Contract

between

the State of the Netherlands

National Institute for Public Health and the Environment (RIVM)

and

Supplier

concerning the supply of

Vaccine

contract number ……

Content

Annexes

The undersigned

The **State of the Netherlands**, represented by his Minister of Public Health, Welfare and Sport, on behalf of the Minister represented by *Name*, Director-General of the National Institute for Public Health and the Environment (Rijksinstituut voor Volksgezondheid en Milieu) **(RIVM),** having his home office at Antonie van Leeuwenhoeklaan 9, 3721 MA Bilthoven, the Netherlands,

hereinafter referred to as "**Purchaser"**

and

Name supplier and address data, duly represented by *Name*, Managing Director,

hereinafter referred to as **"Supplier"**,

whereas

Purchaser acts as the exclusive procurement agency under order of the Ministry of Health, Welfare and Sport (VWS) for *Vaccine* for the Dutch Immunisation Programme.

Purchaser desires to purchase *Vaccine* for the agreed period as specified below in this contract in relation to the Dutch Immunisation Programme (including the Dutch Caribbean).

Purchaser therefore initiated an Invitation To Tender in accordance with Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC (hereafter: Directive 2014/24/EC) implemented in the Netherlands in the "Aanbestedingswet 2012".
This Public Procurement Act 2012 was amended by law on June 22nd 2016 in connection with the implementation of the procurement directives 2014/23/EC, 2014/24/EC and 2014/25/EC.

Supplier replied to this Invitation To Tender with tender reference number Nx …….. on *Day/month/year*.

Purchaser wishes to award the contract to Supplier based on the Invitation To Tender of Purchaser and the Tender of Supplier.

now therefore have agreed as follows:

1. Definitions

In this Contract, the following terms shall be interpreted as indicated:

"Contract" means the agreement entered into between Purchaser and Supplier, as defined in the contract signed by the parties, including all Annexes thereto and all documents incorporated by reference therein.

"Contract Price" means the price per dose payable to Supplier under the Contract for the full and proper performance of the contractual obligations.

"Days" means calendar days.

"Goods" means all *Vaccine* and necessary documents to be supplied by Supplier, as specified in the Note Of Information (Annex 1) and Invitation To Tender number Nx …… (Annex 2) of the Contract.

"Party" means either Purchaser or Supplier.

2. Supply of the Goods

2.1 Supplier agrees to supply to Purchaser and Purchaser agrees to purchase from Supplier the Goods in accordance with the provisions of the Contract and in accordance with the conditions and specifications stated in the Note Of Information (Annex 1), the Invitation To Tender (Annex 2) and Supplier's Tender (Annex 3).

2.2 Purchaser desires to purchase …… doses (+/-……. percent) per contract year of the Goods as specified in paragraph 7.3.1 of the scope of supply of the relevant Invitation To Tender (Annex 2) of *Vaccine*. *Desribe details about the type of vaccine, dosage form, packaging, labelling, shelf live, allowed number of batches, safety stock etc.* All labelling and leaflets are in the Dutch language and are in compliance with the European Commission 'Guideline on the readability of the labelling and package leaflet of medicinal products for human use (Revision 1, 12 January 2009)'.

3. Delivery

3.1 All Goods shall be delivered by Supplier in accordance with the Incoterms 2010 ICC Delivery Duty Paid, to:

Name + address Logistics Service Provider

or at any other location in the Netherlands indicated by RIVM-DVP.

In case Purchaser decides to change the place of delivery outside the Netherlands during the contract period, parties will work towards an appropriate solution.

3.2 The Goods and all necessary documents shall be delivered at the place of delivery in accordance with the schedules specified in Annex 2. For the purpose of a smooth delivery Supplier shall inform Purchaser not less than 2 (two) weeks before the date of delivery via *mail address.*

3.3 Each regular delivery consists of at most 1 (one) batch. If Supplier fails to deliver in at most 1 (one) batch, a compensation of ……. per extra batch must be paid.

