Doc. 1

Contract

between

the State of the Netherlands

National Institute for Public Health and the Environment (RIVM)

and

Sanofi-Aventis Netherlands B.V.

concerning the supply of

Revaxis®

contract number 4410001827

10.2.e.

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 10.2.e., 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

Sanofi-Aventis Netherlands B.V., having his office at Kampenringweg 45E, 2803 PE Gouda, The Netherlands, duly represented by 10.2.e., Head of Sanofi Pasteur Benelux,

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 DT-IPV vaccines for the Dutch Immunization Programme.

Purchaser desires to purchase DT-IPV vaccines for the agreed period as specified below in this contract in relation to the Dutch Immunization Programme (including the Dutch Caribbean).

Purchaser therefore initiated an Invitation To Tender in accordance with Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public works contracts, public supply contracts and public service contracts (hereafter "Directive 2004/18/EC"), implemented in the Netherlands by Royal Decree of 11 February 2013 on procedures for the award of public works contracts, public supply contracts and public service contracts ("Aanbestedingswet 2012").

Supplier replied to this Invitation To Tender with tender reference number Nx 61991 on July 25th, 2017.

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:

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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 DT-IPV vaccines and necessary documents to be supplied by Supplier, as specified in the Note of Information (annex 1) and Invitation To Tender number Nx 61991 (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 yearly a number of doses of the Goods as specified in paragraph 7.3.1 of the scope of supply of the relevant Invitation To Tender (annex 2) of DT-IPV vaccines. The vaccine is presented in a prefilled single-dose syringe. The prefilled syringes are suitable for use in combination with a safety needle. The packaging is a ten-pack, 10.1.c. are packed per transportation carton and each euro pallet will contain maximally 10.1.c. . 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)'. The vaccines shall have a remaining shelf life after delivery to the RIVM of at least 10.1.c. . Each delivery to the RIVM consists of at most 10.1.c.

3. Delivery

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

Movianto
Keltenweg 70
5342LP OSS

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 dvpcentraal.logistiek@rivm.nl.

3.3 Each regular delivery consists of at most 10.1.c. If Supplier fails to deliver in at most 10.1.c. a compensation of 10.1.c. per extra batch must be paid.

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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 10.1.c. 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 10.1.c. 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 send to Purchaser at the specified dates in the delivery schedule (annex 2). The safety stock can be inspected by Purchaser at all times. The delivery time for DT-IPV vaccine delivered from this labelled safety stock shall be maximum 10.1.c. weeks after a written request of Purchaser, and 10.1.c. 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 3 (three) 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 10.1.c. 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 10.1.c. 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 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 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 10.1.c. 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

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shall be liable to Purchaser for any excess costs for such similar Goods up to a maximum of 10.1.c. 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 and in accordance with Supplier's tender (annex 3).
With respect to the packaging for transportation (par. 7.5.16 ITT) the following will be required:

- One carton layer interposing & separating the first cardboard box layer with second cardboard box layer on the pallet.
- One carton layer interposing & separating the upper cardboard box layer and the cardboard box layer just below.
- One cardboard cover is placed on top of the upper cardboard box layer.
- Each corner of the pallet is covered by 4 angle cartons.
- The euro pallet configuration will be designed with crossed lines of cartons protecting from any collapse and shift as compared with a pallet configuration built in columns.
- The entire euro pallet is wrapped in plastic film.

In case these packaging specifications are not satisfactory, parties will work towards an appropriate solution.

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 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 10.1.c. .
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.

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.

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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 whether or not the negligence, omission, breach of duty or default of Supplier caused or contributed to such loss, damage or injury. 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 whether or not the negligence, omission, breach of duty or default of Supplier caused or contributed to such loss, damage or injury 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. The liability per event is limited to an amount of 10.1.c. . 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 10.1.c. 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 10.1.c. 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 10.1.c. 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 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 months starting on January 1st, 2018 and is as follows (per dose in Euro excl. VAT): € x.

9.2 The Contract Price mentioned in article 9.1 is DDP Oss, 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 months starting January 1st, 2018, (hereafter "12 Monthly Period"). For the following 12 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 Monthly Period. Purchaser has to agree in writing with the proposed Contract Price, before it is fixed for the following 12 Monthly Period.
This indexation will be the CBS (based on the Dutch "consumentenprijsindex (CPI), totaal bestedingen 2017 = 100").

The following calculation method applies:
(CPI index (new month (e.g. May)) - CPI index (old month (e.g. May))/CPI index (old month) X 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 send 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. The invoices should state the unique number as mentioned on the purchase order. Both documents should be send digitally to the following e-mail address in .pdf format: invoices@rivm.nl.

On each invoice the correct address must be stated:

RIVM Crediteuren afd.
Postbus 1
3720 BA BILTHOVEN

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 sub-contracts

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 sub-contracts 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 and 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 June 29th, 2017
Annex 2: Invitation To Tender number Nx 61991
Annex 3: Tender July 25th, 2017
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 January 1st, 2018 and will remain in force for a period of 12 (twelve) months. The Contract will be tacitly extended for a one time period of 12 (twelve) months at a maximum of [redacted] times after the first year, up to a total maximum of [redacted] months of duration unless the Purchaser decides to terminate the Contract. Purchaser may terminate the Contract at any point in time 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 or any other agreement concluded with Supplier, 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 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 Immunization Programme (e.g. expansion target groups).

The above provisions 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 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 two months (starting from the moment one party gives notice to the other party that there is a dispute), exhaust all possible 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 two languages, the Dutch version 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

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Name : 10.2.e.
Position : Director-General

Place : Bilthoven
Date : 27-09-2017

For Supplier

Sanofi-Aventis Netherlands B.V.

10.2.e.

(authorised signature)

Name : 10.2.e.
Position : Head of Sanofi Pasteur Benelux

Place : Gouda
Date : 9/10/17.

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Annex 4 Quality Agreement

		SUMMARY OF AGREEMENTS AND RESPONSIBILITIES	RIVM	Sanofi-Aventis
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 Registration number is: RVG 24534		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 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: qp@rivm.nl		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: qp@rivm.nl and dvpcentraal.logistiek@rivm.nl		X

		SUMMARY OF AGREEMENTS AND RESPONSIBILITIES	RIVM	Sanofi-Aventis
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 10 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
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
	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
		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

		SUMMARY OF AGREEMENTS AND RESPONSIBILITIES	RIVM	Sanofi-Aventis
	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	Supplier agrees that RIVM or his duly authorised representatives have the right to carry out a GMP-inspection before signing the contract.	X	X
	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

10.2.e.

(authorised signature)

Name: 10.2.e.
Responsible Person, RIVM

Date: 26 sep 2017

For Sanofi-Aventis Netherlands B.V.

10.2.e.

(authorised signature)

Name: 10.2.e.
Qualified Person, Sanofi-Aventis Netherlands B.V.

Date:

10.2.e.

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 10.2.e. [redacted]

Position ☐ Qualified & Responsible Person ☐ Responsible Person

Signature

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

10.2.e. [redacted]

Annex 6 **Communication table**

Purchaser		Supplier	
Function	**Contract management / Purchaser**		
Name	10.2.e.		
e-mail			
telephone			
Function			
e-mail			
Finance			
Function			
e-mail			
telephone			
Function			
Name			
e-mail			
telephone			
Mobile phone			

10.2.e.

