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Subject: Pfizer Responses to Dutch National Institute for Public Health and the Environment (RIVM) Questions

Overall

1. What is the maximum time that the vial can be kept outside the refrigerator before dilution?

5.1.1c

2. RIVM is looking for multiple logistical partners and would be helped if Pfizer can provide the RIVM with further suggestions (companies) experienced with ULT logistics and storage.

5.1.1c

Falsified Medicine Directive (FMD)

3. Do the vaccines have a 2D-barcode (in the original packaging) as part of the FMD?

For the initial product artwork:

Vial:

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Carton tray:

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4. Is the serialization information uploaded in the National Medicines Verification System (NMVS) (for the Netherlands) or European Medicines Verification System (EMVS) for all packs bearing a 2D-barcode, prior to the release of the batch? How is this going to work?

5.1.1c

Batch release

5. Will every individual delivery be accompanied by an EU Official Control Authority Batch Release Certificates (OMCL: Official Medicines Control Laboratories)?

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Volumes allocated to the markets and timing of deliveries

6. Is there any indication by when Pfizer could start supplying (after EMA approval)? And how are the doses being allocated per market?

Pfizer will manage contract dose commitments through global/regional/market S&OP planning. Specific initial ship-to/quantity purchase orders and timing, in addition to existing order adjustments, will be managed as part of the market allocation process.

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Additional questions

7. RIVM would be very much helped when Pfizer could offer diluent, or advise the RIVM where to purchase diluent.

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8. RIVM will need training and instruction materials (including videos), and if possible provided with the text, so this can be translated and subtitled (in case of a video)

Pfizer is planning to develop HCP education resources (print/infographics and video format) to help to educate vaccinating HCPs and healthcare staff on product storage/handling, preparation and administration. We can share an overview of HCP education materials to discuss how we can partner with the government for appropriate HCP education.