3.4 All time periods for performance by Supplier, as agreed upon in writing by Supplier and Purchaser, are terms to be observed on penalty of forfeiture of rights. When Supplier fails to perform within an agreed time period Supplier is immediately in default as referred to in article 6:83, sub a of the Dutch Civil Code.

3.5 If at any time during performance of the Contract, Supplier should encounter conditions impeding timely delivery of the Goods and/or documents, Supplier shall promptly notify Purchaser in writing of the fact of the delay, its likely duration and its cause(s). As soon as possible after receipt of

Supplier's notice, Purchaser shall evaluate the situation and may at his sole discretion decide to extend Supplier's time for performance.

3.6 If Supplier fails to deliver within the time period(s) any or all of the Goods and documents specified in paragraph 7.3 and 7.6 of the ITT (Annex 2), Purchaser shall, without prejudice to other remedies under the Contract or given by law, including but not limited to Purchaser's right to terminate the Contract or any agreement resulting therefrom, deduct from the Contract Price, as liquidated damages, a sum equivalent to …… percent of the Contract Price of the delayed Goods for each calendar week (Days pro rata) of delay starting from the contractually agreed delivery date, until actual delivery or performance, up to a maximum deduction of …….. percent of the Contract Price of the delayed Goods. Notwithstanding the foregoing, Purchaser may claim his actual damages suffered as a result of the delay in so far as these damages exceed the liquidated damages.

3.7 From the labelled safety stocks an OMCL batch release certificate shall be sent to Purchaser at the specified dates in the delivery schedule (Annex 2, ITT). The Supplier shall confirm each safety stock to Purchaser with a separate statement as specified in 7.4.1 of the ITT (Annex 3). The safety stock can be inspected by Purchaser at all times. The delivery time for *Vaccine* delivered from this labelled safety stock shall be maximum ….. weeks after a written request of Purchaser, and …….. weeks after a written request of Purchaser for unlabelled safety stock.

3.8 Supplier's duty to keep a safety stock for the supply described in Annex H of the ITT (Annex 2), expires …… months after the last delivery date. If Supplier fails to keep or fails to deliver timely the safety stocks specified in the Contract, Purchaser shall, without prejudice to other remedies under the Contract or given by law, including but not limited to Purchaser's right to terminate the Contract or any agreement resulting therefrom, deduct from the Contract Price, as liquidated damages, a sum equivalent to ……. percent of the Contract Price of the delayed Goods for each calendar week (Days pro rata) of delay until actual delivery or performance, up to a maximum deduction of percent of the Contract Price of the delayed Goods. Notwithstanding the foregoing, Purchaser may claim his actual damages suffered as a result of the delay in so far as these damages exceed the liquidated damages.

3.9 If Supplier fails to deliver or delivers any or all of the Goods that are not in conformity with the agreed specifications as laid down in this Contract, whether or not as a consequence of an event that can be considered as an event of force majeure, Supplier is obliged – in case the Supplier itself cannot meet the given deadline of 28 (twenty-eight) days – to negotiate and contract with a third party (another Supplier) in such a way that Supplier shall deliver the agreed upon Goods whether or not through a third party under the same conditions as laid out in this Contract within 28 (twenty-eight) days after a written notice has been sent by Purchaser that the delivered Goods are not in conformity with the agreed specifications laid down in this Contract. Such is without prejudice to Purchaser's rights under this Contract or by law (which includes, but is not limited to, the right to purchase the agreed upon Goods himself through another Supplier if necessary). Supplier shall be liable to Purchaser for any excess costs for such similar Goods up to a maximum of ……. percent of the Contract Price of the non-delivered Goods and/or delivered Goods which are not in conformity with the agreed specifications.

3.10 If Supplier's permits or certificates required for the performance of the contract are withdrawn, whether or not as a consequence of an event that can be considered as an event of force majeure, Supplier is obliged to negotiate and contract with a third party (another Supplier) in such a way that Supplier shall deliver the agreed upon Goods whether or not through a third party under the same conditions as laid out in this Contract. Such is without prejudice to Purchaser's rights under this Contract or by law (which includes, but is not limited to, the right to purchase the agreed upon Goods himself through another Supplier if necessary). Supplier shall be liable to Purchaser for any excess costs for such similar Goods up to a maximum of …….. percent of the Contract Price of the non-delivered Goods and/or delivered Goods which are not in conformity with the agreed specifications.

