The EU Commission - AstraZeneca contract on Covid-19 vaccines

avgi.gr/diethni/378044_eu-commission-astrazeneca-contract-covid-19-vaccines-download

29 janvier 2021

2’
29.01.21 19:37

Αυγή Newsroom
Avgi.gr reveals a large part of the EU-AstraZeneca contract on Covid-19 vaccines, which were "redacted” by offiicials. **See below**.

Avgi.gr brings to light a large part of the uncensored text of the contract of the pharmaceutical company AstraZeneca with the European Commission.

The EU Commission published the contract in a censored form as there are no significant points of the agreement such as the price and the number of installments, as these are considered “sensitive data” for the sake of maintaining enterprise competition.

Avgi.gr has concluded that the contract has a special provision for the patents and IP licences of the vaccine, which are maintained by AstraZeneca, until the abandonment of the contract. In other words, the Commission could have negotiated different terms regarding the ownership of the vaccine.

That is why the proposal of Alexis Tsipras that the EU should take over patents to facilitate the production of vaccines is important and timely. The proposal made by leader of SYRIZA and leader of the opposition in Greece, was adopted by the Council of Europe as a proposal of the Left.

Some very interesting points

(11.2) IP Rights Following Abandonment. The Commission, or any third party designated by the Commission, shall have the right to obtain a license or sublicense from AstraZeneca for the Vaccine IP Rights to the extent reasonably necessary to enable the ...

(7.4 b) To the extent that the total Cost of Goods exceed the estimated amount of 870 million Euros by less than 20%, AstraZeneca shall provide an updated purchase and payment schedule to the Commission, which shall state the delivery schedule of the Init...

(7.7) . Late Payments. In the event the Commission or the Participating Member States fail to pay any amount payable under this Agreement or the Order Form within twenty (20) days of the due date for any such payment, without prejudice to any other right...

(7.2) (b The Commission shall pay to AstraZeneca one-third of the Initial Funding (second Installment) within twenty (20) days following the receipt from AstraZeneca of relevant evidence of the use of the first Installment and a relevant progress report of...

(7.3) . Subsequent Funding. The Participating Member States shall pay the Fill/Finish/Packaging Costs, storage and distribution costs of the Vaccine, destruction for any material produced at risk, and costs and expenses directly incurred for, or fairly ...

(9.3) Additional Doses. AstraZeneca shall provide any agreed Additional Doses at Cost of Goods until 1 July 2021, unless AstraZeneca determines in good faith that the COVID-19 Pandemic has not ceased as of 1 July 2021, in which case AstraZeneca shall p...

(11.1) Ownership. The Commission acknowledges that AstraZeneca has pre-existing obligations to its upstream licensor and throughout the term of this Agreement, may incur obligations to its CMOs and other contractors in respect of patents, know-how and ...

(11.2) IP Rights Following Abandonment. The Commission, or any third party designated by the Commission, shall have the right to obtain a license or sublicense from AstraZeneca for the Vaccine IP Rights to the extent reasonably necessary to enable the ...

2020.08.27 APA - FINAL AZ signature only - Legal Redactions

1. Definitions.

1.1. “Accounting Standards” means International Financial Reporting Standards (IFRS).

1.2. “Additional Doses” has the meaning given in Section 5.3.

1.3. “Affiliate” means, with respect to a Party, any Person that Controls, is Controlled by or is under common Control with such Party.

1.4. “Agreement” has the meaning given in the preamble, namely the Advance Purchase Agreement.

1.5. “Alliance Manager” has the meaning given in Section 2.3.

1.6. “Applicable Law” means any law or statute, any rule or regulation (including written governmental interpretations thereof, the guidance related thereto, or the application thereof) issued by a Governmental Authority or Regulatory Authority and an...

1.7. “AstraZeneca” has the meaning given in the preamble.

1.8. “AZ Exchange Rate” has the meaning given in Section 1.15.

1.9. “Best Reasonable Efforts” means

(a) in the case of AstraZeneca, the activities and degree of effort that a company of similar size with a similarly-sized infrastructure and similar resources as AstraZeneca would undertake or use in the development and manufacture of a Vaccine at the...

(b) in the case of the Commission and the Participating Member States, the activities and degree of effort that governments would undertake or use in supporting their contractor in the development of the Vaccine having regard to the urgent need for a ...

1.10. “Binding Allocation” has the meaning given in Section 8.3.

1.11. “CMOs” means contract manufacturing organizations.

1.12. “Commission” has the meaning given in the preamble.

