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From: 5.1.2e @aemps.es

Sent: Thur 10/21/2021 6:47:08 AM

Subject: RE: IMPORTANT UPDATE_[CONFIDENTIAL] BioNTech-Pfizer - Pausing of Doses - Q4 2021 - Breakdown donations to COVAX vs. bilateral donations/resell

Received: Thur 10/21/2021 6:47:18 AM

[Copia de EC Q4 Donations 19 OCT 2021 \(ES\).xlsx](#)

Dear 5.1.2e

Please, find enclosed the excel sheet with the date of the offer notice acceptance by GAVI for the Spanish donations.
Would us be still on time to donate doses from November? (provided we manage to finish everything before the 25 of October).
Best regards,

5.1.2e

Departamento de Medicamentos de Uso Humano/Department of Medicines for Human Use
Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)
Calle Campezo 1 • Edificio 8 • E-28022 Madrid • España/Spain

CONFIDENCIALIDAD. El contenido de este mensaje y el de cualquier documentación anexa es confidencial y va dirigido únicamente al destinatario del mismo. Si Usted no es el destinatario, le solicitamos que nos lo indique, no comunique su contenido a terceros y proceda a su destrucción.

CONFIDENTIALITY. The content of this message and any attached information is confidential and exclusively for the use of the addressee. If you are not the addressee, we ask you to notify to the sender, do not pass its content and delete the original.

De: 5.1.2e <5.1.2e@pfizer.com>

Enviado el: miércoles, 20 de octubre de 2021 18:10

Para: 5.1.2e @ec.europa.eu; 5.1.2e <5.1.2e@health.fgov.be>; 5.1.2e @commissariat.fed.be' <5.1.2e@commissariat.fed.be>; 5.1.2e @fagg-afmps.be' <5.1.2e@fagg-afmps.be>; 5.1.2e @dgtresor.gouv.fr' <5.1.2e@dgtresor.gouv.fr>; 5.1.2e @igf.finances.gouv.fr; 5.1.2e @bmg.bund.de; 5.1.2e @bmg.bund.de' <5.1.2e@bmg.bund.de>; 5.1.2e @bmg.bund.de; 5.1.2e @bmg.bund.de; 5.1.2e @hse.ie' <5.1.2e@hse.ie>; 5.1.2e @health.gov.ie' <5.1.2e@health.gov.ie>; 5.1.2e @sanita.it' <5.1.2e@sanita.it>; 5.1.2e @covid19.difesa.it; 5.1.2e @ms.etat.lu' <5.1.2e@ms.etat.lu>; 5.1.2e @ms.etat.lu' <5.1.2e@ms.etat.lu>; 5.1.2e @minvws.nl; 5.1.2e @minbuza.nl' <5.1.2e@minbuza.nl>; 5.1.2e @infarmed.pt' <5.1.2e@infarmed.pt>; 5.1.2e @infarmed.pt' <5.1.2e@infarmed.pt>;

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Asunto: RE: IMPORTANT UPDATE_ [CONFIDENTIAL] BioNTech-Pfizer - Pausing of Doses - Q4 2021 - Breakdown donations to COVAX vs. bilateral donations/resell

Importancia: Alta

Privileged and Confidential

Dear Esteemed Member States Representatives,

Thank for your collaboration during the past days. We have great progress on the EC donations so far, yet we need to work closely with all involved parties, COVAX/GAVI/recipient countries, to make those deliveries happen asap.

