To: 5.1.2e .[5.1.2e @cbg-meb.nl]; 5.1.2e [5.1.2e @cbg-meb.nl]; 5.1.2e .(5.1.2e)[5.1.2e @minvws.nl]; 5.1.2e)[5.1.2e @minvws.nl]; 5.1.2e @rivm.nl[5.1.2e @rivm.nl]; 5.1.2e @rivm.nl[5.1.2e @rivm.nl]
From: 5.1.2e .
Sent: Thur 12/31/2020 3:54:40 PM
Subject: RE: Update on the use of Comirnaty's vial overfill
Received: Thur 12/31/2020 3:54:40 PM

Collega"s

De discussie die we hier eerder deze week over hadden, was wat de consequentie van een dergelijk besluit zal zijn.

Hier is vandaag Europees over gesproken.

De verwachting is dat Pfizer zal zeggen dat ze meer leveren en dat we dus sneller ons totale volume hebben bereikt.

Alternatieven zijn dat ze minder vials, maar uiteindelijk evenveel doses, gaan leveren (en dat ze die vrijgespeelde vials elder verkopen).

Het maakt ook veel uit hoe de EMA het gaat verwoorden.

Zegt men dat " wanneer het lukt om er zes doses uit te halen, het verantwoord is om die te gebruiken". Of is de conclusie dat een vial vanaf nu uit zes doses bestaat?

Dat eerste is natuurlijk het interessantst!

Wordt vervolgd.

Groet,
5.1.2e

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Onderwerp: FW: Update on the use of Comirnaty's vial overfill

Beste collega's,

Hieronder vinden jullie de meest recente informatie over de indiening van een variatie door Pfizer bij de EMA betreffende het aantal doses dat kan worden gehaald uit 1 vial van het vaccin Comirnaty.

Met vriendelijke groet,

Hugo 5.1.2e .

5.1.2e

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Van: 5.1.2e < 5.1.2e @ema.europa.eu> **Namens** 5.1.2e
Verzonden: donderdag 31 december 2020 12:16
Aan: 5.1.2e < 5.1.2e @ema.europa.eu>
CC: De Verdiere Morgane < 5.1.2e @ema.europa.eu>; 5.1.2e < 5.1.2e @ema.europa.eu>; 5.1.2e < 5.1.2e @ema.europa.eu>; 5.1.2e < 5.1.2e @ema.europa.eu>
Onderwerp: Update on the use of Comirnaty's vial overfill

Dear Colleagues,

Following the EMRN discussion yesterday regarding Comirnaty's vials overfill, we would like to inform you that the company has now submitted a variation to request a change. This will now be reviewed by CHMP in the shortest possible timeframe.
We will keep you informed once the assessment has concluded. In the meantime, please find below the lines that we are using to respond to press queries:

In its marketing authorisation application for Comirnaty, the company described the finished product as a 5 dose multidose concentrate to be diluted prior to intramuscular injection. Each vial is designed to deliver a total of 5 doses after dilution.

The overfill in the vial is required to ensure that the full five doses can be removed from the multi-dose vial after dilution and correctly administered, taking account of potential loss of product during the syringe filling and administration steps (most loss is due to dead-space in syringe and needle which is lost after dose administration).

In its assessment of the pharmaceutical development data and finished product testing, EMA's human medicines committee (CHMP) was reassured that that 5 doses can be consistently extracted from the vial and delivered after dilution.

The Committee already prompted the company at that time to submit data showing that 6 doses can be extracted from the vial consistently (See Recommendation 21 (REC21) in the assessment report).

The company has now submitted a request for change, which will be reviewed by the CHMP in the shortest possible timeframe. If the CHMP finds that 6 doses can be extracted consistently, it will recommend a change to the current terms of the authorisation to support Member States in their roll-out of the vaccine.

If you need further information, please do not hesitate to contact me.

Best regards,

Juan García Burgos
Head of Public and Stakeholders Engagement
Stakeholders and Communication Division

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