1.13. “Confidential Information” has the meaning given in Section 16.1.

1.14. “Control” means: (i) to possess, directly or indirectly, the power to direct the management or policies of a Person, whether through ownership of voting securities or by contract relating to voting rights or corporate governance, or (ii) to own,...

1.15. “Cost of Goods” means the fully burdened aggregate reasonable direct and indirect costs and expenses incurred by AstraZeneca to manufacture the Vaccine Doses, consisting of:

(a) direct labor costs (salaries, wages, employee benefits, overtime costs and shift premiums);

(b) direct materials (including raw materials and intermediates and interim packaging) costs;

(c) a fair and reasonable allocation of operating costs of facilities and equipment (including start up and cleaning costs of production), including an allocation of the cost of idle capacity at relevant manufacturing sites, in each case, calculated b...

(d) quality, release and in-process control costs;

(e) charges for reasonable spoilage, scrap or rework costs;

(f) amounts (without mark-up) that are paid to a third party, in connection with their manufacture of the Vaccine or any component thereof including any costs associated with technology transfer and/or establishment of manufacturing capacity;

(g) the reasonable allocation of facility overhead, both fixed and variable, to such manufacturing operation (including the allocable costs of administrators and managers overseeing manufacturing and production) maintenance, engineering, safety, finan...

(h) any non-refundable or non-creditable Indirect Taxes, customs and excise duties, or similar Taxes; and

(i) any royalties paid or payable to third parties in connection with the exploitation of the Vaccine, such royalties to be calculated as a percentage of the costs described in (a) through (h) above.

(a) costs and expenses for pharmacovigilance directly incurred for, or fairly allocable to, the Vaccine;

(b) regulatory filing fees for the Vaccine and other regulatory costs and expenses directly incurred for, or fairly allocable to, the Vaccine;

(c) supporting functions and the cost of working capital directly incurred for, or fairly allocable to, the Vaccine; and

(d) any other costs and expenses directly incurred for, or fairly allocable to, the Vaccine (e.g., legal, finance, reporting, compliance and executive management oversight).

(a) costs related to the operation of the facility incurred while using the facility to manufacture other products;

(b) industrial operations-related corporate costs (such as but not limited to corporate projects, strategic analysis);

(c) any refundable or creditable Indirect Taxes, customs and excise duties, or similar Taxes

(d) storage and distribution of the Vaccine;

(e) destruction for any material produced at risk; and

(f) costs and expenses directly incurred for, or fairly allocable to, post-launch safety and risk management studies for the Vaccine.

1.16. “COVID Pandemic” has the meaning given in the recitals.

1.17. “Defect” means the characteristic of a product that does not provide the safety which a person is entitled to expect taking all circumstances into account, including: (a) the presentation of the product; (b) the use to which it could reasonably ...

1.18. “Disclosing Party” has the meaning given in Section 16.1(b).

1.19. “Distribution Hubs” has the meaning given in Section 8.1.

1.20. “Dose” means approximately 5.0 x 1010 virus particles/dose in no more than 0.5m1 with the understanding that the final commercial dose and dose volume will be informed by the data emerging from the clinical development program and the optimizati...

1.21. “Effective Date” has the meaning given in the preamble.

1.22. “EMA” means European Medicines Agency.

1.23. “Executive Officer” means, with respect to AstraZeneca, its EVP Europe and, with respect to the Commission, the Director-General of the Directorate General Health and Food Safety (DG SANTE).

1.24. “Fill/Finish/Packaging Costs” has the meaning given in Schedule A.

1.25. “Funding” has the meaning given in Section 7.1.

1.26. “Good Manufacturing Practices” means the current practices for manufacture required by the standards, rules, principles and guidelines set out in Directive 2001/83/EC (as amended by Directive 2004/27/EC), Directive 2003/94/EC and EudraLex - Volu...

1.27. “Governmental Authority” means any court, agency, department, authority or other instrumentality of any nation, supranational body, state, county, city or other political subdivision.

1.28. “Indemnified Persons” has the meaning given in Section 14.1.

1.29. “Indemnifying Party” has the meaning given in Section 14.2.

1.30. “Indirect Taxes” means value added, sales, consumption, goods and services taxes or other similar Taxes required by Applicable Laws to be disclosed as a separate item on the relevant invoice.

1.31. “Initial Europe Doses” has the meaning given in the recitals.

1.32. “Initial Funding” has the meaning given in Section 7.2.