4. Packaging, labelling and documentation

4.1 All Goods shall be packed, labelled, marked and handled in accordance with the specifications laid down in paragraph 7 in Annex 2 (ITT) and in accordance with Supplier's Tender (Annex 3).

5. Transportation

5.1 In offering the Goods to be delivered for transportation or in transporting them, Supplier shall comply with any and all applicable rules and regulations in all countries through which the Goods to be delivered will pass. Supplier shall provide all information required and desired by Purchaser of the Goods, including but not limited to any information regarding or required for their handling, import, custom clearance or taxation.

6. Guarantees and liability

6.1 Supplier guarantees that the delivered Goods (including the documents and packaging material) are in conformity with the Contract. This means that the delivered Goods will be suitable for the purpose for which they are intended by Purchaser. Supplier further guarantees that the delivered Goods are in conformity with the agreed specifications (including but not limited to the specifications laid down in paragraph 7 in Annex 2 (ITT) and in accordance with Supplier's Tender (Annex 3) and any approved samples), that the Goods do not infringe any rights of third parties and that the Goods are free from defects, including at any rate errors in the design, material and manufacture, and comply with all applicable statutory rules and regulations.

6.2 All Goods shall have a remaining shelf life after delivery to the RIVM of minimum ……. months. The expiry date must be shown on the product, packaging, on the Certificate of Analysis and on the batch release certificate. Products supplied with insufficient shelf life shall be subject to free of charge replacement.

6.3 If the Goods are not in conformity with the Contract, Purchaser may, at his discretion, require that the Goods be repaired or replaced free of charge, or that the purchase price be reimbursed, without prejudice to Purchaser's other rights under this Contract or by law. Apart from Supplier's obligations under article 3.7 Supplier will also compensate Purchaser as follows. If the aforementioned lack of conformity results in additional efforts by Purchaser and/or the executing third parties, the costs of these additional efforts will be fully compensated by Supplier. Such additional efforts can consist of, but are not limited to, quality investigations, complaint handling, communication, training, etc.

6.4 Purchaser may return or keep Goods that are not in conformity with the Contract at Suppliers costs until Supplier has issued further instructions as to what should be done with the Goods. Any costs to be incurred by Purchaser will be for Suppliers account. Storage of the Goods will be for Suppliers account and risk.

6.5 Supplier shall assume full responsibility and shall indemnify Purchaser from all losses, liabilities, claims, costs, damages and expenses resulting from the Goods supplied. Damage(s) include, but are not limited to, damage(s) resulting from death or injury, loss of profit, loss of contracts, loss of reputation, loss of management or employee productivity, increase in legal fees or any other form of loss. Supplier shall further indemnify Purchaser from all losses, liabilities, claims, costs, damages and expenses resulting from the Goods supplied, incurred by claims - in connection with the Goods under this Contract - of third parties. Damage(s) include, but are not limited to, damage(s) resulting from death or injury, loss of profit, loss of contracts, loss of reputation, loss of management or employee productivity, increase in legal fees or any other form of loss. Purchaser will not be able to rely on this indemnification clause if the damages concerned are the result of actions on the part of Purchaser. The liability per event is limited to an amount of …….. However, this limitation of liability does not apply: in the event of third-party claims for compensation resulting from death or injury and/or in the event of intent or gross negligence on the part of the Supplier or his Staff.

6.6 Supplier shall have and maintain an insurance of at least € ……. against any damage incurred by Purchaser as a consequence of Suppliers failure to perform any of his obligations, or as a consequence of a wrongful act committed against Purchaser or a third party. The insurance shall amongst others cover product liability. Supplier shall provide Purchaser the relevant insurance

certificate. Supplier shall inform Purchaser immediately and without any delay when there are changes (to be expected) regarding the relevant insurance certificate.