In this spirit, we would like to share with you below an important update for both **October & November doses**:

For October Paused/Redistributed Doses:

- ***Locking our supply plans*** – we have locked our supply plans based on the attached final overview (please refer to the first sheet October 2021 doses). Unfortunately, no further requests will be accepted for October paused doses (i.e. columns F & L cannot be updated.)
- ***Offer Notice Acceptance Date by GAVI/COVAX*** – We are still missing the acceptance of GAVI/COVAX for some markets (highlighted in red): (1) Portugal (2) Ireland (3) Spain (4) The Netherlands (5) Luxembourg (6) Norway. Please note GAVI/COVAX has 10 business days to accept the offer notices as per the tripartite agreement with France/Pfizer. If requests are not explicitly accepted by GAVI/COVAX, that means the process has not actually been kicked-off. Kindly urge you to reach out and follow up closely with GAVI/COVAX on their swift acceptance within the 10 business days.
- ***Allocation of Gavi Shared Doses & Shipment Requests/PO issuance*** – as of today, we have not received the confirmed allocation by GAVI/COVAX and Shipment Requests/POs by the procuring agencies (please refer to column J which is now empty). Our common goal is to deliver the doses asap, receiving the POs is the trigger to ensure deliveries are scheduled within the average 4 weeks lead time. Our team stands ready to make this happen, once we have those POs in hand. We would encourage you to follow up closely with all relevant parties to ensure swift actions are taken.

For November Paused/Redistributed Doses:

- We are happy to share with you that we finalized our proposal for November doses and onward donations under the 3rd EC Contact. We understand the EC team has shared this proposal with the Member States. We are planning to join you this Friday to discuss this proposal and take all your questions.
- Accordingly, we have added a sheet for November doses in the attached file. We have reflected those Member States, who confirmed their willingness to donate all their November allocation (4 weeks of November) based on the attached pdf shared by the EC team on 28 September 2021.

- In parallel to our discussion, please confirm the number of donated doses and complete any missing information highlighted in **red**. We might have a room to make those deliveries happen in November if the process is finalized before **25 October 2021** (to accommodate for the 4 weeks lead time).

Should you have any inquiries, please do not hesitate to contact me.

BR,

5.1.2e

Pfizer Bldg, Dubai Media City, Dubai, UAE
P.O. Box 502749

5.1.2e 5.1.2e
5.1.2e @pfizer.com



From: 5.1.2e

Sent: Monday, October 18, 2021 10:57 AM

To: 5.1.2e @ec.europa.eu; 5.1.2e <5.1.2e @health.fgov.be>; 5.1.2e @commissariat.fed.be'
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Subject: RE: IMPORTANT UPDATE_ [CONFIDENTIAL] BioNTech-Pfizer - Pausing of Doses - Q4 2021 - Breakdown donations to COVAX vs. bilateral donations/resell

Importance: High

Privileged and Confidential

Dear All,

Please find attached the most updated summary as of today. Please share with me any missing information highlighted in **red** before end of business day.

We will have to lock this today and share it with the our supply chain team.

For any correspondence related to COVAX donations, please ensure you copy myself,

5.1.2e

(instead of 5.1.2e

Thank you for your continuous cooperation.

BR,

5.1.2e

Pfizer Bldg. Dubai Media City, Dubai, UAE

P.O. Box 502749



5.1.2e



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5.1.2e

@pfizer.com



From: 5.1.2e

Sent: Friday, October 8, 2021 7:01 PM

To: 5.1.2e @ec.europa.eu; 5.1.2e <5.1.2e @health.fgov.be>; 5.1.2e @commissariat.fed.be'
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Subject: IMPORTANT UPDATE_ [CONFIDENTIAL] BioNTech-Pfizer - Pausing of Doses - Q4 2021 - Breakdown donations to COVAX vs. bilateral donations/resell

Importance: High

Privileged and Confidential

Dear 5.1.2e & esteemed member states representative,

For October Paused/Redistributed Doses:

- We have noticed few timelines are missed in the process we shared on September 21, 2021. Accordingly, we would like to share with you this **important update**.
- We are happy to share with you the attached **excel file**, which compile all the information we have received so far. This file should continue to be a live document that we will keep updating until all redistributed doses are fully delivered.
- We would need your urgent support to:

1. For each involved member states, please review and complete all inputs in **columns D to H** on the attached excel sheet and confirm back to us in writing latest by **October 11, 2021 EoB CET**.