1.33. “Know-How” means (a) inventions, technical information, know-how, show-how, data (including physical data, chemical data, toxicology data, animal data, raw data, clinical data, and analytical and quality control data), formulae, assays, sequence...

1.34. “Losses” has the meaning given in Section 14.1.

1.35. “Order Form” has the meaning given in Section 3.1.

1.36. “OMCL” means Official Medicines Control Laboratories.

1.37. “Optional Doses” has the meaning given in Section 5.2.

1.38. “Participating Member States” has the meaning given in the preamble.

1.39. “Person” means any individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, incorporated association, joint venture or s...

1.40. “Phase I/II Trial Results” has the meaning given in Section 4.2(a).

1.41. “Price Per Dose” has the meaning given in Section 7.4(a).

1.42. “Receiving Party” has the meaning given in Section 16.1(b).

1.43. “Regulatory Authority” means the European Medicines Agency (EMA) or any other Governmental Authority regulating the conduct, manufacture, market approval, sale, distribution or use of the Vaccine within the EU.

1.44. “Related Persons” means spouses, heirs, children (whether natural or adopted), descendants, successors and assigns, estates, or legal representatives, executors, administrators or any other person or entity representing the rights of the injured...

1.45. “Representative” has the meaning given in Section 2.2.

1.46. “Tax” means any form of tax or taxation, levy, duty, charge, social security, charge, contribution, or withholding of whatever nature (including any related fine, penalty, surcharge or interest) imposed by, or payable to, a Tax authority.

1.47. “Tender Specifications” has the meaning given in Section 18.9.

1.48. “Third Party Claim” has the meaning given in Section 14.2.

1.49. “Upfront Costs” has the meaning given in Schedule A.

1.50. “Vaccine” has the meaning given in the recitals.

1.51. “Vaccine IP Rights” has the meaning given in Section 11.1.

1.52. “Willful Misconduct” means an act or omission taken (a) intentionally to achieve a wrongful purpose; (b) knowingly without legal or factual justification; and (c) in disregard of a known or obvious risk that is so great as to make it highly prob...

2. Roles of the Parties

2.1. The Commission:

(a) Development of the Vaccine as described in Section 4;

(b) Funding process as described in Section 7, except for the payments resulting from the obligations assumed directly by the Participating Member States as described in Sections 7.3 and 7.4.

(c) Audit of costs, as described in Section 7.6.

(d) Allocation, as described in Section 8.3.

(e) Any other subject not specifically attributed to the Participating Member States according to Section 2.2.

2.2. The Participating Member States.

(a) Manufacturing and supply as described in Section 5.4.

(b) Payments resulting from the obligations assumed by the Participating Member States as described in Sections 7.3 and 7.4.

(c) Orders and delivery of the Vaccine Doses to the Distribution Hubs as described in Section 8.1.

(d) Distribution of the Vaccine Doses as described in Section 8.3.

(e) Indemnification as described in Section 14.

(f) Release; Limitation of Liability; Disclaimer of Warranties as described in Section 15.

2.3. Alliance Manager. Promptly after the Effective Date, the Commission and AstraZeneca shall each appoint one Person who shall oversee contact between the Commission, on the one hand, and AstraZeneca, on the other hand, and such appointed Persons sh...

3. Subject matter

3.1. Order Form

(a) Attached as Exhibit A to this Agreement is an Order Form which has been negotiated on behalf of the Member States by the Commission. In order to maintain the right to purchases Doses of Vaccine as contemplated by this Agreement, an EU Member Stat...

(b) The Parties acknowledge and agree that the Order Form is an essential and important part of this Agreement and AstraZeneca has entered into this Agreement in reliance on Member States executing such Order Forms as contemplated hereby. Such Order F...

4. Development.

4.1. Development. As between the Parties, AstraZeneca shall have the sole right and responsibility for all aspects relating to the research and development of the Vaccine with the goal of establishing a Vaccine that is safe and efficacious for manufa...

4.2. Reporting.

(a) Along with its offer, AstraZeneca has provided to the Commission reports of the interim and final results of the Oxford University-sponsored Phase I/II clinical study of the Vaccine (the "Phase I/II Trial Results") from Oxford University. AstraZe...

(b) On reasonable notice and as reasonably requested, AstraZeneca shall enable the Commission (or an independent expert appointed by the Commission as set forth below) to access all clinical trial data (including communications and correspondence with...

5. Manufacturing and Supply.

5.1. Initial Europe Doses. AstraZeneca shall use its Best Reasonable Efforts to manufacture the Initial Europe Doses within the EU for distribution, and to deliver to the Distribution Hubs, following EU marketing authorization, as set forth more fully...