6.7 If at any time Purchaser decides to recall the Goods due to the fact that the Goods do not comply with the Contract or for any other sound reason, Purchaser shall notify Supplier in writing immediately. Upon receipt of such notice Supplier shall replace, at his own risk and costs, the defective Goods as soon as possible. Supplier shall indemnify Purchaser for any costs resulting from or connected with the product recall up to a maximum of …… percent of the Contract Price of the recalled Goods.

7. Industrial and intellectual property rights

7.1 Supplier shall indemnify Purchaser against all loss or damage (including legal costs) incurred by Purchaser as a result of any claim that the possession, distribution and/or use of the Goods, made available to Purchaser under this Agreement, infringes or are alleged to infringe the intellectual property rights of any third party up to a maximum of ……. percent of the Contract Price of the delivered Goods which infringes or are alleged to infringe the intellectual property rights of any third party.

8. Audits and inspections

8.1 Supplier agrees that Purchaser or his duly authorised representatives have the right to audit the premises where the products are manufactured and/or stored on the basis of the European GMP/GDP directives.

8.2 These audits will be scheduled to be mutually convenient to both parties. Corrective and preventive actions resulting from the observations during the inspection have to be performed in the soonest possible way. Supplier shall bear all costs resulting therefrom or connected therewith. Supplier will report to Purchaser about his efforts in the carrying out of the corrective and preventive actions within a laid down time frame.

8.3 In the event that a third party, subject to clause 12, is involved in the manufacture or storage of the Goods, Supplier shall use his best efforts to ensure that Purchaser may regularly inspect the third party's premises. The centralised control for these audits towards the third party shall be the responsibility of Supplier. This encompasses the scheduling as well as the surveillance concerning corrective and preventive actions. Purchaser shall not contact the third party directly.

9. Prices

9.1 The Contract Price for the Goods to be supplied under the Contract is fixed for the specified first period of 12 (twelve) months starting on *date* and is as follows (per dose in Euro excl. VAT): € …….

9.2 The Contract Price mentioned in article 9.1 includes delivery on a DDP basis to ….., or another place within the Netherlands specified by RIVM. In case Purchaser has to change the place of delivery outside the Netherlands during the contract period, parties will collaborate towards an appropriate solution.

9.3 The Contract Price, as specified and stated in article 9.1, is fixed for the first 12 (twelve) months starting *day/month/year*. For the following 12 (twelve) Monthly Period a new Contract Price may be proposed by Supplier using solely an indexation on the Contract Price. Such a proposal needs to be made minimum 6 (six) months before the end of the previous 12 (twelve) Monthly Period. Purchaser has to agree in writing with the proposed Contract Price, before it is fixed for the following 12 (twelve) Monthly Period.
This indexation will be based on the Dutch "consumentenprijsindex (CPI), totaal bestedingen 2019 = 100").

The following calculation method applies:
(CPI index (new month (e.g. May 2020)) - CPI index (old month (e.g. May 2019))) / CPI index (old month) * 100%.

The new month is the most recent month for which the final price index is known, and the old month is the same month a year earlier. Every following indexation, the chosen month should be used.

10. Payment and documents

10.1 Each delivery shipment has to be accepted by Purchaser's QP Department by signing the Certificate of Payment (Annex 5). Subsequently, this Certificate of Payment will be sent within a period of maximum 2 weeks after the acceptance of the delivery by Purchaser's QP Department to Supplier.

10.2 Supplier will prepare proper electronic invoices and will send the invoices together with the signed Certificate of Payment digitally to Purchaser. Invoices will only be processed by RIVM if they have been submitted electronically in XML format to RIVM via one of the ways mentioned on www.tradeinterop.com/rivm-en and if the purchase order number of RIVM is stated on the invoice, to which the invoice relates. Supplier will receive the instructions to be followed from the Purchaser.

All consequences, due to delay in forwarding the documents to Purchaser, will be for Supplier's account.

