

To: [redacted] [redacted] [redacted] @rivm.nl
Cc: [redacted] [redacted] [redacted] @rivm.nl; [redacted] [redacted] [redacted] @rivm.nl
From: [redacted] [redacted] [redacted]
Sent: Mon 1/18/2021 9:43:35 AM
Subject: RE: bewaar- en transport condities Comirnaty
Received: Mon 1/18/2021 9:43:36 AM
[Transport en bewaarcondities Comirnaty opm \[redacted\] 20210118.docx](#)

Ha [redacted]

Hierbij wat input van mij op je vragen/comments. Ik zou het "niet schudden" ook wel expliciet benoemen, want dat lijkt voor deze vaccins erg belangrijk.

Met vriendelijke groet,

[redacted] [redacted] [redacted]



Rijksinstituut voor Volksgezondheid
en Milieu
Ministerie van Volksgezondheid,
Welzijn en Sport

Dienst Vaccinvoorziening en Preventieprogramma's (RIVM-DVP)

T 030 [redacted] [redacted]
M 06 [redacted] [redacted]
E [redacted] @rivm.nl

From: [redacted] [redacted] <[redacted]@rivm.nl>

Sent: zondag 17 januari 2021 21:13

To: [redacted] [redacted] [redacted] <[redacted]@rivm.nl>; [redacted] [redacted] <[redacted]@rivm.nl>; [redacted] [redacted] <[redacted]@rivm.nl>
<[redacted]@rivm.nl>

Subject: bewaar- en transport condities Comirnaty

En hierbij die voor Comirnaty. Graag jullie kritische blik. Ik verwijs een paar keer naar de mail van Pfizer 15/1, die staat hieronder.

Met vriendelijke groet,

[redacted] [redacted] [redacted]

[redacted] [redacted]

Dienst Vaccinvoorziening en Preventieprogramma's (RIVM-DVP)
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A. van Leeuwenhoeklaan 9 | 3721 MA Bilthoven | Kamer [redacted] | Postbak 31
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Werkdagen [redacted] [redacted]

Van: [redacted] [redacted] <[redacted]@rivm.nl>

Verzonden: vrijdag 15 januari 2021 10:35

Aan: [redacted] [redacted] <[redacted]@rivm.nl>

Onderwerp: Ter info FW: Vervolg: Transport verdund vaccin

From: <5.1.2e, 5.1.2e, 5.1.2e <5.1.2e @pfizer.com>
Sent: vrijdag 15 januari 2021 10:33
To: <5.1.2e, 5.1.2e <5.1.2e @rivm.nl>
Cc: <5.1.2e, 5.1.2e <5.1.2e @pfizer.com>; <5.1.2e, 5.1.2e <5.1.2e @pfizer.com>; <5.1.2e, 5.1.2e <5.1.2e @pfizer.com>
Subject: Vervolg: Transport verdund vaccin

Hi <5.1.2e>

Zoals beloofd heb ik nog verder navraag gedaan over de transportvraag. Zie hieronder wat <5.1.2e> hierover terugkoppelde.

En zoals altijd: Pfizer suggereert of beveelt het gebruik van COMIRNATY op geen enkele andere manier aan dan beschreven in de Samenvatting van de productkenmerken.

Groet,

<5.1.2e>

From: <5.1.2e, 5.1.2e <5.1.2e @pfizer.com>
Sent: vrijdag 15 januari 2021 08:27
To: <5.1.2e, 5.1.2e <5.1.2e @pfizer.com>; <5.1.2e, 5.1.2e <5.1.2e @pfizer.com>
Subject: Transport verdund vaccin

Hi <5.1.2e>

Volgend op ons gesprek over vragen met betrekking tot het niet toegestane transport van het verdunde vaccin, heb ik nog de volgende informatie voor je gevonden. Dit kan het RIVM helpen bij vragen over verplaatsing van het verdunde vaccin vanuit ziekenhuisapotheken naar andere afdelingen op het terrein van het ziekenhuis, zoals jij aangaf. Ik weet niet of het nog aan de orde is voor jou en/of <5.1.2e> want ik heb de vraag sinds gisteren al niet meer gekregen.

Zie met name de opmerking (in geel) over shaking stress, die naast tijd en microbiologisch risico relevant is.

Let wel, Pfizer raadt aan de richtlijnen en SMPC te volgen en staat niet in voor de kwaliteit als daar van afgeweken wordt.

Internal Data

Vials

The in-use period for the diluted vial is 6 hours between 2°C and 30°C. Some countries have limited the label conditions to between 2°C and 25°C due to concerns around the potential for microbiological growth at warmer temperatures. Pfizer has conducted physical and chemical stability studies which have shown that the vaccine maintains all its measured quality attributes when diluted vaccine is stored in the vial at 2°C to 30°C for up to a cumulative period of 18 hours, in addition to the routine/labelled in-use period. Microbiological risk must be considered.¹

For easier reference, the results of the stability studies are also provided in table format:

Temperature Conditions	Vials: 2°C to 30°C
CUMULATIVE EXCURSION TIME for Diluted Vaccine at Point-Of-Use (time beyond routine allowance)	18 hours physical and chemical stability. Microbiological risk must be considered.
Point-Of-Use ROUTINE/LABELLED Handling Allowances for Diluted Vaccine	6 hours, including up to 6 hours of transport

Pfizer has not studied storage of diluted vaccine in vials that have been stored between 2°C to 32°C for >24 hours, at temperatures <2°C or at temperatures >32°C.

Syringes

Pfizer has conducted physical and chemical stability studies which have shown that the vaccine maintains all its measured quality

attributes when diluted vaccine is stored in **syringes** for 6 hours at 2°C to 30°C. Microbiological risk must be considered. Degradation of RNA in the vaccine has been observed when stored for longer than 6 hours in syringes. Pre-drawing can increase risk of medication errors.¹

For easier reference, the results of the stability studies are also provided in table format:

Temperature Conditions	Syringes: 2°C to 30°C
CUMULATIVE EXCURSION TIME for Diluted Vaccine at Point-Of-Use (time beyond routine allowance)	None
Point-Of-Use ROUTINE/LABELLED Handling Allowances for Diluted Vaccine	6 hours. 6 hours of physicochemical data to support transport . Microbiological risk must be considered.

Microbiological risk was assessed through a microbiological challenge study. No logarithmic growth of spiked microorganisms was seen until 12 hours at 25°C. A 2x safety factor is applied resulting in the 6 hours in use period. Microbiological growth has greater potential to occur after 6 hours.¹

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Internal Data

Vials should be mixed before and after dilution by gentle inversion. No studies have been done to evaluate shaking of vials during preparation, **but the results of the transportation study support the conclusion that the vaccine can be exposed to some shaking stress**. Without additional data, vaccine vials which are aggressively shaken should be discarded. Studies have been conducted demonstrating that the solution is fully mixed after at least 2 inversions prior to dilution, and 2 inversions after dilution. Vials that have not been gently inverted 2 times should be remixed by gently inverting to ensure they are fully mixed. Vials gently inverted for more than 10 times are safe to use.

Groeten,

5.1.2e