Contract

between

the State of the Netherlands

National Institute for Public Health and the Environment (RIVM)

and

Merck Sharp & Dohme B.V.

concerning the supply of

Vaxelis®

contract number 4410002010

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 10.2 e, 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

Merck Sharp & Dohme B.V., having his office at Waarderweg 39, 2031 BN, Haarlem, the Netherlands, duly represented by 10.2 e, 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 DTaP-IPV-Hib-HepB vaccines for the Dutch Immunization Programme.

Purchaser desires to purchase DTaP-IPV-Hib-HepB vaccines for the agreed period as specified below in this contract in relation to the Dutch Immunization 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 67012 on January 29th, 2018.

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 DTaP-IPV-Hib-HepB vaccines and necessary documents to be supplied by Supplier, as specified in the two Notes of Information (Annex 2) and Invitation To Tender number Nx 67012 (Annex 3) 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 "Revised Annex H – Quotation form, delivery schedule (April, 2018)" (Annex 1) of the Contract, the two Notes Of Information (Annex 2), the Invitation To Tender (Annex 3) and Supplier's Tender (Annex 4).

2.2 Purchaser desires to purchase yearly a number of doses of the Goods as specified in paragraph 7.3.1 of the scope of supply of the relevant Invitation To Tender (Annex 3) of DTaP-IPV-Hib-HepB vaccines.

The vaccine is presented as a prefilled single dose syringe without a needle. The prefilled syringes are suitable for use in combination with a safety needle. The packaging is a ten-pack, [redacted] are packed per transportation carton. All labelling and leaflets are only 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)'. The vaccines shall have a remaining shelf life after delivery to the RIVM of at least [redacted] The safety stock is of a different batch number than already delivered to the RIVM. Each delivery to the RIVM consists of at most [redacted]
Besides ten-packs, a minimum of [redacted] doses per year will be ordered as single-packs without needle or with a separate needle in the packaging. All labelling and leaflets are in the Dutch language. Two additional Western European languages are acceptable for these single packs.

3. Delivery

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

Movianto
Keltenweg 70
5342LP OSS

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 1 of the Contract. For the purpose of a smooth delivery Supplier shall inform Purchaser not less than 2 (two) weeks before the date of delivery via dvpcentraal.logistiek@rivm.nl.

3.3 Each regular delivery consists of at most [redacted] If Supplier fails to deliver in at most [redacted] a compensation of [redacted] 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 3), 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 [redacted] 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 [redacted] 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 send to Purchaser at the specified dates in the delivery schedule (Annex 1 of the Contract). 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 DTaP-IPV-Hib-HepB vaccine delivered from this labelled safety stock shall be maximum [redacted] weeks after a written request of Purchaser, and [redacted] 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 1 of the Contract, expires 3 (three) 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 [redacted] 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 [redacted] 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 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 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 [redacted] 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 [redacted] 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 3 (ITT) and in accordance with Supplier's tender (Annex 4).

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 3 and in accordance with Supplier's Tender (Annex 4) 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 [redacted]. 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.

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 insofar the negligence, omission, breach of duty or default of Supplier caused or contributed to such loss, damage or injury. 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. Supplier shall further indemnify Purchaser from all losses, liabilities, claims, costs, damages and expenses resulting from the Goods supplied insofar the negligence, omission, breach of duty or default of Supplier caused or contributed to such loss, damage or injury 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. The liability per event is limited to an amount of [10.1.c] The entire liability of the Supplier is limited to an amount of [10.1.c] 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 [10.1.c] 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 [10.1.c] 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 [10.1.c] 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 months starting on June 1st, 2018 and is as follows (per dose in Euro excl. VAT): € x.

9.2 The Contract Price mentioned in article 9.1 is DDP Oss, 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 months starting June 1st, 2018, (hereafter "12 Monthly Period"). For the following 12 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 Monthly Period. Purchaser has to agree in writing with the proposed Contract Price, before it is fixed for the following 12 Monthly Period.
This indexation will be the CBS (based on the Dutch "consumentenprijsindex (CPI), totaal bestedingen 2017 = 100").

The following calculation method applies:
(CPI index (new month (e.g. October)) - CPI index (old month (e.g. October))/CPI index (old month) **X** 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 6). Subsequently, this Certificate of Payment will be send 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. The invoices should state the unique number as mentioned on the purchase order. Both documents should be send digitally to the following e-mail address in .pdf format: invoices@rivm.nl.

On each invoice the correct address must be stated:

RIVM Crediteuren afd.
Postbus 1
3720 BA BILTHOVEN

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 sub-contracts

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 sub-contracts 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: Revised Annex H – Quotation form, delivery schedule (April, 2018)
Annex 2: Two Notes Of Information belonging to the Invitation To Tender - October 24th, 2017 and November 2nd, 2017
Annex 3: Invitation To Tender number Nx 67012
Annex 4: Tender January 29th, 2018
Annex 5: Quality Agreement
Annex 6: Certificate of Payment
Annex 7: 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 June 1st, 2018 and will remain in force for a period of 12 (twelve) months. The Contract will be tacitly extended for a one time period of 12 (twelve) months at a maximum of [redacted] times after the first year, up to a total maximum of [redacted] months of duration unless the Purchaser decides to terminate the Contract. Purchaser may terminate the Contract at any point in time 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 or any other agreement concluded with Supplier, 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 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 Immunization Programme (e.g. expansion target groups).

The above provisions 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 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 two months (starting from the moment one party gives notice to the other party that there is a dispute), exhaust all possible 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 7.

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 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	For Supplier
on behalf of the Dutch Minister of Public Health, Welfare and Sport	Merck Sharp & Dohme B.V.
10.2.e	10.2.e
(auth	(authorised signature)
Name : 10.2.e	Name : 10.2.e
Position : Director-General	Position : Managing Director
Place : Bilthoven	Place : Haarlem
Date : 16-04-2018	Date : 23-04-18

Doc. 2

Annex 1 Revised Annex H – Quotation form, delivery schedule (April, 2018)

The delivery dates and the quantity of vaccines needed by Purchaser are listed in the table below.

Delivery date	Number of doses changeover to another vaccine	Safety stock supplier** # if changeover to another vaccine
July, 2018	10.1.c.	10.1.c.
October, 2018		
December, 2018		
March, 2019		
Delivery dates optional years	**Number of doses***	**Safety stock supplier** #**
June, 2019	10.1.c.	10.1.c.
September, 2019		
December, 2019		
March, 2020		
June, 2020		
September, 2020		
December, 2020		
March, 2021		
June, 2021		
September, 2021		
December, 2021		
March, 2022		

* 10.1.c.
10.1.c. The exact number of doses required (if different from the numbers stated above) will be ordered by Purchaser as soon as possible but at least six months before the required delivery date to the safety stock. Purchaser and Supplier will consult each other with regard to the delivery dates of extra doses eventually ordered by Purchaser.

** The actual number of doses in safety stock will be adjusted to the number of doses ordered for the next delivery.

The last safety stock of the first contract year and each optional year shall be labelled, unless Purchaser decides not to extend the contract for the optional years. Only in that case the safety stock is allowed to be unlabelled.

Assessment methodology

- The supplier who can guarantee the labelled safety stock of 175,000 doses on July 3th, 2018 receives 100 points (see 7.4.3)
- For every week of delay for the first safety stock of 175,000 doses to be available at the Supplier's site, 10 points are deducted to a maximum of 40 points deduction.

Labelled safety stock available on July 3th, 2018	10.1.c.
If no, date to be guaranteed for the safety stock	-

Single doses

The first delivery of 2.500 single doses will take place in July 2018.

The undersigned hereby declares that he/she unconditionally agrees to the above mentioned delivery schedule.

