20.07.2021, 15:17 Uhr

Corona-Impfung ab 12 Jahren: Müssen Eltern eigentlich zustimmen?

Im Landkreis Augsburg steuern nun mobile Impfteams Schulen an. Die Eltern mussten ihre Kinder vorher anmelden. Doch ist die Zustimmung der Erziehungsberechtigten vor einer Corona-Impfung überhaupt nötig? Ein Medizinrechtler bezieht Stellung.

Eine Corona-Impfung von Minderjährigen ist auch ohne Zustimmung der Eltern möglich, sagt Prof. Josef Lindner, Medizinrechtler der Universität Augsburg. "Das ist natürlich ein heikler Punkt und im Medizinrecht ein generelles Problem, aber ich denke, dass man die Frage der Impfung nicht wie bei der Geschäftsfähigkeit handhaben kann, die ja erst ab 18 eintritt", so Lindner.

- Zum FAQ: Corona-Impfung für Kinder

Welche Rolle der Impfarzt spielt

Es gehe um die körperliche Integrität. "Dabei ist entscheidend, ob der Jugendliche reif genug ist, um selbst entscheiden zu können. Ob er versteht, was eine Impfung bedeutet." Dies müsse letztlich der Impfarzt entscheiden. "Das geht nur über ein Gespräch zwischen dem Arzt und dem Jugendlichen. Wenn ein Jugendlicher dabei zum Beispiel Rückfragen stellt, sich mit dem Thema auseinandersetzt und im Gespräch nicht überfordert wirkt, dann wäre das ein Beleg, dass er reif genug ist, um selbst über eine Impfung zu entscheiden", so Lindner weiter. Eine Impfung nur von der Zustimmung der Eltern abhängig zu machen, ginge dem Juristen zu weit. "Das würde ja de facto ein Veto-Recht bedeuten."

Juristen sprechen von drei Gruppen

Grundsätzlich werde in der juristischen Literatur in drei Gruppen unterschieden. Ab 16 Jahren könnten Jugendliche entscheiden, die Eltern müssten einer Impfung nicht zustimmen, ihr Widerspruch wäre unbeachtlich. Etwas Anderes gilt nur dann, wenn die Einsichtsfähigkeit erkennbar nicht vorhanden sei.

Von 14 Jahren bis 16 Jahren komme es auf die konkrete Einwilligungsfähigkeit des Jugendlichen an. Sei diese gegeben, genüge dessen Einwilligung. Sei sie nicht gegeben, müssten die Eltern zustimmen. Vor Vollendung des 14. Lebensjahres sei die Einwilligungsfähigkeit grundsätzlich nicht gegeben, so dass die Eltern zustimmen müssten. Doch auch hier könne es im Einzelfall Ausnahmen geben, wenn der Jugendliche für sein Alter schon sehr reif sei.

Pfizer Draft 1.6.2021
CONFIDENTIAL

MANUFACTURING AND SUPPLY AGREEMENT

BY AND AMONG

PFIZER EXPORT B.V.,

ALBANIA MINISTRY OF HEALTH AND SOCIAL PROTECTION

MINISTER OF STATE FOR RECONSTRUCTION

AND

INSTITUTE OF PUBLIC HEALTH

42 "**Product**" means all vaccines manufactured, in whole or in part, or supplied, directly or indirectly, by or on behalf of Pfizer or BioNTech or any of their Affiliates pursuant to this Agreement that are intended for the prevention of the human disease COVID-19 or any other human disease, in each case which is caused by any of the virus SARS-CoV-2, and/or any or all related strains, mutations, modifications or derivatives of the foregoing.

SUPPLY OF PRODUCT.

Agreement to Supply.

(a) During the Term, Pfizer shall use Commercially Reasonable Efforts to supply or have supplied the Product to Purchaser, and Purchaser shall purchase the Product, subject to and in accordance with the terms and conditions of this Agreement.