5.2. Optional Doses. The Commission shall have an option to increase its order on behalf and in the name of the Participating Member States of the Vaccine Doses by an additional 100 million Doses ("Optional Doses"). In order to exercise such option, ...

5.3. Additional Doses. AstraZeneca shall consider in good faith any request for additional Vaccine Doses made by the Participating Member States, but shall not be required to manufacture and supply Vaccine Doses in excess of the Initial Europe Doses a...

5.4. Manufacturing Sites. AstraZeneca shall use its Best Reasonable Efforts to manufacture the Vaccine at manufacturing sites located within the EU (which, for the purpose of this Section 5.4 only shall include the United Kingdom) and may manufacture ...

5.5. Reporting. AstraZeneca shall notify the Commission as soon as (a) it selects initial manufacturing sites and (b) it changes any of its manufacturing sites for the Vaccine.

6. Acquisition of Materials and Services.

6.1. Materials. The Commission and the Participating Member States shall use their Best Reasonable Efforts to enable AstraZeneca to timely supply the Initial Europe Doses. AstraZeneca shall secure the supply of all drug substances needed and drug prod...

6.2. Capacity Limitations. In the event AstraZeneca's ability to fulfill its obligations under this Agreement is impeded by a competing agreement entered into by or on behalf of the Commission, AstraZeneca shall promptly inform the Commission. While A...

6.3. Reporting and Notification to the Commission. AstraZeneca will report to the Commission in regular intervals on whether it has been able to secure the supply of all drug substances needed and drug product capacity (if required) as well as compone...

7. Funding Process and Audit.

7.1. Generally. The Commission and the Participating Member States shall provide funding to enable AstraZeneca to: (i) harness sufficient drug substance and drug filling and finishing capacity in Europe, (ii) advance procurement of critical components...

7.2. Initial Funding. In partial consideration of the Vaccine Dose purchase rights granted by AstraZeneca to the Commission acting on behalf and in the name of the Participating Member States hereunder, the Commission shall pay to AstraZeneca a fixed ...

(a) The Commission shall pay to AstraZeneca two-thirds of the Initial Funding (first Installment) within five (5) working days of the Effective Date; and

(b) The Commission shall pay to AstraZeneca one-third of the Initial Funding (second Installment) within twenty (20) days following the receipt from AstraZeneca of relevant evidence of the use of the first Installment and a relevant progress report of...

7.3. Subsequent Funding. The Participating Member States shall pay the Fill/Finish/Packaging Costs, storage and distribution costs of the Vaccine, destruction for any material produced at risk, and costs and expenses directly incurred for, or fairly ...

7.4. Mechanism for Updated Total Costs of Goods.

(a) The Parties agree that, notwithstanding any other provision of this Agreement, and while AstraZeneca acknowledges its obligation is to supply the Vaccine Doses at no profit, AstraZeneca shall not be requested or required to supply the Vaccine Dose...

(b) To the extent that the total Cost of Goods exceed the estimated amount of 870 million Euros by less than 20%, AstraZeneca shall provide an updated purchase and payment schedule to the Commission, which shall state the delivery schedule of the Init...

(c) If AstraZeneca becomes aware that the estimated Cost of Goods are reasonably expected to exceed 870 million Euros by 20% or more, then AstraZeneca shall notify the Commission of such excess and provide the relevant evidence in this respect. Follow...

(d) If following the finalization of the matters contemplated hereby, documentary evidence provided by AstraZeneca indicates that the Cost of Goods for the Initial Europe Doses sold is less than 870 million Euros or the Participating Member States pai...

7.5. Method of Payments. All payments to AstraZeneca under this Agreement shall be made by deposit of Euros by wire transfer of immediately available funds in the requisite amount to such bank account as AstraZeneca may from time to time designate by ...

7.6. Audits and protection of EU financial interests.

(a) During the term of the Agreement and for a period of five (5) years after termination or expiration of the Agreement, AstraZeneca shall permit the Commission to perform or request an audit of the Cost of Goods of the Initial Europe Doses (and any ...

(b) AstraZeneca must keep all original documents stored on any appropriate medium, including digitised originals, if allowed by the national law, for a period of five (5) years starting from the last payment made under the last Order Form.

(c) In accordance with Council Regulation (Euratom, EC) No 2185/96 of 11 November 1996 concerning on-the-spot checks and inspection carried out by the Commission in order to protect the European Communities' financial interests against fraud and other...