Name	10.2.e.
Position	
Organisation	
Signature	
Date	4-4-18

Annex 5 Quality Agreement

		SUMMARY OF AGREEMENTS AND RESPONSIBILITIES	RIVM	MSD
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/1/15/1079/001 (OP1) and EU/1/15/1079/002 (OP2)		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 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: gp@rivm.nl		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: gp@rivm.nl and dvpcentraal.logistiek@rivm.nl		X

		SUMMARY OF AGREEMENTS AND RESPONSIBILITIES	RIVM	MSD
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 10 doses of the product, each clearly marked with the registration number.		X
	3.3	All labelling is in the Dutch language. In case single dose packs will be supplied, 2 additional Western European languages, besides the Dutch language are acceptable. All labelling is suitable for cold storage.		X
	3.4	Each packaging contains a leaflet for patients in the Dutch language. In case single dose packs will be supplied, 2 additional Western European languages, besides the Dutch language are acceptable.		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
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
	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

		SUMMARY OF AGREEMENTS AND RESPONSIBILITIES	RIVM	MSD
	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	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 GMP/GDP Directives, before contract undersigning and during the course of the contract.	X	X
	10.2	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

10.2.e

(authorised signature)

Name: 10.2.e
Responsible Person, RIVM

Date: 16-apr-2018

For Merck Sharp & Dohme B.V.

10.2.e

(authorised signature)

Name: 10.2.e
Qualified Person, Merck Sharp & Dohme B.V.

Date: 24 APR 2018

Annex 6: 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 10.2.e

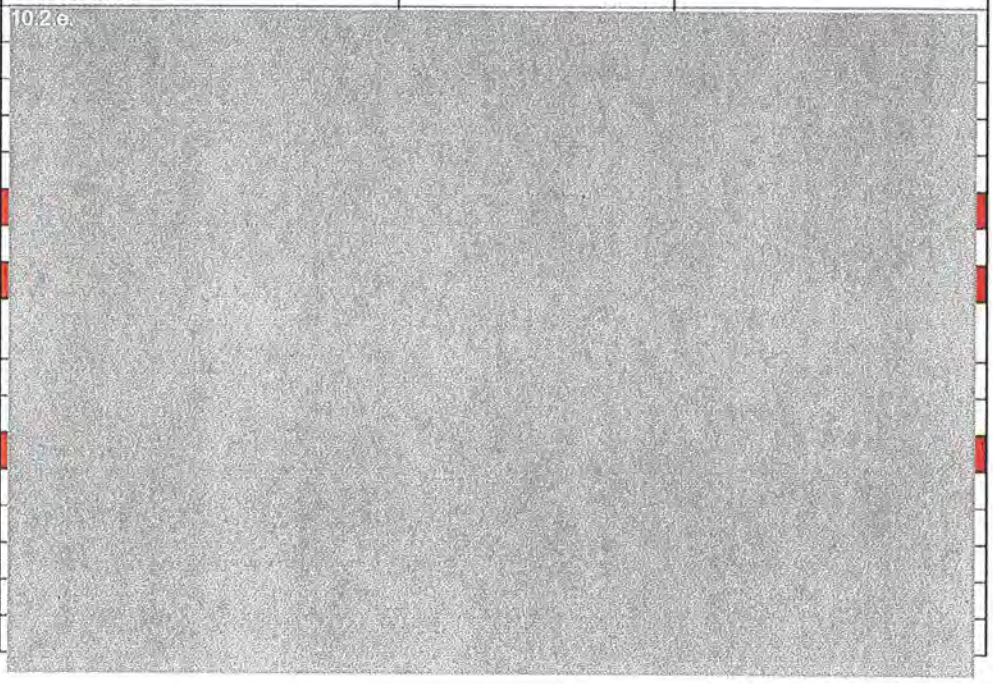
Position ☐ Qualified & Responsible Person ☐ Responsible Person

Signature

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

Annex 7 **Communication table**

Purchaser		Supplier	
Function	**Contract management / Purchaser**	**Demand planner**	**Assoc. Dir, Commercial Contracting**
Name			
e-mail			
telephone			
Function			
e-mail			
Finance			
Function			
e-mail			
telephone			
Function			
Name			
e-mail			
telephone			
Mobile phone			



Doc. 3

Contract

between

the State of the Netherlands

National Institute for Public Health and the Environment (RIVM)

and

GlaxoSmithKline BV

concerning the supply of

Boostrix Polio ®

contract number 4410002032

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 10.2.e. , 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

GlaxoSmithKline BV, having his office at Huis ter Heideweg 62, 3705 LZ, Zeist, The Netherlands, duly represented by 10.2.e. , General Manager & Vice President,

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 TdaP-IPV vaccines for the Dutch Immunization Programme.

Purchaser desires to purchase TdaP-IPV vaccines for the agreed period as specified below in this contract in relation to the Dutch Immunization 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 80661 on April 10th, 2018.

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 TdaP-IPV vaccines and necessary documents to be supplied by Supplier, as specified in the Note of Information (Annex 1) and Invitation To Tender number Nx 80661 (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 Notes Of Information (Annex 1), the Invitation To Tender (Annex 2) and Supplier's Tender (Annex 3).

2.2 Purchaser desires to purchase yearly a number of doses of the Goods as specified in paragraph 7.3.1 of the scope of supply of the relevant Invitation To Tender (Annex 2) of TdaP-IPV vaccines.

The vaccine is presented as a prefilled single dose syringe without a needle. The prefilled syringes are suitable for use in combination with a safety needle. The packaging is a ten-pack, [redacted] 10.1.c. are packed per transportation carton. All labelling and leaflets are only 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)'. The vaccines shall have a remaining shelf life after delivery to the RIVM of at least 10.1.c. . The safety stock is of a different batch number than already delivered to the RIVM. Each delivery to the RIVM consists of at most 10.1.c. Purchase orders will be submitted 6 months before the required delivery to the safety stock.

3. Delivery

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

Movianto
Keltenweg 70
5342LP OSS

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 dvpcentraal.logistiek@rivm.nl.

3.3 Each regular delivery consists of at most 10.1.c. If Supplier fails to deliver in at most 10.1.c. a compensation of 10.1.c. 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 10.1.c. 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 10.1.c. 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 safety stock can be inspected by Purchaser at all times. The delivery time for TdaP-IPV vaccine delivered from this labelled safety stock shall be maximum 10.1.c. weeks after a written request of Purchaser, and 10.1.c. 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 3 (three) 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 10.1.c. 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 10.1.c. 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 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 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 10.1.c. 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 10.1 c. 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 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 of 10.1 c. s. 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.

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 [10.1c] 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 € [10.1c] 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 [10.1c] 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 [10.1c] 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 24 months starting on July 1st, 2018 and is as follows (per dose in Euro excl. VAT): € x.

9.2 The Contract Price mentioned in article 9.1 is DDP Oss, 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 24 months starting July 1st, 2018. For the following 12 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 Contract Period. Purchaser has to agree in writing with the proposed Contract Price, before it is fixed for the following 12 Monthly Period.
This indexation will be the CBS (based on the Dutch "consumentenprijsindex (CPI), totaal bestedingen 2018 = 100").

The following calculation method applies:
(CPI index (new month (e.g. November)) - CPI index (old month (e.g. November)/CPI index (old month) X 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 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. The invoices should state the unique number as mentioned on the purchase order. Both documents should be sent digitally to the following e-mail address in .pdf format: invoices@rivm.nl.