(b) Purchaser acknowledges and agrees that (i) Pfizer's efforts to develop and manufacture the Product are aspirational in nature and subject to significant risks and uncertainties, and (ii) the fact that any other drug or vaccine to prevent, treat or cure COVID-19 infection is successfully developed or granted authorization earlier than the granting of Authorization for the Product shall not change the current situation of urgent needs for prevention of the spread of the COVID-19 infection that poses serious threats to and harmful effects on the lives and health of the general public.

c) Notwithstanding the efforts and any estimated dates set forth in the Delivery Schedule, the Parties recognize that the Product has completed Phase 2b/3 clinical trials and that, despite the efforts of Pfizer in research, and development and manufacturing, the Product may not be successful due to technical, clinical, regulatory, manufacturing, shipping, storage, or other challenges or failures.

d) Accordingly, Pfizer and its Affiliates shall have no liability for any failure by Pfizer or its Affiliates to develop or obtain Authorization of the Product in accordance with the estimated dates described in this Agreement. Even if the Product is successfully developed and obtains Authorization, Pfizer shall have no liability for any failure to deliver doses in accordance with any estimated delivery dates set forth herein (other than as expressly set out in this Agreement), nor shall any such failure give Purchaser any right to cancel orders for any quantities of Product.

(b) Purchaser hereby waives all rights and remedies that it may have at Law, in equity or otherwise, arising from or relating to: (i) any failure by Pfizer to develop or obtain Authorization of the Product in accordance with the estimated dates described in this Agreement; or (ii) any failure by Pfizer to deliver the Contracted Doses in accordance with the Delivery Schedule. In the event of an inconsistency between the provisions of this Section 2.5 (Product Shortages) and those of other sections of this Agreement, the provisions of this Section 2.5 (Product Shortages) shall control and supersede over those of other sections of this Agreement to the extent of such inconsistency.

2.6 Delivery Delays.

Under no circumstances will Pfizer be subject to or liable for any late delivery penalties.

) Purchaser shall be the sole importer of the Products in front of the relevant customs authorities in Albania ("**Importer of Record**") and shall be responsible to obtain, where applicable, at its own risk and expense, any import license or other official authorization and carry out all customs formalities for the import of the Products in Albania. Purchaser shall also be responsible to pay, where applicable, all duties, taxes and other charges, as well as the costs of carrying out customs formalities payable upon import of the Products. Given the nature of the Product, Purchaser undertakes to support the Shipping Agent to swiftly clear the Products from the relevant customs authorities **within one (1) Business Day** from the arrival of the Product at the Point of Delivery; any delay in such clearance process might affect the overall shelf-life of the Products. Subject to Pfizer's prior written approval, the

Without prejudice to the generality of the foregoing, following the transfer of title to and risk of the Product to Purchaser at the Point of Delivery as defined under Section 2.8(a), Purchaser shall be fully responsible for and liable in relation to any Product wastage, and for ensuring appropriate disposal in accordance with Sections 2.7(d) and 2.7(e). For absolute clarity, even though Pfizer will support in the transportation of the Product from the Point of Delivery to the Place(s) of Destination through the Shipping Agent, Pfizer will not be liable for any risks of loss or damage to the Product after the Point of Delivery, including without limitation, temperature excursions, theft, or damages of any kind to the Product.

(d) Without prejudice to Section 4.4, Purchaser acknowledges that Pfizer will not, in any circumstances, accept any returns of Product (or any dose). In particular, following receipt of the Product in accordance with this Section 2.8, no Product returns may take place under any circumstances (inclusive of future changes in stock, expired Products, changes in Product allocation, delivery, demand or new product launch).

Invoices and Payment.

(a) In partial consideration of the Contracted Doses, Purchaser shall pay an upfront payment of $2,997,540 USD (calculated as $12.00USD/dose multiplied by 249,795 of the Contracted Doses) within thirty (30) days of receipt of an invoice from Pfizer issued upon Purchaser's receipt of Approval set forth in Section 9.6 (the "**Advance Payment**"); provided, however, that Pfizer shall have no obligation to ship or deliver Product until receipt of the Advance Payment. All amounts due hereunder shall be converted to EUR which shall be determined based on the exchange rate used by The Wall Street Journal, Eastern U.S. Edition, one (1) Business Day prior to the date of this Agreement.

Method of Payment.

(a) Purchaser shall pay all undisputed (in good faith) amounts due in EUR within thirty (30) days from the date of the invoice. Payment shall be remitted by wire transfer in immediately available funds to a bank and account designated by Pfizer. Any payment which falls due on a date which is not a Business Day may be made on the next succeeding Business Day. Any dispute by Purchaser of an invoice shall be provided to Pfizer in writing (along with substantiating documentation and a reasonably detailed description of the dispute) within ten (10) days from the date of such invoice. Purchaser will be deemed to have accepted all invoices for which Pfizer does not receive timely notification of disputes, and shall pay all undisputed amounts due under such invoices within the period set forth in this Section 3.3(a). The Parties shall seek to resolve all such disputes expeditiously and in good faith.