(d) Without increasing or decreasing the rights existing under Applicable Laws, the Parties acknowledge that the Court of Auditors and the European Public Prosecutor's Office established by Council Regulation (EU) 2017/1939 ('the EPPO') also have rig...

7.7. Late Payments. In the event the Commission or the Participating Member States fail to pay any amount payable under this Agreement or the Order Form within twenty (20) days of the due date for any such payment, without prejudice to any other right...

(a) interest shall accrue on that outstanding amount for the period beginning on the due date for payment and ending on the date of actual payment at the rate applied by the European Central Bank for its principal refinancing operations in euros (the ...

(b) without prejudice to Section 7.7(a) and subject to giving the Commission or the Participating Member States twenty (20) days prior written notice of its intention to do so, AstraZeneca shall be entitled to suspend its obligations under this Agreem...

8. Delivery, Allocation, Distribution and Storage.

8.1. Delivery.

(a) AstraZeneca shall notify the Alliance Manager and Representative of each Participating Member State in good time prior to such time that AstraZeneca expects Doses to be available. Such notification shall include an estimate of the total number of...

(b) Following receipt of such notification, AstraZeneca shall issue an invoice to the Participating Member States. Each Participating Member State shall pay such invoice in accordance with Section 7.5. AstraZeneca and the Representative for each Par...

8.2. Suspension of payments: In case of non-delivery or late delivery past the firm delivery date, the obligation of payment will be suspended. The obligation of payment will resume once the delivery has been completed. In that case, the Commission an...

8.3. Allocation.

(a) No later than thirty (30) working days following the Effective Date, the Commission shall deliver to AstraZeneca a final and binding written allocation of Initial Europe Doses between the Participating Member States (the "Binding Allocation"), wh...

(b) In the event that the Commission does not provide a Binding Allocation within the thirty (30) working day period or the number of Doses set forth in the Binding Allocation does not equal 300 million, then, unless otherwise agreed in writing by the...

(c) The Participating Member States may also resell, at no profit, Initial Europe Doses and/or Optional Doses to European countries that are not Member States if such other European countries agree to be bound by the terms and conditions of this Agree...

8.4. Distribution by Participating Member States. Upon and after delivery by AstraZeneca to the respective Distribution Hubs, the Participating Member States shall be responsible for transportation and distribution of the Vaccine Doses allocated to t...

8.5. Storage and Destruction. Pursuant to Section 8.1 of this Agreement, AstraZeneca will provide the Participating Member States with at least five (5) working days' notice of when the Doses are available for delivery. In the event a Participating M...

9. Pricing.

9.1. Initial Doses. AstraZeneca shall manufacture and supply to the Participating Member States the Initial Europe Doses at a price equal to their total Cost of Goods, with no profit or loss for AstraZeneca, which, as of the Effective Date, is estimat...

9.2. Optional Doses. In the event the Commission exercises the option on behalf of and in the name of the Member States to obtain the Optional Doses in accordance with Section 5.2, AstraZeneca shall manufacture and supply the Optional Doses at a price...

9.3. Additional Doses. AstraZeneca shall provide any agreed Additional Doses at Cost of Goods until 1 July 2021, unless AstraZeneca determines in good faith that the COVID-19 Pandemic has not ceased as of 1 July 2021, in which case AstraZeneca shall p...

10. Regulatory Matters.

10.1. Compliance; Assistance. AstraZeneca shall be responsible for timely complying with all legal requirements of approval processes of the clinical trials and the market authorization of the Vaccine in the Member States. Notwithstanding the foregoin...

10.2. Reporting. AstraZeneca shall promptly inform the Commission if, in the process of reviewing the results or progress of AstraZeneca's clinical trials, AstraZeneca reasonably determines that the ongoing or planned clinical trials by AstraZeneca an...

10.3. Post-Launch Safety and Risk Management Studies. In the event that post-launch safety or risk management studies for the Vaccine are (i) required by the EMA, (ii) required by another Regulatory Authority and relied upon by EMA for approval, or (...

11. Intellectual Property.

11.1. Ownership. The Commission acknowledges that AstraZeneca has pre-existing obligations to its upstream licensor and throughout the term of this Agreement, may incur obligations to its CMOs and other contractors in respect of patents, know-how and ...

11.2. IP Rights Following Abandonment. The Commission, or any third party designated by the Commission, shall have the right to obtain a license or sublicense from AstraZeneca for the Vaccine IP Rights to the extent reasonably necessary to enable the ...