10.3 Only invoices with a signed Certificate of Payment will be approved. Within 30 (thirty) days Purchaser shall effect payment of the approved invoices.

11. Confidentiality

11.1 In connection with the Contract, Supplier and Purchaser (as to information disclosed, the Disclosing Party) may each provide the other Party (as to information received, the Receiving Party) with Confidential Information. Confidential Information is all commercial and technical information and knowledge acquired in the performance of the Contract (including commercial terms). The Receiving Party agrees not to disclose any Confidential Information and shall use Confidential Information only for the purpose intended by the Contract. Each Party shall obligate his employees and his advisors to respect said confidentiality. The obligations of the Parties under this section shall survive the termination of the Contract regardless of the manner of such termination.

11.2 The foregoing obligation shall not apply to any information which:

- was known and can be shown to be known to the Receiving Party prior to the time it was received;
- was known to the public or generally available to the public prior to the time it was received;
- becomes known to the public or generally available to the public without the Receiving Party being responsible thereof;
- was received at any time from a third party who, to the knowledge of the Receiving Party, is under no obligation to maintain the confidentiality of such information;
- was independently developed by the Receiving Party and can be shown to have been so developed by contemporaneous written records;
- has to be disclosed due to applicable laws or regulations or a court or administrative order.

11.3 The obligation under this section shall not hinder the Receiving Party to forward to the competent authorities any information, which has to be disclosed in connection with registration, release by the OMCL (Official Medicines Control Laboratories) and/or use or sale of the Goods.

11.4 Without mutual permission, no party shall have the right to make public announcements of the fact of this Contract and the activities hereunder. A copy of such announcement shall first be provided to the other Party for his comment and consent no less than 14 (fourteen) days prior to the proposed release date. The consent of the other Party shall not be unreasonably withheld.

12. Assignment and subcontracts

12.1 Supplier shall not assign, in whole or in part, his obligations to perform under the Contract, except with Purchaser's prior written consent.

12.2 Subject to clause 12.1, Supplier shall notify Purchaser in writing of all subcontracts awarded under the Contract if not already specified in his bid. Such notification, in his original bid or later, shall not relieve Supplier from any liability or obligation under the Contract or under the law.

13. Contract amendments

13.1 No variation in or modification of the terms of the Contract shall be made except by written amendment signed by both parties.

14. Annexes

14.1 The following Annexes form an integral part of the Contract:
Annex 1: Note Of Information belonging to the Invitation To Tender *day/month/year*
Annex 2: Invitation To Tender number Nx …….
Annex 3: Tender *day/month/year*
Annex 4: Quality Agreement
Annex 5: Certificate of Payment
Annex 6: Communication table

14.2 In case any inconsistencies between the Contract and the Annexes will occur, the Contract shall have priority above the Annexes. In case of any inconsistencies between the Annexes, the order of numbering of the Annexes will be decisive, i.e. Annex 1 shall have priority above Annex 2, etc.

15. Term and termination

15.1 This Contract will enter into force on *day/month/year* and will remain in force for a period of …. months. The Contract will be tacitly extended for a one time period of …. months at a maximum of ….. times after the first period, up to a total maximum of ……. months of the duration of the contract unless the Purchaser decides to terminate the Contract. Purchaser may terminate the Contract observing a notice period of 6 (six) months without any further liability to Supplier.

15.2 Notwithstanding clause 15.1 above and without prejudice to his other rights under this Contract or by law, Purchaser will at any point in time be entitled to suspend payment or terminate this Contract, in full or in part with immediate effect, except for (iv) for which a notice period of 3 (three) weeks will be applicable and (vi) for which a notice period of 6 (six) months will be applicable, or any other agreement concluded with Supplier, in full or in part, if

(i) any Goods made available by Supplier to Purchaser become subject to attachment;
(ii) Supplier is granted a suspension of payments or is declared bankrupt provided that such termination will not prejudice or affect any right of action or remedy which has accrued or will accrue thereafter to Purchaser;
(iii) any permits or certificates are withdrawn required for the performance of the Contract;
(iv) Supplier defaults in complying with one or more of his obligations ensuing from this Contract or any other agreement with Purchaser, provided that if the default is remediable, Supplier fails to remedy the default within 2 (two) weeks of being sent a default letter stating the default and the required performance;
(v) Supplier ceases his business or if a change occurs in the control of that business;
(vi) a change occurs in the Dutch Immunisation Programme (e.g. expansion target groups, change in vaccination schedule).