(b) Any amount required to be paid by a Party hereunder which is not paid on the date due shall bear interest, to the extent permitted by law, at the higher of (a) the rate applied by the European Central Bank for its main refinancing operations in euros (the reference rate) plus five points (or such centralized bank reference rate set forth in the Vaccine Order Form) and (b) 2%. The reference rate is the rate in force, as published in the C series of the *Official Journal of the European Union*, on the first day of the month in which the payment period ends. Such interest shall be computed on the basis of a year of three hundred sixty (360) days for the actual number of days payment is delinquent. In addition to all other remedies available under this Agreement or at Law, if Purchaser fails to pay any undisputed amounts when due under this Agreement, Pfizer may (i) suspend the delivery of the Product or (ii) terminate this Agreement.

(c) Purchaser shall not, and acknowledges that it will have no right, under this Agreement, any Purchase Order, any other agreement, document or Law, to withhold, offset, recoup or debit any amounts owed (or to become due and owing) to Pfizer, whether under this Agreement or otherwise, against any other amount owed (or to become due and owing) to it by Pfizer or a Pfizer Affiliate.

Legal and Regulatory Filings and Requests.

(a) Pfizer shall (a) comply with all regulatory or government licenses and permits, and (b) comply with all cGMP with respect to its manufacturing and packaging processes, the Facilities or otherwise, to permit the performance of its obligations hereunder. Notwithstanding the foregoing, Pfizer shall use Commercially Reasonable Efforts to obtain the Authorization provided that the Purchaser shall waive, to the extent applicable, all the requirements set out in Attachment H Part 2 of this Agreement in respect of the issue of the Authorization.

PART 1

SAMPLE

1. Shipping Document/Airway Bill "AWB"
2. Commercial Invoice
3. Packing List
4. Copy of the Certificate of Origin
5. Copy of the Certificate of Analysis "COA"
6. Copy of Export Declaration.

PART II

- Any other documents not included in the global Pfizer dossier for Pfizer BioNTech Covid 19 Vaccine registration, will be waived by the Purchaser or any other Government authority.

- Any notarization, legalization and/or certification of the documents required for issuing the Marketing Authorization in Albania, will be waived by the Purchaser or any other relevant Government authority (e.g. GMPs, CPP, etc).

- Any required analysis to issue the Marketing Authorization in Albania, will be waived by the Purchaser or any other relevant Government authority (e.g. registration samples and reference standards).

requirements.

(c) Prior to delivery, Pfizer shall comply with all conditions (in the relevant timescales) set out in the Authorization; provided, however, that Purchaser shall grant, or obtain on Pfizer's behalf, all exemptions, exceptions, and waivers of country specific requirements for the Product granted or permitted by the Government authority (including but not limited to serialization, applicable laboratory or quality testing and/or marketing information form submission and approval), which requirements,

absent an exemption, exception or waiver, would prevent Pfizer from supplying and releasing the Product in Albania upon receipt of the Authorization.

(e) Due to the current pandemic situation and the fact that any anticipated Authorization will be initially under an emergency use authorization, and the Parties agreement that Pfizer will only supply the Purchaser directly, the Purchaser agrees to the below conditions and, as a condition precedent to supply of the Product, will issue, or make any other Government authority to issue, any necessary approvals to ensure enforceability of the same:

(i) During the Term, Pfizer will not be required by the Purchaser or any other Government authority to appoint a local agent, distributor, or any responsible Person, including without limitation, for purposes of selling or supplying the Product or applying for the Albanian Conditional Approval, unless Pfizer decides otherwise at a later stage to appoint a local agent or distributor. For the avoidance of doubt, Purchaser also agrees that (i) Pfizer or any of its Affiliates will be the entity applying and submitting any regulatory files required for issuance of Albanian Conditional Approval, and (ii) Albanian Conditional Approval will be issued under Pfizer's or any of its Affiliates name.

(ii) During the Term, Pfizer will not be required by the Purchaser or any other Government authority to submit a price reference certificate for purposes of applying for Albanian Conditional Approval or otherwise.

Rejection of Product; Disposal of Rejected Shipments.