On each invoice the correct address must be stated:

RIVM Crediteuren afd.
Postbus 1
3720 BA BILTHOVEN

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 sub-contracts

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 sub-contracts 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	Two Notes Of Information belonging to the Invitation to Tender – March 13th and March 22nd, 2018
Annex 2	Invitation To Tender number Nx 80661
Annex 3	Tender April 10th, 2018
Annex 4	Quality Agreement
Annex 5	Certificate of Payment
Annex 6	Communication

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 July 1st, 2018 and will remain in force for a period of 24 (twenty-four) months. The Contract will be tacitly extended for a one time period of 12 (twelve)

months at a maximum of [redacted] times after the first contract period of 24 (twenty-four) months, up to a total maximum of [redacted] months of duration unless the Purchaser decides to terminate the Contract. Purchaser may terminate the Contract at any point in time 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 or any other agreement concluded with Supplier, 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 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 Immunization Programme (e.g. expansion target groups).

The above provisions 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 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 two months (starting from the moment one party gives notice to the other party that there is a dispute), exhaust all possible 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 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		For Supplier	
on behalf of the Dutch Minister of Public Health,		GlaxoSmithKline BV	
Name	: 10.2.e.	Name	: 10.2.e.
Position	: Director-General	Position	: General Manager & Vice President
Place	: Bilthoven	Place	: Zeist
Date	:	Date	: 23 mei 2011

For Supplier

GlaxoSmithKline BV

_____

(authorised signature)

Name :
Position :

Place :
Date :

Annex 4 Quality Agreement

		SUMMARY OF AGREEMENTS AND RESPONSIBILITIES	RIVM	GSK
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 Registration number is: RVG 35123		X
2.		***Rlease 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 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: qp@rivm.nl		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: qp@rivm.nl and dvpcentraal.logistiek@rivm.nl		X

SUMMARY OF AGREEMENTS AND RESPONSIBILITIES			RIVM	GSK
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 10 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
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
	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

		SUMMARY OF AGREEMENTS AND RESPONSIBILITIES	RIVM	GSK
	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	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 GMP/GDP Directives, before contract undersigning and during the course of the contract.	X	X
	10.2	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

* RIVM can only initiate a product recall

Signatures

For RIV 10.2.e.

(author

Name: 10.2.e.
Responsible Person, RIVM

Date: 01-MAY-2018

10.2.e.

For GlaxoSmithKline BV

10.2.e.

(authorised signature)

10.2.e.

Date: 22-05-2018

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 10.2.e.

Position ☐ Qualified & Responsible Person ☐ Responsible Person

Signature

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

Annex 6 Communication table

Purchaser		Supplier	
Function	**Contract management / Purchaser**		
Name	10.2.e.		
e-mail			
telephone			
Function			
e-mail			
Finance			
Function			
e-mail			
telephone			
Function			
Name			
e-mail			
telephone			
Mobile phone			

Doc. 3

Annex 6 **Communication table**

Purchaser		Supplier	
Function	**Contract management / Purchaser**	**Tender and Supply Manager**	
Name	10.2.e.		
e-mail			
telephone			
Function			
e-mail			
Finance			
Function			
e-mail			
telephone			
Function			
Name			
e-mail			
telephone			
Mobile phone			

Inzien uittreksel - GlaxoSmithKline B.V. (27141630)

Kamer van Koophandel, 16 mei 2018 - 15:45

KvK-nummer 27141630

Woonadressen zijn geen openbare gegevens en alleen beschikbaar voor in artikel 51 Handelsregisterbesluit genoemde organisaties.

Rechtspersoon

RSIN	001470772
Rechtsvorm	Besloten Vennootschap
Statutaire naam	GlaxoSmithKline B.V.
Statutaire zetel	Zeist
Datum akte van oprichting	24-09-1921
Datum akte laatste statutenwijziging	29-10-2008
Geplaatst kapitaal	EUR 115.000,00
Gestort kapitaal	EUR 115.000,00
Deponering jaarstuk	De jaarrekening over boekjaar 2016 is gedeponeerd op 30-10-2017.

Onderneming

Handelsnamen	GlaxoSmithKline B.V. GW GSK SB GlaxoWellcome SmithKline Beecham GlaxoSmithKline Amsterdam
Startdatum onderneming	23-06-1921
Activiteiten	SBI-code: 46461 - Groothandel in farmaceutische producten SBI-code: 78202 - Uitleenbureaus SBI-code: 2120 - Vervaardiging van farmaceutische producten (geen grondstoffen) SBI-code: 2059 - Vervaardiging van overige chemische producten
Werkzame personen	420

Vestiging

Vestigingsnummer	000017838762
Handelsnamen	GlaxoSmithKline B.V. GW GSK SB GlaxoWellcome SmithKline Beecham GlaxoSmithKline Amsterdam
Bezoekadres	Huis ter Heideweg 62, 3705LZ Zeist
Postadres	Postbus 780, 3700AT Zeist
Telefoonnummer	0306938100
Datum vestiging	23-06-1921

Deze rechtspersoon drijft de vestiging sinds	[redacted]27-01-1972
Activiteiten	SBI-code: 46461 - Groothandel in farmaceutische producten SBI-code: 78202 - Uitleenbureaus SBI-code: 2120 - Vervaardiging van farmaceutische producten (geen grondstoffen) SBI-code: 2059 - Vervaardiging van overige chemische producten De import, koop, verkoop, opslag en distributie van farmaceutische producten, alsmede het verrichten of doen verrichten van klinisch onderzoek in het kader van de ontwikkeling van zodanige producten. Ter beschikking stellen van arbeidskrachten.
Werkzame personen	420

Enig aandeelhouder

Naam	S.R. One International B.V.
Bezoekadres	Huis ter Heideweg 62, 3705LZ Zeist
Ingeschreven onder KvK-nummer	27135195
Enig aandeelhouder sedert	20-12-2006

Bestuurders

Naam	van Asperen, Marcel
Geboortedatum en -plaats	07-10-1975, Boskoop
Adres	Nieuwstraat 124, 2771XE Boskoop
Datum in functie	31-05-2015 (datum registratie: 01-06-2015)
Titel	Directeur
Bevoegdheid	Gezamenlijk bevoegd (met andere bestuurder(s), zie statuten)
Naam	Gijbels, Daniël
Geboortedatum en -plaats	22-07-1970, Amsterdam
Adres	Spaarndammerstraat 9 B, 1013SR Amsterdam
Datum in functie	15-05-2018 (datum registratie: 16-05-2018)
Titel	Directeur
Bevoegdheid	Gezamenlijk bevoegd (met andere bestuurder(s), zie statuten)

Gegevens zijn vervaardigd op 16-05-2018 om 15.45 uur.

Contract

between

the State of the Netherlands

National Institute for Public Health and the Environment (RIVM)

and

Pfizer B.V.

concerning the supply of

Nimenrix®

contract number 4410002170

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 [redacted] 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

Pfizer B.V., having his office at Rivium Westlaan 142, 2909 LD, Capelle aan den IJssel, The Netherlands, duly represented by [redacted] General Manager,

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 a catch-up vaccination campaign with meningococcal ACWY (MenACWY) vaccine for the Dutch Immunization Programme.

Purchaser desires to purchase MenACWY vaccines for the agreed period as specified below in this contract in relation to the Dutch Immunization 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 97596 on September 18th, 2018.

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 MenACWY vaccines and necessary documents to be supplied by Supplier, as specified in the Note of Information (Annex 2) and Invitation To Tender number Nx 97596 (Annex 3) 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 2), the Invitation To Tender (Annex 3) and Supplier's Tender (Annex 4).

