However, when the calculated interest is EUR 200 or less, it must be paid to the *contractor* (or leader in the case of a joint tender) only if it requests it within two months of receiving late payment.

II.22 RECOVERY

II.22.1 If an amount is to be recovered under the terms of the *FWC*, the *contractor* must repay the *contracting authority* the amount in question.

II.22.2 Recovery procedure. Before recovery, the *contracting authority* 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 *contracting authority* 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 no observations have been submitted and the *contractor* does not pay by the due date, the *contracting authority* may, after informing the *contractor* in writing, recover the amounts due:

(a) by offsetting them against any amounts owed to the *contractor* by the Union or by an executive agency when it implements the Union budget;

(b) by calling in a financial guarantee if the *contractor* has submitted one to the *contracting authority*;

(c) by taking legal action.

II.22.3 Interest on late payment. If the *contractor* does not honour the obligation to pay the amount due by the date set by the *contracting authority* in the debit note, the amount due bears interest at the rate indicated in Article II.21.8. 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 *contracting authority* 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.22.4 Recovery rules in the case of joint tender. If the *FWC* is signed by a group (joint tender), the group is jointly and severally liable under the conditions set out in Article II.6 (liability). The *contracting authority* shall send the debit note first to the leader of the group.

If the leader does not pay by the due date the whole amount, and if the amount due cannot be offset or can only be offset partially in accordance with Article II.21.5 (a), then the *contracting authority* may claim the amount still due to any other member or members of the group by respectively *notifying* them with a debit note in conformity with the provisions laid down in Article II.21.6.

II.23 CHECKS AND AUDITS

II.23.1 The *contracting authority* and the European Anti-Fraud Office may check or require an audit on the *implementation of the contract*. This may be carried out either by OLAF's own staff or by any other outside body authorised to do so on its behalf.

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

The audit procedure is initiated on the date of receipt of the relevant letter sent by the *contracting authority*. Audits are carried out on a confidential basis.

II.23.2 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.

II.23.3 The *contractor* must grant the *contracting authority*'s staff and outside *personnel* authorised by the *contracting authority* the appropriate right of access to sites and premises where the *FWC* is performed 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.23.4 On the basis of the findings made during the audit, a provisional report is drawn

up. The *contracting authority* 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 *contracting authority* may recover all or part of the payments made in accordance with Article II.21 and may take any other measure which it considers necessary.

II.23.5 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 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 *FWC* 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 performance of this *FWC* and up to five years starting from the payment of the balance.

II.23.6 The Court of Auditors and the European Public Prosecutor's Office established by Council Regulation (EU) 2017/1939[4] ('the EPPO') have the same rights as the *contracting authority*, particularly right of access, for the purpose of checks, audits and investigations.

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

Annex III. *Vaccine Order form*

ORDER FORM

	FRAMEWORK *CONTRACT* ***ORDER FORM***

[Indicate the relevant *Contracting authority*] Tel.: E-mail:	Order number: Currency of payment: EUR Tender (date and reference):	(Name and address of the *contractor*)

This order is governed by Framework *Contract* No [ ]

LISTING OF THE SUPPLIES and code	UNIT	QUANTITY	PRICE in €	
			UNIT PRICE	TOTAL
- [complete]				

Delivery according to [redacted] The applicable *Delivery schedule* is attached to the current *Order form*.	Packaging
	Insurance Transport Assembly VAT
	TOTAL:
Place of delivery (according to [redacted]): Final date of deliver: Payment provisions: Guarantee:	***contractor*'s signature** Name: Position: Date:

Date of issue:

Signature [name and position]

The invoice will be paid only if the *contractor* has returned the signed *order form*.

Annex IV: *Delivery schedule* for initial doses

Country	Initial quantity for Q3
Kingdom of Belgium (BE)	[redacted]
Kingdom of Denmark (DK)	
Republic of Ireland (IE)	
Kingdom of Spain (ES)	
French Republic (FR)	
Italian Republic (IT)	
Republic of Cyprus (CY)	
Republic of Latvia (LV)	
Grand Duchy of Luxembourg (LU)	
Republic of Austria (AT)	
Kingdom of the Netherlands (NL)	
Portuguese Republic (PT)	
Kingdom of Sweden (SE)	
Kingdom of Norway (NO)	

Annex V – Reporting template

	Contacting authority		Q1 (Jan. to March)	Q2 (April to June)	Q3 (July to Sept.)	Q4 (Oct. to Dec.)	Actual Delivery/
1	Austria	AT					
2	Belgium	BE					
3	Cyprus	CY					
4	Denmark	DK					
5	France	FR					
6	Germany	DE					
7	Ireland	IE					
8	Italy	IT					
9	Latvia	LV					
10	Luxembourg	LU					
11	Netherlands	NL					
12	Norway	NO					
13	Portugal	PT					
14	Spain	ES					
15	Sweden	SE					
	TOTAL/Orders						