(a) Purchaser may reject any Product that does not materially conform to Specifications or cGMP ("**Non-Complying Product**") by providing written notice of rejection to Pfizer and the delivery carrier and setting out detailed reasons for such rejection: (i) immediately (and in no event more than 24 hours) upon delivery at the Point of Delivery; (ii) immediately and in any event within 24 hours of delivery at the Place(s) of Destination of such Non-Complying Product to Purchaser; or (iii) immediately and in no event more than 24 hours upon its first knowledge of a Latent Defect. In the event notice is not provided within 24 hours from delivery, the Product shall have been deemed accepted. Pfizer shall respond to any rejection and notice of Non-Complying Product from Purchaser in a timely manner. For clarity, Purchaser shall not be entitled to reject any Product based on service complaints unless a Product does not materially conform to Specifications or cGMP.

Pfizer shall conduct an analysis of the causes of any such quality-related complaint, and shall report to Purchaser on any corrective action taken. If Pfizer's inspection and testing reveals, to Pfizer's reasonable satisfaction, that such items of the Product are Non-Complying Product and that any such non-conformity or defect has not been caused or contributed to by any abuse, misuse, neglect, negligence, accident, improper testing, improper storage, improper handling, abnormal physical stress, abnormal environmental conditions or use contrary to any instructions issued by Pfizer, Pfizer shall use Commercially Reasonable Efforts to replace such Non-Complying Product as soon as practicable at no additional charge to Purchaser. In such circumstances, Pfizer will further arrange for reverse logistics for Product collection and manage the destruction of the Non-Complying Product. Until collection, Purchaser shall store and maintain the relevant Non-Complying Product

in appropriately secure locations and in accordance with the manufacturers' specifications. Notwithstanding any other provision of this Agreement, this Section 4.4(b) contains Purchaser's sole and exclusive remedy for Non-Complying Product. The provisions of this Section 4.4 (Rejection of Product; Disposal of Rejected Shipments) shall survive termination or expiration of this Agreement.

All Product delivered to Purchaser shall be: (a) stored securely by Purchaser; and (b) distributed by Purchaser only in Albania in a secure manner appropriate to the transportation route and destination, in each case (a) and (b) to guard against and deter theft, diversion, tampering, substitution (with, for example, counterfeits) resale or export out of Albania, and to protect and preserve the integrity and efficacy of the Product. Purchaser shall promptly notify Pfizer by email[1] within 48 hours (with follow up in writing in line with the notice provisions of this Agreement) if at any time Purchaser believes that any of the Product has been stolen, diverted, tampered with, substituted, or otherwise subjected to abuse, misuse, neglect, negligence, accident, improper testing, improper storage, improper handling, abnormal physical stress, abnormal environmental conditions or use contrary to any instructions issued by Pfizer. The notice shall provide all information relating to the Product diversion, including, but not limited to, detailed information including the date, time, location, number, batch number(s), expiration date, circumstances, and contact person(s) information. Purchaser shall cooperate with Pfizer or its designee, upon Pfizer's request, to cooperate in connection with such Product diversion.

4.7 Recalls.

Purchaser shall be responsible for all costs of any recall or market withdrawal of the Product in Albania, including, without limitation, reasonable costs incurred by or on behalf of Pfizer and its Affiliates or BioNTech and its Affiliates, except to the extent that such recall or market withdrawal results from willful misconduct (being a wrongful act, willingly and knowingly committed without legal or factual justification, with the intent to cause the harmful effects) on the part of, Pfizer or any of its Affiliates or any of their respective Personnel, in which event Pfizer will be responsible solely for: (a) any reasonable and documented out of pocket expenses directly incurred by Purchaser to third parties in implementing such recall or market withdrawal; and (b) replacing, at Pfizer's expense, the Product which has to be recalled.

Mutual Representations and Warranties. Pfizer and Purchaser each represents and warrants to each other the following:

(a) Organization and Authority. It has full right, power and authority to enter into this Agreement and to perform its respective obligations under this Agreement, including, in the case of Purchaser, that all necessary authorizations and approvals have been obtained by Purchaser to authorize entering into this Agreement and its performance of all of its obligations contained herein, that Purchaser is entering into this Agreement pursuant to the Normative Act of the Albanian Council of Ministers no. 38 dated December 31, 2020 "On the approval of agreement for the manufacturing and supply by and between Pfizer Export B.V. and the Ministry of Health and Social Protection, Minister of State for Reconstruction and the Institute of Public Health, and the authorization of procedure for the anticovid-19 vaccination of the population", a true and correct copy of which is attached hereto as Appendix H (the "**Normative Act**"), that this Agreement is exempt from the application of all Albanian Public Procurement Laws and each of the terms and conditions of this Agreement are fully enforceable, that the budgetary allocation set forth in Article 4 of the Normative Act in no respect limits Purchaser's funding or other obligations under this Agreement, including the indemnification obligations set forth in Article 8, that Purchaser has the authority to bind the Republic of Albania and that Purchaser has exercised that authority to bind the Republic of Albania as to each of the provisions and terms and conditions set forth in this Agreement;