2.2 Purchaser desires to purchase a number of doses of the Goods as specified in paragraph 7.3.1 of the scope of supply and annexes H-A and H-B of the relevant Invitation To Tender (Annex 1b, Annex 1c and Annex 3) of MenACWY vaccines.

10.1.c

The vaccine is presented as a single dose vial with the MenACWY components and a prefilled single dose syringe without needle, with reconstitution fluid. The prefilled syringes are suitable for use in combination with a safety needle. The packaging is a ten-pack, 10.1.c doses) are packed per transportation carton. 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)'. The vaccines shall have a remaining shelf life after delivery to the RIVM of at least 10.1.c 10.1.c Each delivery to the RIVM consists of at most 10.1.c

3. Delivery

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

Movianto
Keltenweg 70
5342LP OSS

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 dvpcentraal.logistiek@rivm.nl.

3.3 Each regular delivery consists of at most [redacted] If Supplier fails to deliver in at most of [redacted] a compensation of [redacted] 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 3), 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 [redacted] 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 [redacted] 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 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 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 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 [redacted] of the Contract Price of the non-delivered Goods and/or delivered Goods which are not in conformity with the agreed specifications.

3.8 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 [redacted] 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 3 (ITT) and in accordance with Supplier's tender (Annex 4).

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 3 and in accordance with Supplier's Tender (Annex 4) 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 [redacted] 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 [redacted]

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 [redacted] 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 [redacted] 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 [redacted] 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 period of 12 months starting on January 1st, 2019 and is as follows (per dose in Euro excl. VAT): € x for doses of Lot 1 and € x for doses of Lot 2 (Annex 1a).

9.2 The Contract Price mentioned in article 9.1 is DDP Oss, 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.

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 6). Subsequently, this Certificate of Payment will be sent to Supplier within a period of maximum 2 (two) weeks after the acceptance of the delivery by Purchaser's QP-department.

10.2 Supplier will prepare proper electronic invoices and will send the invoices together with the signed Certificate of Payment digitally to Purchaser. The invoices should state the unique number as mentioned on the purchase order. Both documents should be sent digitally to the following e-mail address in .pdf format: invoices@rivm.nl.

On each invoice the correct address must be stated:

RIVM Crediteuren afd.
Postbus 1
3720 BA BILTHOVEN

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 sub-contracts

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 sub-contracts 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 1a	Revised Annex G Quotation form, financial offer
Annex 1b	Revised Annex I-A Acceptation of the scope of Supply
Annex 1c	Revised Annex I-B Explanation of the scope of supply
Annex 2	Note Of Information belonging to the Invitation to Tender September 6th, 2018
Annex 3	Invitation To Tender number Nx 97596
Annex 4	Tender July 24th, 2018
Annex 5	Quality Agreement
Annex 6	Certificate of Payment
Annex 7	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 January 1st, 2019 and will remain in force for a period of 12 (twelve) months. Purchaser may terminate the Contract at any point in time 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 or any other agreement concluded with Supplier, in full or in part with immediate effect, except for (iv) for which a notice period of 3 (three) weeks 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 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.

The above provisions 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 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 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 7.

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 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 Purchas

on behalf of t alth,
Welfare and

(authorised signature)

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

For Supplier

Pfizer B.V.

(a

Name :
Position : Country Manager
Place : Capelle aan den IJssel
Date : 2018-10-11

For Supplier

Pfizer B.V.

(authorised signa

Name :
Position : Finance Director
Place : Capelle aan den IJssel
Date : 11/10/2018

Annex 5 Quality Agreement

		SUMMARY OF AGREEMENTS AND RESPONSIBILITIES	RIVM	Pfizer
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/1/12/767/002		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 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: qp@rivm.nl		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: qp@rivm.nl and dvpcentraal.logistiek@rivm.nl	N.A.	N.A.

		SUMMARY OF AGREEMENTS AND RESPONSIBILITIES	RIVM	Pfizer
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 10 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
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
	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

10.2
4 oct 2018

		SUMMARY OF AGREEMENTS AND RESPONSIBILITIES	RIVM	Pfizer
	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
	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

10.2.e

Name: 10.2.e
Responsible Person, RIVM
Date: 04-okt-2018

For Pfizer B.V

10.2.e

(authorised s

Name 10.2.e
Qualified Person, *Supplier*
Date: 11-OKT-2018

Annex 6: 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 10.2.e

Position ☐ Qualified & Responsible Person ☐ Responsible Person

Signature

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

Annex 7 Communication table

Purchaser		Supplier	
Function	**Contract management / Purchaser**	**Finance Director**	**Legal Director**
Name	10.2.e.		
e-mail			
telephone			
Function	**Logistics**	**Demand Manager**	
Name	10.2.e.		
e-mail			
Mobile phone			
Finance	invoices@rivm.nl		
Function	**Qualified / Responsible Person**	**Responsible person (GDP)**	**AQO Officer**
Name	10.2.e.		
e-mail			
telephone			
Mobile phone			
Function	**Productmanager**	**Commercial Lead Vaccines**	**Market Access Manager**
Name	10.2.e.		
e-mail			
telephone			
Mobile phone			

Doc. 5

Contract

between

the State of the Netherlands

National Institute for Public Health and the Environment (RIVM)

and

GlaxoSmithKline BV

concerning the supply of

Synflorix ®

contract number 4410002368

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 10.2.e. 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

GlaxoSmithKline B.V., having his office at Huis ter Heideweg 12, 3705 LZ Zeist, The Netherlands, duly represented by 10.2.e., General Manager & Vice President,

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 Pneumococcal conjugate vaccines for the Dutch Immunisation Programme.

Purchaser desires to purchase Pneumococcal conjugate vaccines 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 114530 on May 14th, 2019.

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 Pneumococcal conjugate vaccines and necessary documents to be supplied by Supplier, as specified in the Note Of Information (Annex 1) and Invitation To Tender number Nx 114530 (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 yearly a number of doses of the Goods as specified in paragraph 7.3.1 and 7.3.2 of the scope of supply of the relevant Invitation To Tender (Annex 2) of Pneumococcal conjugate vaccines.

The vaccine is presented as a prefilled single dose syringe without a needle. The prefilled syringes are suitable for use in combination with a safety needle. The packaging is a ten-pack, 10.1.c. ten packs 10.1.c. are packed per transportation carton. All labelling and leaflets are in the Dutch and German 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)'. The vaccines shall have a remaining shelf life after delivery to the RIVM of at least 10.1.c.. The safety stock is of a different batch number than already delivered to the RIVM. Each delivery to the RIVM consists of at most 10.1.c.. Besides ten-packs, up to 10.1.c. doses per year will be ordered as single-packs without needle in the packaging. All labelling and leaflets are in the Dutch language. Two additional Western European languages are acceptable for these single packs.

3. Delivery

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

Movianto
Keltenweg 70
5342LP OSS

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 dvpcentraal.logistiek@rivm.nl.

3.3 Each regular delivery consists of at most 10.1.c. . If Supplier fails to deliver in at most 10.1.c. , a compensation of €10.1.c. 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 10.1.c. 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 10.1. 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 safety stock can be inspected by Purchaser at all times. The delivery time for Pneumococcal conjugate vaccine delivered from this labelled safety stock shall be maximum 10.1.c. weeks after a written request of Purchaser, and 10.1 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 3 (three) 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 10. 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 10.1.c. 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 10.1.c. 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 10.1.c. 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 10.1. 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 10.1.c 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 10.1.c 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 10.1.c 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 10.1.c 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 January 1st, 2020 and is as follows (per dose in Euro excl. VAT): € x.

