Ministerie van Volksgezondheid, Welzijn en Sport

5.1.2e

Deadline: 16-10-2020

Directoraat Generaal Volksgezondheid
Publieke Gezondheid Crisisbeheersing en Infectieziekten
Ontworpen door
5.1.2e
5.1.2e @minvws.nl

nota

Aankoop Covid-19-vaccin AstraZeneca voor Nederland

(ter beslissing)

Datum
13 oktober 2020
Kenmerk
Zaaknummer
5.1.2e

Paraaf directeur

Paraaf 5.1.2e
5.1.2e

1 Aanleiding voor deze nota

Na het sluiten van de overeenkomst met AstraZeneca, wordt gevraagd om een zogenoemde Order Form te ondertekenen. Hierin wordt nogmaals de Nederlandse commitment bevestigd, worden een aantal praktische zaken geregeld en wordt het vervolg van het proces vastgelegd.

2 Beslispunten, advies en mogelijk alternatief

- Wij adviseren u akkoord te gaan met de bepalingen in de Order Form.
- Indien u akkoord gaat, verzoeken wij u de Order Form te ondertekenen voor 16 oktober 2020, zodat deze voor de deadline van 19 oktober verstuurd kan worden.
- Daarnaast adviseren wij u akkoord te gaan met additionele transportkosten van € 5.1.1c per dosis.

3 Samenvatting en conclusies

Op 27 augustus 2020 heeft de Europese Commissie namens de lidstaten van de Europese Unie een Advanced Purchase Agreement (APA) gesloten met AstraZeneca. Bij brief van 17 augustus 2020 heeft de minister van VWS de Tweede Kamer geïnformeerd geen gebruik te maken van de mogelijkheid van een opt-out. Daarmee is op basis van de ESI-overeenkomst tussen de Europese Commissie en Nederland de APA ook direct bindend voor Nederland. Nu wordt gevraagd om de Order Form ingevuld en getekend te retourneren aan AstraZeneca.
Het Order Form (bijlage 1 en 2) is specifiek voor iedere lidstaat. In de Order Form wordt (her)bevestigd dat Nederland zich committeert aan de APA tussen AstraZeneca en de Europese Commissie en wordt bevestigd dat Nederland 5.1.1c doses van het vaccin zal afnemen.
Daarnaast wordt in afstemming met het RIVM met AstraZeneca een aantal gegevens gedeeld, onder andere de plaats van levering en de

Directoraat Generaal Volksgezondheid
Publieke Gezondheid
Crisisbeheersing en Infectieziekten

Kenmerk
212773-PDC-19

contactgegevens van het RIVM die nodig zijn voor verdere uitvoering van de APA zijn op de Order Form ingevuld.
Advies is om de Order Form te ondertekenen door u in plaats van DGRIVM wat normaliter bij dit soort contracten het proces is. Reden hiervoor is een advies van WJZ, waarbij zij aangeven dat er mogelijk een conflict of interest is bij het RIVM indien zij de Order Form tekent. Dit doordat het RIVM VWS ook adviseert over de wetenschappelijke basis van de vaccins waarvoor een APA wordt gesloten.

Naast de directe kosten die gemaakt worden voor de aanschaf van een goedwerkend vaccin, zullen additionele kosten gemaakt worden ten behoeve van aflevering, distributie, opslag en uitvoering.
Nederland is gevraagd om akkoord te gaan met additionele kosten, deze zijn niet in de APA opgenomen. Het gaat hierbij om transportkosten voor de vaccins van AstraZeneca. AstraZeneca zal in ruil voor deze vergoeding de bestelde vaccins afleveren op het aangegeven adres op de Order Form. Hierdoor hoeft Nederland niet de vaccins op te halen bij de fabriek met alle bijbehorende condities waarop zo'n transport moet plaatsvinden. De kosten bedragen 5.1.1c per dosis; hierdoor zullen deze kosten voor Nederland in totaal 5.1.1c bedragen (bijlage 3). Deze kosten gelden alleen als alle lidstaten meedoen in de kosten; op het moment dat er een land niet geïnteresseerd is, dan zullen de kosten opnieuw berekend worden.
Naast de transportkosten, is er nog geen scherp beeld van de overig genoemde kosten. Zodra daar zicht op is, worden deze apart inzichtelijk gemaakt en verwerkt in de begroting.