(b) No Conflicts or Violations. The execution and delivery of this Agreement by such Party and the performance of such Party's obligations hereunder (i) do not conflict with or violate any Laws existing as of the Effective Date, or upon date of Approval, and applicable to such Party and (ii) do not conflict with, violate, breach or constitute a default under, and are not prohibited or materially restricted by, any contractual obligations of such Party existing as of the Effective Date, or upon date of Approval; and

(c) Valid Execution. Such Party is duly authorized to execute and deliver this Agreement, and the Person executing this Agreement on behalf of such Party is duly authorized to execute and bind such Party to the terms set forth herein.

Anti-Bribery/Anti-Corruption and Global Trade Controls.

(a) The Parties represent and warrant that, beyond the mutual consideration set forth in this Agreement, neither they nor their agents have provided or requested, or will provide or request, any additional incentive or benefit to or from another Party or its agents to induce a Party to enter this Agreement or perform any part of this Agreement.

(b) Pfizer has not made, and will not make, in the performance of this Agreement directly or indirectly any payment, offer, promise, or authorization of payment of money or anything of value to a Government official, political party, candidate for political office, or any other Person, and has not sought and will not seek improperly or corruptly to influence any Government official, political party, candidate for political office, or any other Person, in order to gain an improper business advantage.

Treasury Departments.

No Other Warranty.

Except to the extent set out expressly in this Agreement, all conditions, warranties or other terms which might have effect between the Parties or be implied or incorporated into this Agreement (whether by statute, common law or otherwise) are hereby excluded to the fullest extent permitted by Laws. Without prejudice to the general nature of the previous sentence, unless this Agreement specifically states otherwise and to the maximum extent permitted by Law, Pfizer expressly disclaims any representations or warranties with respect to the Product, including, but not limited to, any representation, warranties or undertaking as to (a) non-infringement of Intellectual Property rights of any third party, (b) that there is no requirement to obtain a license of third party Intellectual Property rights to enable the use or receipt of the Product, (c) merchantability, or (d) fitness for a particular purpose.

5.5 Purchaser Acknowledgement.

Purchaser acknowledges that the Vaccine and materials related to the Vaccine, and their components and constituent materials are being rapidly developed due to the emergency circumstances of the COVID-19 pandemic and will continue to be studied after provision of the Vaccine to Purchaser under this Agreement. Purchaser further acknowledges that the long-term effects and efficacy of the Vaccine are not currently known and that there may be adverse effects of the Vaccine that are not currently known. Further, to the extent applicable, Purchaser acknowledges that the Product shall not be serialized.

Mutual Termination Rights.

(a) In the event: (i) the Product does not obtain Authorization by the EC by June 30, 2021, (ii) Pfizer has supplied to Purchaser no doses of Product by December 31, 2021, subject to the extensions set forth in Section 2.4 (Delivery Schedule), or (iii) Pfizer is unable to supply all of the Contracted Doses by December 31, 2022, then a Party may terminate this Agreement upon written notice to the other Parties. Purchaser may invoice Pfizer for a refund of fifty percent (50%) of the Advance Payment for the initial 249,795 Contracted Doses not delivered (as determined ratably for the doses not delivered) except for cases where the cause of the termination is mainly or solely attributable to Purchaser. In the event this Agreement is terminated pursuant to this Section 6.3(a), the return of fifty percent (50%) Advance Payment shall be Purchaser's sole and exclusive remedy for the failure to deliver any Contracted Doses.

(c) Expiry or termination of this Agreement for any reason shall be without prejudice to a Party's other rights and remedies or to any accrued rights and liabilities as the date of such expiry or termination; provided that (i) Pfizer shall have no liability for any failure by Pfizer to develop or obtain Authorization of the Product in accordance with the estimated dates described in this Agreement and (ii) even if the Product is successfully developed and Pfizer obtains Authorization, Pfizer shall have no liability for any failure to deliver Contracted Doses in accordance with any estimated delivery dates set forth herein.

8. **INDEMNIFICATION**.