2. For **Belgium, Ireland, Spain, Luxembourg and The Netherlands**, kindly ensure you issue the required Offer Notice to France/COVAX latest by **October 11, 2021 EoB CET**. Unfortunately, we will not be able to further extend this timelines, as it would put the whole process at risk.
 3. For **France, Portugal and Spain**, kindly ensure to complete all required steps/paperwork for bilateral donations and/or resale latest by **October 11, 2021 EoB CET**.
- We are also happy to extend the timelines for final COVAX recipient country acceptance, from October 8, 2021 to October 18, 2021. Kindly ask France and all involved member states to ensure receiving COVAX/GAVI's feedback latest by **October 18, 2021 EoB CET**. Unfortunately, we will not be able to further extend this timelines, as it would put the whole process at risk.
 - To accommodate this delay in the process, please note the expected delivery date by Pfizer to recipient countries, whether through COVAX and/or bilateral donations, will not be before the **2nd/3rd week of November 2021**. It may be further revised depending on the achieved progress.

For November Paused/Redistributed Doses:

- We continue to work closely with the Commission to find a solution for November doses. We should be able to provide an update shortly by next week.

Should you have any inquiries, please do not hesitate to contact me.

BR,

5.1.2e

Pfizer Bldg. Dubai Media City, Dubai, UAE
P.O. Box 502749

5.1.2e 5.1.2e
5.1.2e @pfizer.com



From: 5.1.2e

Sent: Thursday, September 30, 2021 10:28 AM

To: 5.1.2e @ec.europa.eu; 5.1.2e <5.1.2e @health.fgov.be>; 5.1.2e @commissariat.fed.be'
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Subject: RE: [CONFIDENTIAL] BioNTech-Pfizer - Pausing of Doses - Q4 2021 - Breakdown donations to COVAX vs. bilateral donations/resell

Dear 5.1.2e esteemed member states representative,

Thank you for sharing your inquiries regarding the allocation for October and November 2021.

We would like to clarify few points that would facilitate the discussion:

- BNT/Pfizer have shared total Q4 doses with all Member States through our local teams on **September 16th**.
- We have also shared total October doses with all Member States through our local teams on **September 16th**.
- We anticipate to finalize the **5.1.1c** doses from the 1st and 2nd EC contracts in November 2021, to ensure a clean cut before we start the new 3rd EC Contract in December 2021.
- Given all complexities, we are trying to avoid a situation where we have to concurrently invoice / deliver doses under different contracts as we have done under the 1st / 2nd contracts.
- Accordingly, we anticipate that total November should indicate the end of the contracts and Q4 2021.

We would also like to clarify our position on pausing doses in November:

- As indicated under July 14th Pausing/Redistributing Process, the maximum duration of a pause can be **4 weeks collectively per quarter/Member State**.
- While we are trying our best to support Member States with this exceptional process, BNT/Pfizer should not be in a difficult position to satisfy their obligations as a result of such process, which is not covered under any of the contracts.
- Member States are still able to donate/resell their doses under the EC APA/PA and the new Donation and Resale Framework Agreement, **without a pause**. They would just need to go through the process and manage the agreed timelines through forward planning.
- Thus, given the tight timelines, we will not be able to commit to redistributing November Allocated Doses (as mentioned above November is anticipated to be end of 1st and 2nd Contract).
- In case any redistribution arrangements did not materialize for any reason including but not limited to: incomplete paperwork, recipient countries operational readiness, logistical barriers...etc.), the EC APA/PA T&Cs will apply. BNT/Pfizer will have to invoice/deliver those doses to per the signed VOFs. We need to ensure appropriate time is allowed to do so if needed.
- We are currently discussing with the Commission some practical solution to manage the delay resulting on COVAX and/or recipient countries side, to help Member States with the redistribution process.

Hope that clarifies.

BR,

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