The above provisions, with the exception of (vi), will not detract from Purchasers right to compensation of any and all losses and expenses ensuing from Suppliers failure to perform

or from his anticipated failure to perform.

15.3 If a force majeure situation arises, Supplier shall immediately notify Purchaser in writing of such condition and the cause thereof, while submitting relevant evidence of the existence of such event. Unless otherwise directed by Purchaser in writing, Supplier shall continue to perform his obligations under the Contract as far as is reasonably practically possible, and shall seek all reasonable alternative means for performance not prevented by the force majeure event. The failure, including the failure to demand such from subcontractors and/or third parties, to maintain any certificate, permit or similar authorisation, consent or approval necessary to perform the work herein contemplated, or failures arising from transportation problems, illness of staff, strikes, or stagnation in the business of Supplier or his Suppliers, other shortcomings of Suppliers and shortage of products, shall not constitute force majeure.

15.4 In the event any case of force majeure will continue for a period of more than 1 (one) month, Parties are entitled to terminate the Contract by giving 30 (thirty) days prior written notice, without owing any compensation whatsoever with respect hereto.

15.5 Obligations which by their nature are intended to persist after the Contract has been performed will remain in force after the expiry of the Contract. These obligations include the provisions on: guarantee, non-performance, liability, termination, documentation, assignment of insurance proceeds, confidentiality and disputes and applicable law.

16. Resolution of disputes

16.1 Purchaser and Supplier shall make every effort to resolve amicably by direct informal negotiation any disagreement or dispute arising between them under or in connection with the Contract.

16.2 A dispute exists if either of the 2 (two) parties makes an allegation to this effect. In any dispute regarding the concluding, the interpretation or execution of this Contract or any other dispute with respect to, or in connection with, this Contract, the parties shall within a period of 2 (two) months (starting from the moment one party gives notice to the other party that there is a dispute), exhaust all reasonable means to arrive at an amicable solution. If they are unable to do so, the dispute shall be submitted to the judgment of the competent court in The Hague, The Netherlands.

17. Notices

All notices and other communications shall be in the form of a document, including, for the avoidance of doubt, an electronic mail message.

The notice and other communications should be addressed in conformance with Annex 6.

18. Governing language

18.1 All contract documents, all communications and documents related to the Contract shall be in the Dutch and/or English language. In case of any discrepancy between these 2 (two) languages, the Dutch version(s) shall prevail.

19. Applicable law

19.1 This Contract and the relationship under it between the parties shall be governed by, and interpreted in accordance with, the Laws of the Netherlands. The UN Convention on Contract for the International Sale of Goods (CISG) is not applicable to this Contract.

Signatures

For Purchaser

on behalf of the Dutch Minister of Public Health, Welfare and Sport

_____
(authorised signature)

Name : ……
Position : Director-General
Place : Bilthoven
Date :

For Supplier

Name Supplier

_____
(authorised signature)

Name : ……
Position : Managing Director
Place : ……
Date :

For Supplier
Name Supplier

_____
(authorised signature)

Name :
Position :

Place :
Date :