8.1 Indemnification by Purchaser. Purchaser hereby agrees to indemnify, defend and hold harmless Pfizer, BioNTech, each of their Affiliates, contractors, sub-contractors, licensors, licensees, sub-licensees, distributors, contract manufacturers, services providers, clinical trial researchers, third parties to whom Pfizer or BioNTech or any of their respective Affiliates may directly or indirectly owe an indemnity based on the research, development, manufacture, distribution, commercialization or use of the Vaccine, and each of the officers, directors, employees and other agents and representatives, and the respective predecessors, successors and assigns of any of the foregoing ("**Indemnitees**"), from and against any and all suits, claims, actions, demands, losses, damages, liabilities, settlements, penalties, fines, costs and expenses (including, without limitation, reasonable attorneys' fees and other expenses of an investigation or litigation), whether sounding in contract, tort, intellectual property, or any other theory, and whether legal, statutory, equitable or otherwise (collectively, "**Losses**") arising out of, relating to, or resulting from the Vaccine, including but not limited to any stage of design, development, investigation, formulation, testing, clinical testing, manufacture, labeling, packaging, transport, storage, distribution, marketing, promotion, sale, purchase, licensing, donation, dispensing, prescribing, administration, provision, or use of the Vaccine.

8.2 Assumption of Defense by Purchaser. The Indemnitee(s) shall notify Purchaser of Losses for which it is seeking indemnification pursuant hereto ("**Indemnified Claims**"). Upon such notification, Purchaser shall promptly assume conduct and control of the defense of such Indemnified Claims on behalf of the Indemnitee with counsel acceptable to Indemnitee(s), whether or not the Indemnified Claim is rightfully brought; provided, however, that Purchaser shall provide advance notice in writing of any proposed compromise or settlement of any Indemnified Claim and in no event may Purchaser compromise or settle any Indemnified Claim without Indemnitee(s)'s prior written consent, such consent not to be unreasonably withheld. Indemnitee(s) shall reasonably cooperate with Purchaser in the defense of the Indemnified Claims.

8.3 Participation Rights. Each Indemnitee shall have the right to retain its own counsel and to participate in Purchaser's defense of any Indemnified Claim, at its own cost and expense except as set forth below. A failure by the Indemnitee(s) to give notice or timely notice or to offer to tender the defense of the action or suit pursuant to this Section 8.3 (Participation Rights) shall not limit the obligation of Purchaser under this Section 8 (Indemnification), except and only to the extent Purchaser is actually prejudiced thereby.

8.4 Assumption of Defense. Notwithstanding the foregoing and without prejudice to Section 12.6, Pfizer, directly or through any of its Affiliates or through BioNTech, may elect to assume control of the defense of an Indemnified Claim (a) within thirty (30) days of Indemnitee's notice to Purchaser of the Indemnified Claim or (b) at any time if, in Pfizer's sole discretion: (i) Purchaser fails to timely assume the defense of or reasonably defend

such Indemnified Claim(s) in good faith to the satisfaction of Pfizer (or Pfizer's Affiliates and BioNTech); or (ii) Pfizer believes (or any of Pfizer's Affiliates or BioNTech believe) in good faith that a bona fide conflict exists between Indemnitee(s) and Purchaser with respect to an Indemnified Claim hereunder. Upon written notice of such election, Pfizer shall have the right to assume control of such defense (directly or through either one of its Affiliates or BioNTech), and Purchaser shall pay (as incurred and on demand), all Losses, including, without limitation, the reasonable attorneys' fees and other expenses incurred by Indemnitee(s), in connection with the Indemnified Claim. In all events, Purchaser shall cooperate with Indemnitee(s) in the defense, settlement or compromise of the Indemnified Claim.

8.5 Privileges and Immunities. Purchaser acknowledges that its indemnification obligations under this Agreement are (a) expressly in addition to, and not limited by, any Privileges and Immunities, and (b) do not waive or relinquish Indemnitees' rights to any Privileges and Immunities.

8.6 Costs. Costs and expenses, including, without limitation, fees and disbursements of counsel, incurred by the Indemnitee(s) in connection with any Indemnified Claim shall be reimbursed on a quarterly basis by Purchaser, without prejudice to Purchaser's right to refund in the event that Purchaser is ultimately held in a final, non-appealable judgment or award to be not obligated to indemnify the Indemnitee(s).

9. **INSURANCE AND LIABILITY**.

9.1 Insurance.

During the Term, Pfizer or its Affiliates shall self-insure or procure and maintain such types and amounts of general liability insurance to cover liabilities related to its activities under this Agreement as is normal and customary in the pharmaceutical industry generally for companies that are similarly situated and providing similar manufacturing and supply services. For absolute clarity, this shall not include, nor constitute, product liability insurance to cover any third party/patients claims and such general liability insurance shall be without prejudice to Purchaser's indemnification obligation as set out in this Agreement.