12. Term and Termination.

12.1. Term. This Agreement shall commence on the Effective Date and, unless earlier terminated as provided in Section 12.2 or 12.3 below, shall remain in effect until the last Initial Europe Doses, Optional Doses (if Optional Doses are ordered pursuan...

12.2. Termination for Abandonment.

(a) In the event that AstraZeneca abandons the development, manufacturing and other efforts hereunder (whether as a result of its determination that the Vaccine cannot be safely or efficaciously developed, manufactured, distributed, or administered or...

(b) In addition, the Commission can terminate this Agreement if AstraZeneca reasonably determines that the ongoing or planned clinical trials by AstraZeneca and its partners are not likely to be sufficient for approval of the Vaccine as set out in Sec...

(c) In the event either Party terminates this Agreement pursuant to Section 12.2(a), upon the request of the Commission, AstraZeneca shall use Best Reasonable Efforts to:

(i) ensure the transfer of all purchased vials and stoppers to the Commission (or its designee) to be repurposed;

(ii) assign the Commission (or its designee) all purchased or reserved drug product manufacturing capacity from the applicable CMO (to the extent permitted by the agreement between AstraZeneca and such CMO); and

(iii) return to the Commission (or its designee), within thirty (30) days after the date of termination of this Agreement, any portion of the Funding that is unspent, if any, after deducting all expenses incurred by AstraZeneca including any non-cance...

(d) Within thirty (30) days following the date of termination of this Agreement, the Commission (with respect to the Initial Funding) and the Participating Member States (with respect to the Subsequent Funding and any other payment, pro rata to the Bi...

Without prejudice to the indemnification rights of AstraZeneca and the other Indemnified Persons under Article 14, no additional compensation shall be claimed from the Commission or any Participating Member State for any damages AstraZeneca might incu...

12.3. Termination for cause.

(a) if AstraZeneca is in material breach of its obligations (considered as a whole) of this Agreement following notice and an opportunity to cure as set forth below;

(b) if the contractor or any person that assumes unlimited liability for the debts of the contractor is in one of the situations provided for in points (a) and (b) of Article 136(1) of the Financial Regulation ;

12.4. Survival. The following provisions shall survive expiration or termination of this Agreement: Sections 2 (“Role of the Parties”), 7.6 (Audit of Production Costs), and 7.7 (Late Payments), and Articles 11 (Intellectual Property), 12 (Term and Ter...

13. Representations and Warranties.

13.1. AstraZeneca. AstraZeneca represents, warrants and covenants to the Commission and the Participating Member States that:

(a) the execution and delivery of this Agreement and the performance by it of the transactions contemplated hereby have been duly authorized by all necessary corporate action;

(b) it has the power and authority to execute and deliver this Agreement and to perform its obligations hereunder;

(c) this Agreement has been duly executed and is a legal, valid and binding obligation on it, enforceable against it in accordance with its terms;

(d) it shall use its Best Reasonable Efforts to ensure that the Initial Europe Doses shall be manufactured in accordance with, and shall comply in all material respects with, current Good Manufacturing Practices in the country where the Initial Europe...

(e) it is not under any obligation, contractual or otherwise, to any Person or third party in respect of the Initial Europe Doses or that conflicts with or is inconsistent in any material respect with the terms of this Agreement or that would impede t...

(f) all information, including historic financial information, submitted to the Commission or Participating Member States in relation to this Agreement is true, complete and accurate in all material respects;

(g) it has not received public funding from any source for the same costs that are funded by the Commission or the Participating Member States and

(h) it shall comply with all Applicable Laws that are applicable to its activities and operations under this Agreement.

13.2. Commission. The Commission and the Participating Member States represents, warrants and covenants to AstraZeneca that:

(a) the execution and delivery of this Agreement by the Commission acting on behalf of itself and the Participating Member States, and the performance by each of them of the transactions contemplated hereby have been duly authorized by all necessary a...

(b) the Commission has the power and authority to execute and deliver this Agreement on behalf of itself and the Participating Member States, and the Commission and each of the Participating Member States have the power and authority to perform each o...

(c) this Agreement has been duly executed by the Commission acting on behalf of itself and the Participating Member States and is a legal, valid and binding obligation on each of them, enforceable against it in accordance with its terms;

(d) the Commission acting on behalf of itself and the Participating Member States is not under any obligation, contractual or otherwise, to any Person or third party that conflicts with or is inconsistent in any material respect with the terms of this...

(e) the Commission and the Participating Member States shall comply with all Applicable Laws that are applicable to each of its activities and operations under this Agreement.