9.2 The Contract Price mentioned in article 9.1 is DDP to Oss, 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 January 1st, 2020. 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 the CBS (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 to Supplier within a period of maximum 2 (two) weeks after the acceptance of the delivery by Purchaser's QP department.

10.2 Supplier will prepare proper electronic invoices and will send the invoices together with the signed Certificate of Payment digitally to Purchaser. The invoices should state the unique number as mentioned on the purchase order. Both documents should be sent via electronic invoicing, Supplier will receive the instructions to be followed from the Purchaser.

On each invoice the correct address must be stated:

RIVM Crediteuren afd.
Postbus 1
3720 BA BILTHOVEN

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 sub-contracts

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 sub-contracts 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 April 16th, 2019
Annex 2 Invitation To Tender number Nx 114530
Annex 3 Tender May 21st, 2019
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 January 1st, 2020 and will remain in force for a period of 12 (twelve) months. The Contract will be tacitly extended for a one time period of 12 (twelve) months at a maximum of 10.1.c. times after the first year, up to a total maximum of 10.1.c. 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 or any other agreement concluded with Supplier, 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 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 [10.2.e.] c Health, Welfare and Spo

10.2.e.

Prof. dr. ir. J. Brug
Director-General

Place : Bilthoven
Date :

For Supplier

GlaxoSmithKline B.V.

10.2.e.

Name : 10.2.e.
Position : General Manager & Vice president
Place : Zeist
Date : 24.06.2019

For Supplier
GlaxoSmithKline B.V.

10.2.e.

Name : 10.2.e.
Position : Director Vaccines
Place : Zeist
Date : 24.06.2019

Annex 4 Quality Agreement

		SUMMARY OF AGREEMENTS AND RESPONSIBILITIES	RIVM	GSK
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 certificate of GMP compliance available.		X
	1.5	Supplier has a valid manufacturing license available.		X
	1.6	The product is registered in the Netherlands EU registration number: EU/1/09/508/002		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* *In case batch number (and/or packaging index) on the 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: qp@rivm.nl		X
	2.3	A Certification of Transport Release is sent by RIVM to the supplier upon arrival of the product. Supplier fills in wether the product may be released after transport and sends it to qp@rivm.nl at earliest convenience.	X	X
	2.4	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: qp@rivm.nl and dvpcentraal.logistiek@rivm.nl		X

		SUMMARY OF AGREEMENTS AND RESPONSIBILITIES	RIVM	GSK
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 10 doses of the product, each clearly marked with the registration number.		X
	3.3	All labelling is in the Dutch language. Only one additional Western European language is allowed: German. All labelling is suitable for cold storage.		X
	3.4	Each packaging contains a leaflet for patients in the Dutch language. Only one additional Western European language is allowed: German.		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 at least a CMR and packing list. It should be possible to link all documentation to each other.		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 are available.		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	Temperature deviation during shipment are immediately reported to RIVM.		X

		SUMMARY OF AGREEMENTS AND RESPONSIBILITIES	RIVM	GSK
	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	GSK
	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

* RIVM can only initiate a product recall

Signa

For R

(autho e)

Name: 10.2.e. Responsible Person
Responsible Person, RIVM
Date: 03 JUN 2019.

For GlaxoSmithKline B.V.

10.2.e.

(authorised signature)

Name: 10.2.e.
Qualified Person, GSK, Responsible Person
Date: 20 JUN 2019

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 10.2.e. [redacted]

Position
☐ Qualified & Responsible Person
☐ Responsible Person

Signature

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

Annex 6 Communication table

Purchaser		Supplier	
Function	**Contract management / Purchaser**	**Function**	**Tender & Supply manager**
Name	10.2.e.	Name	10.2.e.
e-mail		e-mail	
telephone		telephone	
Function			
e-mail			
Finance		Finance	
Function		**Function**	
e-mail		e-mail	
telephone		telephone	
Function		**Function**	
Name		Name	
e-mail		e-mail	
telephone		telephone	

Doc. 5

Doc. 6

Contract

between

the State of the Netherlands

National Institute for Public Health and the Environment (RIVM)

and

Merck Sharp & Dohme B.V.

concerning the supply of

M-M-RVaxpro

contract number 4410002402

10.2.e.

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 [redacted], 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

Merck Sharp & Dohme B.V., having his office Waarderweg 39, 2031 BN Haarlem, The Netherlands, duly represented by [redacted], 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 MMR vaccines for the Dutch Immunisation Programme.

Purchaser desires to purchase MMR vaccines 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 119951 on July 22nd, 2019.

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:

10.2.e.

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 MMR vaccines and necessary documents to be supplied by Supplier, as specified in the Note Of Information (Annex 1) and Invitation To Tender number Nx 119951 (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 10.1.c. 10.1.c. 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 MMR vaccines. 10.1.c. Purchaser will place the regular orders six (6) months before the required delivery to the safety stock. In case optional doses will be ordered, Purchaser will place regular orders six (6) months before delivery to the safety stock. 10.1.c.

The vaccine is a single dose vial with the MMR components and a prefilled single-dose syringe without a needle, with reconstitution fluid. The prefilled syringes are suitable for use in combination with a safety needle. The packaging is a ten-pack, 10.1.c. ten packs 10.1.c. are packed per transportation carton. 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)'. The vaccines shall have a remaining shelf life after delivery to the RIVM of at least 10.1.c. The safety stock is of a different batch number than already delivered to the RIVM. Each delivery to the RIVM consists of at most 10.1.c.

3. Delivery

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

Movianto
Keltenweg 70
5342LP OSS

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.

10.2.e.

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 dvpcentraal.logistiek@rivm.nl.

3.3 Each regular delivery consists of at most 10.1.c. If Supplier fails to deliver in at most 10.1.c., a compensation 10.1.c. 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 10. 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 10.1.c. 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 MMR vaccine delivered from this labelled safety stock shall be maximum 10.1.c. weeks after a written request of Purchaser, and 10.1. 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 3 (three) 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 10.1.c. 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 10.1.c. 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 10.1.c. percent of the Contract Price of the non-delivered Goods and/or delivered Goods which are not in conformity with the agreed specifications.

10.2.e.

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 10.1.c. 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 10.1. 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 € 10.1.c. 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 € 10.1.c. 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 10.1.c. 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 10.1.c. 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.

10.2.e.

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 January 1st, 2020 and is as follows (per dose in Euro excl. VAT): € x.

9.2 The Contract Price mentioned in article 9.1 includes delivery on a DDP basis to Oss, 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 January 1st, 2020. 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 June 27th, 2019
Annex 2: Invitation To Tender number Nx 119951
Annex 3: Tender July 22nd, 2019
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 January 1st, 2020 and will remain in force for a period of 12 (twelve) months. The Contract will be tacitly extended for a one time period of 12 (twelve) months at

a maximum of 10.1.c. times after the first year, up to a total maximum of 10.1.c. 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.

10.2.e.

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 Purc[redacted] olic Health, Welfare

(authoris[redacted]

Name : [redacted]
Position : Director-General
Place : Bilthoven
Date : 31-7-2019

For Supplier

Merck Sharp & Dohme B.V.

[redacted]

Name : [redacted]
Position : Managing Director
Place : Haarlem
Date : 27/8/2019

For Supplier
Merck Sharp & Dohme B.V.