Limits on Liability.

(a) Subject to the exclusions set forth in Section 9.3, in no circumstances shall (i) a Party be liable to the other Parties or its Affiliates, whether arising in tort (including, without limitation, negligence), contract or otherwise, for any indirect, special, consequential, incidental or punitive damages, whether in contract, warranty, tort, negligence, strict liability or otherwise arising out of or relating to this Agreement, the transactions contemplated therein or any breach thereof (whether or not reasonably foreseeable and even if the first Party had been advised of the possibility of another Party incurring such loss or type of loss), and (ii) in the case of Pfizer and its Affiliates, in no event shall Pfizer be liable to Purchaser for any direct damages except to the extent such direct damages were a result of a material breach of a representation or warranty by Pfizer under this Agreement that directly and

solely caused the damage. In no instance shall Pfizer and its Affiliates be liable to Purchaser (whether arising in warranty, tort (including, without limitation, negligence), contract, strict liability or otherwise) for any liabilities of Purchaser to any third party, including, without limitation, through contribution, indemnity, or for any claim for which Purchaser would have to indemnify Pfizer if that claim were brought directly against Pfizer.

(b) The aggregate liability of Pfizer and its Affiliates (whether arising in warranty, tort (including, without limitation, negligence), contract, strict liability or otherwise) arising out of, under or in connection with this Agreement shall not exceed a sum equivalent to one hundred percent (100%) of the total Price actually received by Pfizer under this Agreement for the Contracted Doses.

9.4 Waiver of Sovereign Immunity. Purchaser, on behalf of itself and the Republic of Albania, expressly and irrevocably waives any right of immunity which either it or its assets may have or acquire in the future (whether characterized as sovereign immunity or any other type of immunity) in respect of any arbitration pursuant to Section 12.2 (Arbitration) or any other legal procedure initiated to confirm or enforce any arbitral decision, order or award, or any settlement in connection with any arbitration pursuant to Section 12.2 (Arbitration), whether in Albania or any other foreign jurisdiction, including but not limited to immunity against service of process, immunity of jurisdiction, or immunity against any judgment rendered by a court or tribunal, immunity against order to enforce the judgment, and immunity against precautionary seizure of any of its assets. Purchaser expressly and irrevocably submits to the jurisdiction of the courts of New York, or any other court of competent jurisdiction, for the purposes of enforcing any arbitral decision, order or award, or any settlement in connection with any arbitration pursuant to Section 12.2 and represents and warrants that the person signing this Agreement on its behalf has actual authority to submit to such jurisdiction. Purchaser also expressly and irrevocably waives the application of any Law in any jurisdiction that may otherwise limit or cap its obligation to pay damages arising from or in connection with any Indemnified Claims and represents and warrants that this Agreement and any Indemnified Claims arising hereunder are not subject to the Albanian Public Procurement Laws. Purchaser represents and warrants that the person signing this Agreement on its behalf has actual authority to waive such immunity and bind

9.5 Conditions Precedent to Supply.

Purchaser represents that it has and will continue to have adequate statutory or regulatory authority and adequate funding appropriation to undertake and completely fulfil the indemnification obligations and provide adequate protection to Pfizer and all Indemnitees from liability for claims and all Losses arising out of or in connection with the Vaccine or its use. Purchaser hereby covenants and acknowledges and agrees that a condition precedent for the supply of the Product hereunder requires that Purchaser shall implement and maintain in effect such statutory or regulatory requirements or funding appropriation sufficient to meet its obligations in this Agreement prior to supply of the Product by Pfizer and thereafter shall maintain such statutory and regulatory requirement and funding appropriation, each as applicable, for so long as necessary to meet all of Purchaser's obligations under this Agreement, including, without limitation, any such obligations that, pursuant to Section 6.5, survive expiration or termination of this Agreement. For clarity, the sufficiency of such statutory or regulatory requirements or funding appropriation shall be in Pfizer's sole discretion. Purchaser acknowledges that Pfizer's supply of Product hereunder is in reliance (without any duty of investigation or confirmation by or on behalf of Pfizer or its Affiliates), *inter alia*, on Purchaser's representations and covenants under this Section 9.5, Purchaser implementing and maintaining in effect the requirements and funding appropriation described in this Section 9.5 and the other representations and warranties made by Purchaser under this Agreement.