14. Indemnification.

14.1. Member States. Each Participating Member State shall indemnify and hold harmless AstraZeneca, its Affiliates, subcontractors, licensors, and sub-licensees, and officers, directors, employees and other agents and representatives of each (collect...

14.2. Process. The Indemnified Person shall give (or cause AstraZeneca to give) the Participating Members State(s), as applicable (the “Indemnifying Party”), prompt notice of any claim or lawsuit served upon the Indemnified Person (a “Third Party Clai...

15. Release; Limitation of Liability for claims other than third party indemnification; Disclaimer of Warranties.

15.1. Release. The Commission and each of the Participating Member States each within their respective competencies, on behalf of itself, waive and release any claim against AstraZeneca arising out of or relating to: (a) lack of safety or efficacy of ...

15.2. Limitation of Liability for claims other than third party indemnification. The aggregate liability of AstraZeneca and its Affiliates in respect of claims made by the Commission or Participating Member States, or any affiliates acting on the Com...

15.3. Disclaimer of Warranties. The Parties acknowledge that they are not relying on any understanding, arrangement, statement, representation (including, any negligent misrepresentation but excluding any fraudulent misrepresentation), warranty, condi...

16. Confidentiality.

16.1. Definition of Confidential Information. In this Agreement, “Confidential Information” shall, subject to Section 16.2 mean:

(a) any and all Know-How, software, algorithms, designs, plans, forecasts, analyses, evaluations, research, business information, financial information, business plans, strategies, customer lists, marketing plans, or other information whether oral, in...

(b) any physical items, compounds, components, samples or other materials; disclosed by or on behalf of a Partyor any of that Party’s Affiliates (the “Disclosing Party”) to the other Party or any of the other Party’s Affiliates (the “Receiving Party”)...

16.2. Exclusions from Confidential Information. In this Agreement, Confidential Information shall not include any information or materials, for which the Receiving Party can prove:

(a) is or becomes public knowledge through no improper conduct on the part of the Receiving Party, the Receiving Party’s Affiliates and/or their respective representatives;

(b) is already lawfully possessed by the Receiving Party and/or the Receiving Party’s Affiliates without any obligations of confidentiality or restrictions on use prior to first receiving it from the Disclosing Party; /or

(c) is obtained subsequently by the Receiving Party and/or the Receiving Party’s Affiliates from an unrelated third party without any obligations of confidentiality and such unrelated third party is in lawful possession of such information or material...

(d) the Disclosing Party agreed to release the Receiving Party from the confidentiality obligation earlier.

16.3. Legally Required Disclosure of Confidential Information. The Receiving Party and/or the Receiving Party’s Affiliates may disclose Confidential Information to the extent required by law or regulation or by legal, judicial, regulatory or administ...

16.4. Limitations on Use of Confidential Information. The Receiving Party shall treat all Confidential Information as secret and confidential and shall not use, copy or disclose to any third party any Confidential Information of the Disclosing Party ...

16.5. Use and Disclosures of Confidential Information. The Receiving Party may:

(a) ensure the protection of confidential information or documents with the same level of protection as its own confidential information or documents and in any case with due diligence;

(b) use and disclose Confidential Information of the Disclosing Party solely to the extent necessary to enable the Receiving Party to exploit the rights granted under this Agreement and/or to perform its obligations under this Agreement; provided, tha...

(c) disclose Confidential Information of the Disclosing Party to those of the Receiving Party's Affiliates, officers and employees to whom such disclosure is necessary (and only disclose that part of the Confidential Information which is necessary) to...

(d) after giving written notice to the Disclosing Party, disclose any part of the Confidential Information of the Disclosing Party solely to the extent that it is legally required to do so pursuant to an order of a court of competent jurisdiction or o...

16.6. Protection of Confidential Information. The Receiving Party shall at all times maintain documents, materials and other items (including items in electronic form) containing Confidential Information of the Disclosing Party and any copies thereof...

16.7. Losses of Confidential Material. The Receiving Party shall notify the Disclosing Party immediately if the Receiving Party becomes aware of any unauthorized use or disclosure of, or any unauthorized access to or of any theft or loss of any copie...

16.8. Survival. The provisions of this Article 16 shall commence on the Effective Date and shall continue for so long as either Party has knowledge of any Confidential Information received or derived from the other Party and shall survive termination ...

