

To: [REDACTED] 5.1.2e [REDACTED] 5.1.2e @minvws.nl]; [REDACTED] 5.1.2e @ec.europa.eu[[REDACTED] 5.1.2e @ec.europa.eu]
Cc: [REDACTED] 5.1.2e [REDACTED] 5.1.2e @minvws.nl]; [REDACTED] 5.1.2e @ITS.JNJ.com]; [REDACTED] 5.1.2e [REDACTED] 5.1.2e @its.jnj.com]; [REDACTED] 5.1.2e @its.jnj.com]
From: [REDACTED] 5.1.2e
Sent: Mon 12/21/2020 12:04:58 PM
Subject: Submission VOF
Received: Mon 12/21/2020 12:05:07 PM

Dear [REDACTED] 5.1.2e
 I hope you are doing well.

I am sending this short mail because we are receiving some questions from Member States about the procedure to follow for the submission of the Vaccine Order Form (VOF). There seems to be some unclarity about whether MS have to submit the VOF directly to us or to the EC.

We would highly appreciate when you can re-emphasize and communicate to the MS that we have agreed to centralize the flow of MS VOF's through the EC. In the adjusted flow, PMS will send their VOF to the EC and the EC will send all VOF's on behalf of Participating Member States to Janssen.

Thanks in advance and best regards,

[REDACTED] 5.1.2e
 on behalf of the Janssen team

Kind regards / Met vriendelijke groet

[REDACTED] 5.1.2e



Janssen Vaccines and Prevention B.V.
 Archimedesweg 4-6, 2333 CN Leiden, The Netherlands
 PO Box [REDACTED] 5.1.2e 2301 CA Leiden, The Netherlands
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[\[REDACTED\] 5.1.2e @its.jnj.com](mailto:[REDACTED]@its.jnj.com)

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From: [REDACTED] 5.1.2e <[REDACTED] 5.1.2e @its.jnj.com>
Sent: vrijdag 18 december 2020 14:28
To: [REDACTED] 5.1.2e <[REDACTED] 5.1.2e @minvws.nl>; [REDACTED] 5.1.2e @ec.europa.eu
Cc: [REDACTED] 5.1.2e <[REDACTED] 5.1.2e @minvws.nl>; [REDACTED] 5.1.2e <[REDACTED] 5.1.2e @ITS.JNJ.com>; [REDACTED] 5.1.2e [REDACTED] 5.1.2e <[REDACTED] 5.1.2e @its.jnj.com>
Subject: Janssen-EC operational dialogue platform (ODP) - meeting 10/12/2020

Dear [REDACTED] 5.1.2e
 Thanks a lot for the amended Minutes and the proposal to centralize all MS Order Forms and send them to Janssen via the EC.

With regards to the Minutes:

Please find attached the Minutes with some further minor amendments from our side. I have included a redline version and a clean one.

With regards to the Vaccine Order Form:

As discussed by phone we are in agreement to centralise the flow of MS Order Forms through the EC. In the adjusted flow, PMS will send their Order Form to the EC and the EC will send all Vaccine Order Forms on behalf of Participating Member States to Janssen.

However, we would prefer that the batch of order forms is send to me at 5.1.2e@its.jnj.com (5.1.2e) instead of to the email address 5.1.2e@its.jnj.com that is currently in the Order Form. I've revised the Guidance accordingly.

As discussed in our meeting on the 10th, we would highly appreciate some feedback on the meeting of the Steering Group where the exemption for serialization would be discussed.

5.1.1c

5.1.1c

Thanks in advance and best regards,

(5.1.2e)
on behalf of the Janssen team

Kind regards / Met vriendelijke groet

5.1.2e



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From: (5.1.2e) <(5.1.2e)@ec.europa.eu>

Sent: woensdag 16 december 2020 18:04

To: (5.1.2e) [JRDNL] <(5.1.2e)@its.jnj.com>; (5.1.2e) <(5.1.2e)@minvws.nl>

Cc: (5.1.2e) [JPPBE] <(5.1.2e)@ITS.JNJ.com>; (5.1.2e) [JANBE] <(5.1.2e)@its.jnj.com>; (5.1.2e) <(5.1.2e)@minvws.nl>

Subject: [EXTERNAL] RE: Janssen-EC operational dialogue platform (ODP) - meeting 10/12/2020

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Dear [REDACTED] 5.1.2e

Thanks a lot for these Minutes and other documents which I will pass to Member States.
Please find attached some *comments on the minutes*.

In addition, on the **Vaccine Order Form**, we suggest to centralise all MS Order Forms and send them on to you. I've revised the Guidance accordingly.

- Could you let me know if you're ok with this and I'll send the attached Template VOF to Member States.

Finally, [REDACTED] 5.1.2e could you send me the **Excel file** you would like MS to fill in for **contact details** in their administration and/or distribution hubs?

Thanks in advance.

Best regards,

[REDACTED] 5.1.2e

[REDACTED] 5.1.2e

[REDACTED] 5.1.2e



European Commission

Directorate-General for Health and Food Safety (SANTE)

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From: [REDACTED] 5.1.2e [REDACTED] 5.1.2e <[REDACTED] 5.1.2e @its.jnj.com>

Sent: Friday, December 11, 2020 7:35 PM

To: [REDACTED] 5.1.2e <[REDACTED] 5.1.2e @minvws.nl>; [REDACTED] 5.1.2e (SANTE) <[REDACTED] 5.1.2e @ec.europa.eu>

Cc: [REDACTED] 5.1.2e [REDACTED] 5.1.2e <[REDACTED] 5.1.2e @ITS.JNJ.com>; [REDACTED] 5.1.2e [REDACTED] 5.1.2e <[REDACTED] 5.1.2e @its.jnj.com>; [REDACTED] 5.1.2e

[REDACTED] 5.1.2e <[REDACTED] 5.1.2e @its.jnj.com>; [REDACTED] 5.1.2e <[REDACTED] 5.1.2e @minvws.nl>

Subject: Janssen-EC operational dialogue platform (ODP) - meeting 10/12/2020

Dear [REDACTED] 5.1.2e

Thank you for the first constructive meeting of the Janssen-EC operational dialogue platform on our potential COVID-19 vaccine.

Attached is a short report with the main points we covered. I also highlight below the immediate points for follow up.

It will be important to get your feedback on the serialization exemption following your internal discussion with the Steering Committee, do you know when this might happen?

Please find attached the updated product characteristics, as well as the supply configuration, this can be of interest for the Member States in light of planning for product storage. As discussed we will ship the product at -20°C to Member State central warehouse/drop off point. This change is due to recent labeling guidance from EMA regarding the need for a printed expiry date. The option to thaw at the vaccination point is a recommendation from Janssen but not an obligation

for any member state to follow.

To facilitate the appropriate customer set-up in our systems as well as to prepare for the shipments, attached is the questionnaire for capturing per Member State the Customer Master data and Logistical data requirements. The feedback can be provided direct to our Janssen COVID19 Vaccine Central Hub Mailbox: [REDACTED] 5.1.2e [REDACTED] [@its.jnj.com](mailto:[REDACTED]@its.jnj.com). We appreciate feedback from the Member States as quickly as possible, ideally before December 21st.

My assistant will be in touch with your office to put placeholders for the 3 weekly ODP meetings, starting in 2021.

Let me know if you've any further questions or clarification is needed.

Thanks and best regards,

[REDACTED] 5.1.2e on behalf of the Janssen team

Kind regards / Met vriendelijke groet

[REDACTED] 5.1.2e



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