4 Draagvlak politiek
N.v.t.

5 Draagvlak maatschappelijk en eenduidige communicatie
N.v.t.

6 Financiële en personele gevolgen
Financiële gevolgen van de transportkosten zijn afgestemd met FEZ.
De financiële gevolgen passen binnen de begroting van de Incidentele Suppletoire Begroting VWS 2020 en zijn afgestemd met en geaccordeerd door FEZ en IRF/FIN.

7 Juridische aspecten haalbaarheid
Juridische aspecten met betrekking tot de Order Form afgestemd met WJZ.

8 Afstemming (intern, interdepartementaal en met veldpartijen)
Afgestemd met FEZ, IRF/FIN en RIVM.

9 Gevolgen administratieve lasten
N.v.t.

10 Toezeggingen
N.v.t.

11 Fraudetoets
N.v.t.

5.1.2e

SENSITIVE*
RELEASABLE TO: Need to know basis

ORDER FORM

1. The Kingdom of the Netherlands (the **"Participating Member State"**), represented for the purposes of signing this specific order form by mrs. 5.1.2e, 5.1.2e 5.1.2e Ministry of Health, Welfare and Sports, the Netherlands,

and

2. AstraZeneca AB, a party incorporated in Sweden having a business address of KVARNBERGAG 16, 151 85 SÖDERTÄLJE

Reg Office AstraZeneca AB
SE-151 85 Södertälje, Sweden
Reg No 556011-7482

"AstraZeneca" or **"the contractor"**), represented for the purposes of signing this specific order form by 5.1.2e 5.1.2e

WHEREAS, AstraZeneca and the Commission acting on behalf of and in the name of the Participating Member States entered into that Advance Purchase Agreement for the production, purchase and supply of the ChAdOx1 nCov-19 vaccine in the European Union dated 27 August, 2020 (the **"APA"**).

WHEREAS, the APA provides that each Participating Member State must deliver and execute an Order Form in this form with the information filled in (a **"Order form"**);

WHEREAS, the Participating Member State wishes to order Doses from AstraZeneca in accordance with the terms of the APA.

WHEREAS in accordance with the provisions set out in the APA, AstraZeneca has agreed to supply the Initial Europe Doses allocated to each Participating Member State in a given timeframe, should it manage to develop a safe and effective vaccine against COVID-19 (**"Vaccine"**).

WHEREAS, capitalized terms that are used but not otherwise defined herein shall have the meaning for such capitalized terms set forth in the APA.

HAVE AGREED

Article 1

Subject matter

1.1 This Order Form is entered into as contemplated by the APA **for the production and purchase of a successful COVID-19 vaccine in the European Union**, signed by the parties on 27 August 2020. This Order Form is an integral part of the APA and the terms and conditions of the APA are incorporated into this Order Form by this reference.

1.2 By execution of this Order Form, the undersigned Participating Member State hereby:

(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 **Fout! Verwijzingsbron niet gevonden.** or **Fout! Verwijzingsbron niet gevonden.**, as applicable, of the APA and (ii) the Optional Doses allocated as set forth in Section 5.2 of the APA, in each case, as set forth in the APA and in this Order Form.

Article 2

Entry into force and duration

2.1 This Order Form shall become effective upon execution and delivery by the Participating Member State and counter-execution and delivery by AstraZeneca.

Article 3

Price and Quantity

3.1 Price Per Dose. The Price Per Dose for the Initial Europe Doses and Optional Doses shall equal the amount calculated pursuant to Sections 7.3, 7.4 and 10.3 of the APA, taking into account adjustments provided for therein.