Annex 4 Quality Agreement

		SUMMARY OF AGREEMENTS AND RESPONSIBILITIES	RIVM	*Supplier*
1. GENERAL				
	1.1	In case of any discrepancy on quality issues between the Contract and the Quality Agreement, the latter shall prevail.	X	X
	1.2	All contract documents shall be in the Dutch and/or English language. In case of any discrepancy between these two languages, the Dutch version(s) shall prevail.	X	X
	1.3	Product is designed, produced, analysed and stored under current EU GMP guidelines (Eudralex Chapter IV, GMP guidelines, incl. Chapter 1 Pharmaceutical Quality System).		X
	1.4	Supplier has a valid GMP license available.		X
	1.5	The product is registered in the Netherlands. EU/1/06/337/006		X
2. Release of PRODUCT				
	2.1	Release fulfils the requirements of Annex 16 to the EU GMP.		X
	2.2	Every individual delivery shall be accompanied by the following documentation as being part of the batch documentation: • a batch specific release certificate incl. item numbers of used primary and secondary packaging materials (labels, leaflets and packaging)* • a CoA* • an OMCL certificate • a Marketing Information Form (MIF)* • a complete genealogical tree of production batch numbers from starting materials to the finished product* • a Certification of Transport Release * In case batch number (and/or packaging index) on the vial/syringe label is different than on primary/secondary packaging, both batch numbers should be reported on the documents. The Supplier will send the batch specific documentation to email address: *mail address*		X
	2.3	After each refreshment of the safety stock the Supplier shall confirm the availability of a labelled safety stock, by providing a statement with at least the following information: • product description • batch number • date in safety stock • expiration date • OMCL batch release certificate The Supplier will send the statement to email addresses: *mail addresses*		X

		SUMMARY OF AGREEMENTS AND RESPONSIBILITIES	RIVM	Supplier
3. PACKAGING				
	3.1	The product must be delivered in its original packaging to prevent falsified medicinal products.		X
	3.2	Every packaging shall contain ….. doses of the product, each clearly marked with the registration number.		X
	3.3	All labelling is in the Dutch language. All labelling is suitable for cold storage.		X
	3.4	Each packaging contains a leaflet for patients in the Dutch language.		X
	3.5	The transportation cartons are resistant against cooled transportation and cold storage and suitable for terrestrial transport. The transportation cartons shall be clearly identified with name of manufacturer, product and batch number. Each transportation carton is also marked with the storage temperature. All texts on the cartons shall be in the Dutch language and will be supported by the use of symbols.		X
	3.6	Requirements of Falsified Medicines Directive (Directive 2011/62/EU) 1. Adding safety features (unique identifier and anti-tampering device) to the products; 2. Providing all packs having a readable 2D-barcode; 3. Ensuring that serialisation information is uploaded in the National Medicines Verification System (NMVS) or European Medicines Verification System (EMVS) for all packs bearing a 2D-barcode, prior to the release of the batch; 4. Ensuring that all information contained in the 2D-barcode matches exactly the information that has been uploaded in the NMVS/EMVS; 5. Resolving anomalies detected by Purchaser during inbound verification control or decommissioning process without delay; 6. Batch recall/withdrawl: Supplier is responsible for decommissioning of all unique identifiers of the recalled/withdrawn batch directly through the NMVS/EMVS.		X
4. SHIPMENT				
	4.1	Regulatory and legal requirements for importation from sites outside Europe.	X	X
	4.2	Transport has to be executed using dedicated (for pharmaceutical products only) trucks if sent by road: transport of solely pharmaceuticals or medical devices, accommodated with despatching documentation.		X
	4.3	Storage and transport are executed under current EU GDP guidelines (2013/C 343/01) and Cold Chain requirements.	X	X
	4.4	Specifications for product storage temperatures and recording of temperatures during shipment.		X
	4.5	Packaging for shipment. All transportation cartons packed together on a Euro pallet, are sealed in crimp foil (wrapping foil) and a dedicated tape/label from Supplier has to be tampered to open.		X
	4.6	Reporting of temperature deviation during shipment.		X