17. Data protection.

18. Miscellaneous.

18.1. Interpretation. In this Agreement:

(a) Any phrase introduced by the terms "including", "include" and "in particular" or any similar expression shall be construed as illustrative only and shall not limit the sense of the words preceding these terms;

(b) the headings are for convenience only and shall not affect the interpretation of this Agreement;

(c) the meaning given to defined terms in this Agreement shall also apply to their grammatical variants provided that the initial letter is capitalized; and

(d) in the event of any inconsistencies between this Agreement and any attachments hereto, the terms of this Agreement shall prevail.

18.2. Notices.

18.3. Participating Member States.

(a) Any written notice sent by a Party that is actually received by the other Party shall be deemed to have been properly given and received by that Party irrespective of whether or not the delivery requirements of Section 18.2 have been complied with.

18.4. Governing Law. This Agreement shall be governed by the laws of Belgium.

18.5. Resolution.

(a) In the event of a dispute arising under this Agreement between the Parties, the Parties shall first refer such dispute to informal dispute resolution discussions between their respective Executive Officers. AstraZeneca, on the one hand, or the Co...

(b) Each of the Commission, the Participating Member States and AstraZeneca irrevocably submit to the exclusive jurisdiction of the courts located in Brussels, Belgium to settle any dispute which may arise under or in connection with this Agreement or...

18.6. Waiver. Failure or delay by either Party to exercise any right or remedy under this Agreement shall not be deemed to be a waiver of that right or remedy, or prevent the Party from exercising that or any other right or remedy on any occasion. Any...

18.7. Force Majeure. Neither the Commission nor the Participating Member States nor AstraZeneca shall be held liable or responsible to the other Party or be deemed to have breached this Agreement for failure or delay in fulfilling or performing any te...

18.8. Counterparts. This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Agreement may be executed in writing by facsimi...

18.9. Entire Agreement. This Agreement constitutes the entire agreement and understanding of the Parties relating to the subject matter of this Agreement and supersedes all prior oral or written agreements, representations, understandings or arrangeme...

18.10. Severability. If any provision of this Agreement is held to be void or otherwise unenforceable by a court of competent jurisdiction from whose judgment no appeal is made within the applicable time limit then the provision shall be omitted and ...

18.11. Amendment. No amendment shall be made to this Agreement except in writing signed by the duly authorized representatives of the Commission and AstraZeneca.

18.12. Relationship of the Parties. Nothing in this Agreement shall create or imply an agency, partnership or joint venture between the Parties. No Party shall act or describe itself as the agent of the other Parties nor shall any Party have or repres...

18.13. Opt out and signature. The Commission shall sign this agreement on behalf and in the name of all Participating Member States that have not opted out in conformity with Article 4 of the agreement between the Commission and Member States on procu...

ORDER FORM

Article 1

Subject matter

(a) shall have a legally binding obligation to purchase a portion of (i) the Initial Europe Doses as set forth in the Binding Allocation to be/as determined pursuant to Section 8.3(a) or 8.3(b), as applicable, of the APA and (ii) the Optional Doses al...

Article 2

Entry into force and duration

Article 3

Price and Quantity

3.5. Method of Payment. All payments to AstraZeneca under this Order Form shall be made by deposit of Euros by wire transfer of immediately available funds in the requisite amount to such bank account as AstraZeneca may from time to time designate ...

Article 4

Communication details; Notices

Article 5

(b) the execution and delivery of this Order Form and the performance by it of the transactions contemplated hereby have been duly authorized by all necessary action;

(c) it has the power and authority to execute and deliver this Order Form and to perform its obligations hereunder, including to satisfy the payment obligations hereunder;

(d) this Order Form has been duly executed and is a legal, valid and binding obligation on it, enforceable against it in accordance with its terms;

(e) it is not under any obligation, contractual or otherwise, to any Person or third party that conflicts with or is inconsistent in any material respect with the terms of this Order Form or that would impede the complete fulfillment of its obligation...

(f) it shall comply with all Applicable Laws that are applicable to its activities and operations under the APA;

(g) Upon request by AstraZeneca and in coordination with the Commission, the Participating Member State will use its Best Reasonable Efforts, in accordance with all Applicable Laws and within the framework of its competencies, to assist AstraZeneca in...

(h) Capacity Limitations. In the event AstraZeneca's ability to fulfill its obligations under this Agreement is impeded by a competing agreement entered into by or on behalf of the Participating Member State, AstraZeneca shall promptly inform the Part...

Article 6

Termination

This Order Form shall terminate concurrent with the APA and with the same effects of termination as set forth in Article 12 of the APA. Within thirty (30) days following the date of termination of this Order Form, the Participating Member State (pro ...

Schedule B – Participating Member States