3.2. Initial Europe Doses: Quantity and Binding Order. The precise quantity of the Initial Europe Doses purchased by the Kingdom of the Netherlands as determined pursuant to Sections 8.3(a) and 8.3(b) of the APA is 5.1.1c The number of Initial Europe Doses allocated to each Participating Member State in the Binding Allocation shall be the number of Initial Europe Doses that the Participating Member State is required to purchase pursuant to this Order Form.

3.3. Optional Doses: Quantity and Binding Order. The precise quantity of the Optional Doses to be purchased by the Kingdom of the Netherlands as determined pursuant to Section 5.2 of the APA is [TBD]. The number of Optional Doses set forth in such allocation shall be the total number of Optional Doses that the Participating Member State is required to purchase pursuant to this Order Form.

3.4. Additional Doses. Additional Doses may be agreed to by AstraZeneca and the Kingdom of the Netherlands in accordance with Section 5.3 of the APA. The Price per Dose for Additional Doses would equal the amount calculated pursuant to Section 7.4 of the APA, taking into account adjustments provided for in the APA.

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 by written notice to the Participating Member State. For the purpose of calculating any sums due under, or otherwise reimbursable pursuant to this Agreement 5.1.1c

5.1.1c
5.1.1c following invoicing for such Doses.

3.6. Distribution Hubs. The Distribution Hub for the Participating Member State is as follows:

5.1.2h

Article 4

Communication details; Notices

Any notice given under this Order Form shall be in writing in English, shall refer to the APA and this Order Form and shall be sent by either pre-paid recorded first class post/pre-paid airmail or courier to the principal office or registered office of the recipient or by electronic transmission to the addresses set forth below:

4.1 Participating Member State:

5.1.2e
5.1.2e
National Institute of Public Health and the Environment
Antonie van Leeuwenhoeklaan 9,
3721 MA, Bilthoven, The Netherlands
E-mail: 5.1.2e *@rivm.nl*
T.:+31 5.1.2e

Contractor:
5.1.2e 5.1.2a
5.1.2a
Email: 5.1.2e @ASTRAZENECA.COM

Copy to
5.1.2e Deputy General Counsel
5.1.2a
Email: 5.1.2e @ASTRAZENECA.COM

Article 5

Representations, Warranties and Covenants

5.1 The Participating Member State represents, warrants and covenants to AstraZeneca that:

(a) 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;

(b) 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;

(c) 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;

(d) 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 obligations under this Order Form;

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

(f) 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 securing the supply of any drug substances needed and drug filling and finishing capacity as well as components for the development, manufacture, and supply of the Initial Europe Doses; and

(g) 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 Participating Member State. While AstraZeneca shall continue to use Best Reasonable Efforts to engage with its own contract manufacturers and suppliers to utilize the capacity and/or components, the Participating Member State will assist in finding a mutually acceptable solution for this Agreement and the competing agreement. To the extent AstraZeneca's performance under this Agreement is impeded by any such competing agreements, AstraZeneca shall not be deemed in breach of this Agreement as a result of any such delay due to the aforementioned competing agreement(s).

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. [redacted] following the date of termination of this Order Form, the Participating Member State (pro rata to the Binding Allocation pursuant to Section 8.3(b) of the APA or if there is no Binding Allocation, then pro rata in accordance with the method for allocation set forth in Section 8.3(b) of the APA) shall reimburse AstraZeneca for all reasonably incurred unpaid expenses and any non-cancellable expenses relating to the activities under this Agreement for which Funding has not yet been provided.

Signatures

For the Member State authority,

SENSITIVE*
RELEASABLE TO: Need to know basis

5.1.2e 5.1.2e ,

5.1.2e

Ministry of Health, welfare and Sports,

5.1.2e

signature:
Done at the Hague, (15-10-'20)

In duplicate in English.

8 - 8

5.1.2i Concept