Purchaser shall protect any Confidential Information pursuant to this Agreement on the bases of applicable provisions of public procurement and/or information right Laws in Albania for the protection of confidential information, trade secrets, industrial property rights. Each Recipient shall not use or disclose such Confidential Information except as permitted by this Agreement. Each Recipient shall safeguard the confidential and

foregoing, in all cases, (a) Purchaser may not disclose any of the financial or indemnification provisions contained in this Agreement, including, without limitation, the price per dose of Product or refundability of the Advance Payment or any information that could reasonably ascertain the price per dose of Product, without the prior written consent of Pfizer, and (b) Pfizer may disclose (i) Confidential Information to its Affiliates and BioNTech without prior written consent of Purchaser, and (ii) upon foreign government request, financial information relating to this Agreement, including cost per dose.

10.2 Recipient Precautions.

In order to comply with the obligations contained in this Section 10 (Confidential Information), Recipient shall take at least the following precautions: (a) Recipient shall exercise all reasonable efforts to prevent unauthorized employees and unauthorized third parties from gaining access to Confidential Information (and in no event less than reasonable care); (b) Recipient shall disclose Confidential Information only to such of its Representatives who have a need to know such Confidential Information to fulfill its

obligations under this Agreement; provided, however, before any disclosure of Confidential Information, Recipient shall bind its Representatives receiving such Confidential Information to a written agreement of confidentiality at least as restrictive as this Agreement; and (c) prior to any disclosure, Recipient shall instruct its Representatives of the confidential nature of, and to maintain the confidentiality of, the Confidential Information. Recipient shall be responsible for all actions of its Representatives, including, without limitation, any breach of the terms hereof, regardless of whether or not such Representatives remain employed or in contractual privity with the Recipient.

10.4 Survival.

The provisions of this Section 10 (Confidential Information) shall survive the termination or expiration of the this Agreement for a period of ten (10) years, except with respect to any information that constitutes a trade secret (as defined under Law), in which case the Recipient of such information will continue to be bound by its obligations under this Section 10 (Confidential Information) for so long as such information continues to constitute a trade secret, but in no event for a period of less than the ten (10)-year period specified above.

Tirana, Albania 1001
Email: ishp@shendetesia.gov.al

If to MOH:
[**Insert Purchaser notice information**]
If to MOR
Insert Purchaser notice information

If to Pfizer:

PFIZER EXPORT B.V.
Rivium Westlaan 142, 2909LD
Capelle aan den Ijssel,
The Netherlands
Attn: Andrew Richmond
Email: Andrew.Richmond@Pfizer.com

mailto:Andrew.Richmond@Pfizer.com

With a copy (which shall not constitute notice) to:
Pfizer SRB d.o.o.
Tresnjinog cveta 1/VI
11070 Novi Beograd
Serbia
Attn: Mila Zrnic
Email: Mila.Zrnic@Pfizer.com

With a copy (which shall not constitute notice) to:
Pfizer Inc.
235 East 42nd Street
New York, NY 10017
Attention: General Counsel
LegalNotice@Pfizer.com

12.2 Arbitration.

Any dispute, controversy, or claim arising out of, relating to, or in connection with this Agreement, including with respect to the formation, applicability, breach, termination, validity or enforceability thereof, or relating to arbitrability or the scope and application of this Section 12.2 (Arbitration), shall be finally resolved by arbitration. The arbitration shall be conducted by three arbitrators, in accordance with the Rules of Arbitration of the International Chamber of Commerce ("**ICC**"). The claimant shall nominate an arbitrator in its request for arbitration. The respondent shall nominate an arbitrator within thirty (30)

.6 Third Party Rights.

(a) Purchaser agrees the applicable rights granted or provided to Pfizer under this Agreement are also granted or provided to Pfizer's Affiliates or to BioNTech to the extent that those rights relate to such Affiliates or BioNTech, including but not limited to the indemnification in Section 8(a) (each a "**Third Party Beneficiary**" and together the "**Third Party Beneficiaries**"). Each Third Party Beneficiary shall be entitled to enforce the terms of this Agreement; provided that, to the extent permissible by Law and where reasonably practicable, any claims, demands or actions from any Third Party Beneficiary shall be brought by Pfizer itself on behalf of the relevant Third Party Beneficiary.

(b) Any Losses suffered by a Third Party Beneficiary will not be treated as being indirect solely because it has been suffered by a Third Party Beneficiary and not by Pfizer directly.