NVT

(authorised signature)

Name :
Position :

Place :
Date :

Annex 4 Quality Agreement

		SUMMARY OF AGREEMENTS AND RESPONSIBILITIES	RIVM	MSD
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: qp@rivm.nl		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: qp@rivm.nl and dvpcentraal.logistiek@rivm.nl		X

		SUMMARY OF AGREEMENTS AND RESPONSIBILITIES	RIVM	MSD
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 10 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	MSD
	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	MSD
	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 10.2.e.

(authorise 10.2.e.

Name: Responsible Person
Responsible Person, RIVM
Date: 23-JUL-2019

For Merck Sharp & Dohme B.V.

10.2.e.

(authorised signature)

Name: 10.2.e.
Qualified Person, MSD
Date: 22 AUG 2019

10.2.e.

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 10.2.e.

Position ☐ Qualified & Responsible Person ☐ Responsible Person

Signature

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

10.2.e.

Annex 6 Communication table

Purchaser		Supplier	
Function	**Contract management/ Purchaser**	Demand planner	Assoc. Dir, Commercial Contracting
Name	10.2.e.		
e-mail			
telephone			
Function	**Logistics**	Haarlem orderdesk	
e-mail	10.2.e.		
Finance			
Function	**Qualified/Responsible Person**	Quality Responsible Person	cc Ado van Langerak
e-mail	10.2.e.		
telephone			
Function	**Product manager**	Ass. Dir, Comm. Contracting	Demand planner
Name	10.2.e.		
e-mail			
telephone			

10.2.e.

Doc. 6

Annex 6 **Communication table**

Purchaser		Supplier	
Function	**Contract management/ Purchaser**		
Name	10.2.e.		
e-mail			
telephone			
Function	**Logistics**		
e-mail	10.2.e.		
Finance			
Function	**Qualified/Responsible Person**		
e-mail	10.2.e.		
telephone			
Function	**Product manager**		
Name	10.2.e.		
e-mail			
telephone			

10.2.e.

Doc. 6

Doc. 7

Contract

between

the State of the Netherlands

National Institute for Public Health and the Environment (RIVM)

and

GlaxoSmithKline B.V.

concerning the supply of

Boostrix®

contract number 4410002397

10.2.e.

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 10.2.e. 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

GlaxoSmithKline B.V., having his office at Huis ter Heideweg 12, 3705 LZ Zeist, The Netherlands, duly represented by 10.2.e. General Manager & Vice President,

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 Tdap (-IPV) vaccines.

Purchaser desires to purchase Tdap (-IPV) vaccines for the agreed period as specified below in this contract for maternal immunisation.

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 118921 on July 5th, 2019.

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:

10.2.e.

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 Tdap (-IPV) vaccines and necessary documents to be supplied by Supplier, as specified in the Note Of Information (Annex 1) and Invitation To Tender number Nx 118921 (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 10.1.c. 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 Tdap (-IPV) vaccines. For the first contract year 10.1.c. doses are required. 10.1.c. 10.1.c. Furthermore Purchaser can order up to 10.1.c. per year as single-dose packs without needle. Purchaser will place the regular orders six (6) months before the required delivery to the Safety Stock. 10.1.c. 10.1.c.

The vaccine is presented as a prefilled single dose syringe without a needle. The prefilled syringes are suitable for use in combination with a safety needle. The packaging is a ten-pack, 10.1.c. ten packs 10.1.c. are packed per transportation carton. 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)'. The vaccines shall have a remaining shelf life after delivery to the RIVM of at least 10.1.c months. The safety stock is of a different batch number than already delivered to the RIVM. Each delivery to the RIVM consists of at most 10.1.c.

3. Delivery

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

Movianto
Keltenweg 70
5342LP OSS

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 dvpcentraal.logistiek@rivm.nl.

10.2.e.

3.3 Each regular delivery consists of at most [10.1.c.] If Supplier fails to deliver in at most one batch, a compensation of [10.1.c.] 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 [10.1.c.] 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 [10.1.c.] 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 safety stock can be inspected by Purchaser at all times. The delivery time for Tdap (-IPV) vaccine delivered from this labelled safety stock shall be maximum [10.1.c.] weeks after a written request of Purchaser, and [10.1.c.] [10.1.c.] 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 3 (three) 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 [10.1.c.] 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 [10.1.c.] 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 [10.1.c.] 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

[10.2.e.]

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 10.1.c. 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 10.1.c. 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,

10.2.e.

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 10.1.c. 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 10.1.c. 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 10.1.c. 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 10.1.c. 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.

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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 October 1st, 2019 and is as follows (per dose in Euro excl. VAT): € x.

9.2 The Contract Price mentioned in article 9.1 is DDP to Oss, 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 October 1st, 2019. 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 the CBS (based on the Dutch "consumentenprijsindex (CPI), totaal bestedingen 2019 = 100").

The following calculation method applies:
(CPI index (new month (e.g. February 2020)) - CPI index (old month (e.g. February 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 sub-contracts

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 sub-contracts 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: Notes Of Information belonging to the Invitation to Tender June 7th, 2019
(June 7th - first NOI; June 11th – NOI II; June 18th – NOI III; June 24th – NOI IV)
Annex 2: Invitation To Tender number Nx 118921
Annex 3: Tender July 5th, 2019
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 October 1st, 2019 and will remain in force for a period of 12 (twelve) months. The Contract will be tacitly extended for a one time period of 12 (twelve) months at

a maximum of 10.1.c. times after the first year, up to a total maximum of 10.1.c. 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 1 (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.

10.2.e.

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 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

10.2.e.

(authori

Name
Position : Director-General
Place : Bilthoven
Date : 31-July-2019

For Supplier

GlaxoSmithKline B.V.

10.2.e.

(authorised signature)

Name 10.2.e.
Position : VP & GM Benelux
Place : Zeist
Date : 12.08.2019

For Supplier

GlaxoSmithKline B.V.

10.2.e.

Name :
Position : Com. Dir Vaccines
Place : Zeist
Date : 12-08-2019

10.2.e.

Doc. 8

Contract

between

the State of the Netherlands

National Institute for Public Health and the Environment (RIVM)

and

GlaxoSmithKline BV

concerning the supply of

Cervarix®

contract number 4410002632

10.2.e.

Content

Annexes

10.2.e.

The undersigned

The **State of the Netherlands**, represented by his Minister of Public Health, Welfare and Sport, on behalf of the Minister represented by 10.2.e. 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

GlaxoSmithKlineBV, having his office at Huis ter Heideweg 62, 3705 LZ, Zeist, The Netherlands, duly represented by 10.2.e. Commercial 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 HPV vaccines for the Dutch Immunisation Programme.

Purchaser desires to purchase Human Papillomavirus (HPV) vaccines 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 135847 on March 12th, 2020.

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:

10.2.e.

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 HPV vaccines and necessary documents to be supplied by Supplier, as specified in the Note Of Information (Annex 1) and Invitation To Tender number Nx 135847 (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).

Purchaser desires to purchase yearly a number of doses of the Goods as specified in paragraph 7.3.1 of the scope of supply of the relevant Invitation To Tender (Annex 2) of HPV vaccines.
For the first contract year the demand for HPV vaccine will be 10.1.c. doses. The demand for HPV vaccine for each additional contract year is estimated to be 10.1.c. 10.1.c. 10.1.c. Purchaser will place the regular orders five (5) months before the required delivery to the Safety Stock. 10.1.c. 10.1.c.