SUMMARY OF AGREEMENTS AND RESPONSIBILITIES			RIVM	Supplier
	4.7	Evaluation of temperature deviation(s) during shipment on influence on product quality will be performed and reported to RIVM together with statement that there is no suspicion on counterfeit.		X
5. DEVIATIONS AND COMPLAINT MANAGEMENT				
	5.1	The Supplier must have a comprehensively designed and correctly implemented Pharmaceutical Quality System (Eudralex Chapter IV, GMP guidelines, Chapter 1 (Pharmaceutical Quality System)).		X
	5.2	Any quality issue reported to and/or recorded by Supplier that might eventually affect the quality and/or supply of the product, shall be reported to RIVM within 5 working days.		X
	5.3	A system for the investigation and documentation of any quality issue.	X	X
	5.4	Supplier should provide documented proof that the shown quality issues were processed and completed according to GMP.		X
6. CHANGE CONTROL MANAGEMENT				
	6.1	Supplier has a management system for follow-up, review, implementation and evaluation of changes.		X
	6.2	Supplier is obliged to report all changes, proceeding to introduction, regarding all changes that may affect product quality or regulatory aspects.		X
	6.3	Supplier is obliged to report all changes regarding the registration (e.g. product information, SAE, shelf life, content or availability) of the Goods to Purchaser immediately. Supplier shall inform Purchaser immediately and without any delay when there are changes (to be expected) regarding the applicable GMP certificate.		X
7. RECALL				
	7.1	Decision of product recall.	X	X
	7.2	Notification to the Dutch Inspectorate.	X	X
	7.3	Notification to the Dutch Regulatory Authority.	X	X
	7.4	Organisation of recall.	X	X
8. DOCUMENTATION				
	8.1	Keeping of documentation related to EU Release at the disposal of the competent authorities.		X
	8.2	Keeping of reference samples related to EU Release at the disposal of the competent authorities.		X
	8.3	Keeping shipping documentation at the disposal of the competent authorities.	X	X
9. ASSIGNMENT AND SUBCONTRACTS				
	9.1	Supplier shall not assign, in whole or in part, his obligations to perform under the Contract, except with RIVM's prior written consent.		X
	9.2	Supplier shall notify RIVM in writing of all subcontracts awarded under the Contract if not already specified in his bid. Such notification, in his original bid or later, shall not relieve Supplier from any liability or obligation under the Contract or under the law.		X
10. AUDITS				
	10.1	RIVM has the right to inspect the production site(s), in correspondence with the European GMP and GDP directives, during the course of the contract.	X	X

		SUMMARY OF AGREEMENTS AND RESPONSIBILITIES	RIVM	*Supplier*
	10.2	Supplier agrees that RIVM or his duly authorised representatives have the right to audit the premises where the products are stored on the basis of the European GDP Directives, before contract undersigning and during the course of the contract.	X	X
	10.3	Corrective and preventive actions resulting from the observations during the audit have to be performed in the soonest possible way and reports may be evaluated and inspected by RIVM.		X

Signatures

For RIVM

_____
(authorised signature)

Name:
Responsible Person, RIVM
Date:

Name Supplier

_____
(authorised signature)

Name:
Qualified Person, *Name Supplier*
Date:

Annex 5: Certificate of Payment

Rijksinstituut voor Volksgezondheid
en Milieu
Ministerie van Volksgezondheid,
Welzijn en Sport

CERTIFICATE OF PAYMENT

Concerning the supply of (Brand Name Vaccine)	
Batch Number	
Supplier	
SAP Article Number RIVM	
PO Number RIVM	
Number of Doses	
Number of Packages	

Acting on behalf of RIVM, the (first) undersigned, authorised for this purpose by the RIVM, hereby declares that the vaccines and necessary documents have been supplied to RIVM timely, according requirements and thereby deemed to have been accepted

Bilthoven, Date

On behalf of the RIVM,

Name	☐ Name QP ☐ Name RP
Position	☐ Qualified Person ☐ Responsible Person
Signature	

This Certificate of Payment releases only payment of the received invoice of the above mentioned batch

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Annex 6 Communication table

Purchaser		Supplier	
Function	**Contract management/ Purchaser**		
Name			
e-mail			
telephone			
Function	**Logistics**		
e-mail			
Finance	i		
Function	**Qualified/Responsible Person**		
e-mail			
telephone			
Function	**Product manager**		
Name			
e-mail			
telephone			