

Van: 5.1.2e <5.1.2e@pfizer.com>
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Aan: 5.1.2e
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Onderwerp: Verslag en actiepunten n.a.v. RIVM-Pfizer overleg 18 December 2020
Bijlagen: Contact details - Pfizer RIVM 20201209.docx; Verslag en actiepunten overleg RIVM - Pfizer 18_12_2020 Fin.docx

Beste allen,
 Hierbij het verslag en actiepunten zoals vrijdag j.l. besproken, met aanpassingen van afgelopen weekend (dosis allocatie).
 Hieronder ook antwoord op de vragen die door 5.1.2e zijn opgevolgd (stikking tray en ompakken bij 2-8 gr C).
 Tevens het contact overzicht aangevuld met de gegevens van onze MedInfo collega 5.1.2e (graag jullie contact persoon hieraan toevoegen).

1. Does the tray have an anti-tampering sticker? Yes, the tray label serves as tamper-evident sticker, see below.
 Dit is trouwens niet de batchno. voor NL.



2. Our customer, which is the Dutch BOH, would like to repack at room temperature as they do not have the facility to do it within 2-8C. They have received the PGS guidance document (Redistribution considerations) from us and have a question about the max. 2h at room temp (slide 20) 'Repacking should be done in a 2° to 8°C environment whenever possible. Otherwise, time at room temp should be tracked and minimized to stay within the 2-hour allowance for room temperature'.

Their question is: if we repack at room temperature and then return the repacked vials to 2-8C within 1 hour.

Is the assumption correct that we then have up to 5 days to get the repacked vials at 2-8C to the vaccination location. Once the vials arrive at this location and the vials are placed at room temperature to prepare them for administration, should this be done within (2-1h) 1 hour?

My answer: (after checking the MedInfo memo stability & handling summary for Pfizer Biotech C19 vaccine, I can confirm (see also screenshot below) that your assumption is correct.

BNT162b2 must be thawed before use. It is recommended to thaw in the refrigerator (2-8°C). It will take about 3 hours for an entire 195 count tray to thaw in the refrigerator. A smaller number of vials, or those spaced apart, will thaw more quickly. Vials needed for immediate use can be thawed at room temperature. They will typically thaw in less than 10 minutes, but it is recommended to wait approximately 30 minutes to ensure complete thawing. Vials thawed at room temperature may be returned to the refrigerator for storage if necessary, but total time at room temperature must be tracked to ensure the vial stays within the 2 hours at room temperature limit. It is also recommended to allow vials to come to room temp (not cold to touch) prior to dilution to ensure thawing is complete. No impact to vaccine stability is anticipated if diluent is added to a vial with a small amount of undetected unthawed product remaining. No data is available if diluent is added directly into a vial of frozen vaccine.

Hartelijke groeten,

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