The vaccine is presented in a prefilled single-dose syringe without a needle. The single-dose syringes shall be packed in ten-packs, 10.1.c. are packed per transportation carton. The prefilled syringes are suitable for use in combination with a safety needle. All labelling and leaflets are only 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)'. The vaccines shall have a remaining shelf life after delivery to the RIVM of at least 10.1.c. The safety stock is of a different batch number than already delivered to the RIVM. Each delivery to the RIVM consists of at most 10.1.c. 10.1.c.

3. Delivery

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

Movianto
Keltenweg 70
5342LP OSS

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.

10.2.e.

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 dvpcentraal.logistiek@rivm.nl.

3.3 Per delivery of 100,000 doses 10.1.c. is allowed. If Supplier fails to deliver 100,000 doses in 10.1.c. a compensation of 10.1.c. 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 10.1.c. 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 10.1.c. 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 2). The safety stock can be inspected by Purchaser at all times. The delivery time for HPV vaccine delivered from this labelled safety stock shall be maximum 10.1.c. weeks after a written request of Purchaser, and 10.1.c. 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 3 (three) 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 10.1.c. 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 10.1.c. 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 foresees not being able to deliver or fails to deliver any or all of the Goods 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 to send promptly a written notice to Purchaser. In addition, the supplier is required within 28 (twenty-eight) days after the written notice has been sent to:

a. propose alternative Goods acceptable to the Purchaser; or
b. 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 conform article 12 of 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 alternative Goods (a.) or Goods by another supplier (b.) 10.1.c. of 10.2.e.

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 10.1.c. 10.1.c. 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 of 10.1.c. 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.

10.2.e.

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 October 1st, 2020 and is as follows (per dose in Euro excl. VAT): € x.

9.2 The Contract Price mentioned in article 9.1 includes delivery on a DDP basis to Oss, 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 October 1st, 2020. 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 2021 = 100").

The following calculation method applies:
(CPI index (new month (e.g. March 2022)) - CPI index (old month (e.g. March 2021))) / 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 (two) 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

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 10.1.c. 10.1.c. euros) and the amount of the total liability will be capped at 10.1.c. 10.1.c. . 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 10.1.c. 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 10.1.c. 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 10.1.c. 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.

10.2.e.

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. Review clause (conform Directive 2014/24/EU, article 72)

14.1 Purchaser is in any case able to change the Contract during the term if the following conditions apply:

a. VWS decides to change the target group of the HPV vaccine within the Dutch Immunisation Programme; and
b. as a result, the number of doses of the Goods conform article 2.2 of the Contract, will proportionally (pro rata) decrease or increase with the number of doses that is related to the decision of VWS.

14.2 Purchaser is also able to change the Contract during the term if the following conditions apply:

a. The average vaccination rate of the HPV vaccine drops below 50% or increases to 85% or higher; and
b. as a result, the number of doses of the Goods conform article 2.2 of the Contract, will proportionally (pro rata) decrease or increase with the number of doses that is related to the current vaccination rate.

14.3 The financial consequence of a change as referred to in paragraphs 14.1 and 14.2 will be worked out between parties to come to an appropriate solution.

14.4 The delivery schedule (conform Annex 2 ITT) will be adjusted as a result of a change as referred to in paragraphs 14.1 and 14.2 in good consultation between both parties, whereby at least a delivery period of 6 (six) months is observed.

14.5 Supplier and Purchaser agree to a change as referred to in paragraphs 14.1 and 14.2 in writing in accordance with article 13 of this Contract.

15. Annexes

15.1 The following Annexes form an integral part of the Contract:
Annex 1a: Note Of Information (2) belonging to the Invitation to Tender February 25th, 2020
Annex 1b: Note Of Information belonging to the Invitation to Tender February 18th, 2020
Annex 2 : Invitation To Tender number Nx 135847
Annex 3 : Tender March12th, 2020
Annex 4 : Quality Agreement
Annex 5 : Certificate of Payment
Annex 6 : Communication table

15.2 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.

16. Term and termination

16.1 This Contract will enter into force on October 1st, 2020 and will remain in force for a period of 12 (twelve) months. The Contract will be tacitly extended for a one time period of 12 (twelve) months at a maximum of 10.1.c. times after the first year, up to a total maximum of 10.1.c. 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.

16.2 Notwithstanding clause 16.1 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 or scope).

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.

16.3 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

10.2.e.

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.

16.4 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.

16.5 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.

17. Resolution of disputes

17.1 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.

17.2 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.

18. 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.

19. Governing language

19.1 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.

20. Applicable law

20.1 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 be[redacted]lic Health, Welf[redacted]

(auth[redacted]

Nam[redacted]
Position : Director-General
Place : Bilthoven
Date : 26 March 2020

For Supplier

[redacted]

Name : [redacted]
Position : Commercial Director
Place : Zeist
Date : 31 March 2020

For Supplier
GlaxoSmithKline BV

(authorised signature)

Name :
Position :

Place :
Date :

Annex 4 Quality Agreement

		SUMMARY OF AGREEMENTS AND RESPONSIBILITIES	RIVM	GSK
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	Supplier has a valid manufacturing licence available.		
	1.6	The product is registered in the Netherlands. Registration number is: EU/1/07/419/001-012		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* * 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: qp@rivm.nl		X
	2.3	A Certification of Transport Release is sent by RIVM to the supplier upon arrival of the product. Supplier fills in wether the product may be released after transport and sends it to qp@rivm.nl at earliest convenience.	X	X
	2.4	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: qp@rivm.nl and dvpcentraal.logistiek@rivm.nl		X

	SUMMARY OF AGREEMENTS AND RESPONSIBILITIES		RIVM	GSK
3.	**PACKAGING**			
	3.1	The product must be delivered in its original packaging to prevent falsified medicinal products.		
	3.2	Every packaging shall contain 10 doses of the product, each clearly marked with the registration number.		
	3.3	All labelling is in the Dutch language. All labelling is suitable for cold storage.		
	3.4	Each packaging contains a leaflet for patients in the Dutch language. >		
	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.		
	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.		
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 of at least a CMR and packing list. It should be possible to link all documentation to each other.		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 are available.		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	Temperature deviations during shipment are immediately reported to RIVM.		X

		SUMMARY OF AGREEMENTS AND RESPONSIBILITIES	RIVM	GSK
	4.7	Influence of temperature deviation(s) during shipment on influence on product quality will be assessed 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 critical changes, proceeding to introduction, 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 or manufacturing licence.		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

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		SUMMARY OF AGREEMENTS AND RESPONSIBILITIES	RIVM	GSK
	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

10.2.e.

(a ure)

10.2.e.

Name: Responsible Person

Responsible Person, RIVM

Date: 26-MRT-2020

10.2.e.

10.2.e.

Name:

~~Qualified Person~~/ Responsible Person*, GSK

* Strike through if not applicable

Date: 09 APR 2020

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 10.2.e.

Position ☐ Qualified Person ☐ Responsible Person

Signature

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

10.2.e.

Annex 6 Communication table

Purchaser		Supplier	
Function	**Contract management/ Purchaser**		
Name	10.2.e.		
e-mail			
telephone			
Function			
e-mail			
Finance			
Function			
e-mail			
telephone			
Function			
Name			
e-mail			
telephone			

10.2.e.

Annex 6 Communication table

Purchaser		Supplier	
Function	**Contract management / Purchaser**	**Function**	**Tender & Supply manager**
Name	10.2.e.		
e-mail			
telephone			
Function			
e-mail			
Finance			
Function			
e-mail			
telephone			
Function			
Name			
e-mail			
telephone			

Toegevoegde pagina

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