To: 5.1.2e [5.1.2e @ec.europa.eu]
Cc: 5.1.2e [5.1.2e @ec.europa.eu]; 5.1.2e [5.1.2e @ema.europa.eu]; 5.1.2e @ema.europa.eu[5.1.2e @ema.europa.eu]; 5.1.2e [5.1.2e @cbg-meb.nl]; 5.1.2e . 5.1.2e [5.1.2e @cbg-meb.nl]; 5.1.2e .[5.1.2e @cbg-meb.nl]; 5.1.2e [5.1.2e @rivm.nl]; 5.1.2e . (5.1.2e)[5.1.2e @minvws.nl]; 5.1.2e .[5.1.2e @igj.nl]; 5.1.2e @minvws.nl'[5.1.2e @minvws.nl]; 5.1.2e 5.1.2e @minvws.nl'[5.1.2e @minvws.nl] 5.1.2e 5.1.2e @cbg-meb.nl]
From: 5.1.2e .
Sent: Mon 12/21/2020 1:45:50 AM
Subject: RE: Follow-up of the ad-hoc EMRN meeting on the marketinginformation form
Received: Mon 12/21/2020 1:45:54 AM

Dear 5.1.2e ,

The Netherlands will follow the Commission's recommendation as mentioned in 5.1.2e email below. That means we will skip the MIF for the first batches of the BFT/PFZ vaccine.

Kind regards,

5.1.2e

5.1.2e

CBG MEB | MEDICINES EVALUATION BOARD

Medicines Evaluation Board
5.1.2e @cbg-meb.nl
+31 (5.1.2e | +31 (0 5.1.2e | www.cbg-meb.nl
Graadt van Roggenweg 500 | 3531 AH Utrecht
The Netherlands

GOOD MEDICINES USED BETTER

Van: 5.1.2e < 5.1.2e @ec.europa.eu>
Verzonden: vrijdag 18 december 2020 17:02
Aan: 5.1.2e < 5.1.2e @ec.europa.eu>; 5.1.2e @ema.europa.eu; 5.1.2e < 5.1.2e @ansm.sante.fr>; 5.1.2e @phs.moh.gov.cy; 5.1.2e @sukl.cz; 5.1.2e @fimea.fi; 5.1.2e @bfarm.de; 5.1.2e @urpl.gov.pl; 5.1.2e @noma.no; 5.1.2e @ema.europa.eu; 5.1.2e @hpra.ie; 5.1.2e @aifa.gov.it; 5.1.2e @ms.etat.lu; 5.1.2e @ages.at; 5.1.2e @ms.etat.lu; 5.1.2e @sukl.sk; 5.1.2e @ema.europa.eu; 5.1.2e @dkma.dk; 5.1.2e @zva.gov.lv; 5.1.2e @ema.europa.eu; 5.1.2e < 5.1.2e @ec.europa.eu>; 5.1.2e @vvkt.lt; 5.1.2e @ema.europa.eu; 5.1.2e @pei.de; 5.1.2e @halmed.hr; 5.1.2e @sukl.cz; 5.1.2e @ima.is; 5.1.2e @anm.ro; 5.1.2e @ema.europa.eu; 5.1.2e @ema.europa.eu; 5.1.2e @lakemedelsverket.se; 5.1.2e @aemps.es; 5.1.2e @llv.li; 5.1.2e @gov.mt; 5.1.2e @ema.europa.eu; 5.1.2e @eof.gr; 5.1.2e @ema.europa.eu; 5.1.2e @fagg-afmps.be; 5.1.2e @jazmp.si; 5.1.2e @ema.europa.eu; 5.1.2e @ema.europa.eu; 5.1.2e @anm.ro; 5.1.2e @bda.bg; 5.1.2e @ogyei.gov.hu; 5.1.2e . < 5.1.2e @cbg-meb.nl>; 5.1.2e 5.1.2e @mpa.se; 5.1.2e @ema.europa.eu; 5.1.2e < 5.1.2e @ema.europa.eu>; 5.1.2e @pei.de; 5.1.2e @infarmed.pt; 5.1.2e @dkma.dk; 5.1.2e < 5.1.2e @ec.europa.eu>; 5.1.2e @ravimiamet.ee

CC: 5.1.2e < 5.1.2e @urpl.gov.pl>; 5.1.2e @aemps.es; 5.1.2e - IMA < 5.1.2e @lyfjastofnun.is>; 5.1.2e @ema.europa.eu; 5.1.2e < 5.1.2e @dkma.dk>; 5.1.2e , 5.1.2e . < 5.1.2e @cbg-meb.nl>; 5.1.2e @aifa.gov.it>; 5.1.2e < 5.1.2e @dkma.dk>; 5.1.2e @ema.europa.eu; 5.1.2e @ema.europa.eu; 5.1.2e @ema.europa.eu; 5.1.2e @ema.europa.eu 5.1.2e < 5.1.2e @ec.europa.eu>; 5.1.2e < 5.1.2e @ec.europa.eu>

Onderwerp: RE: Follow-up of the ad-hoc EMRN meeting on the marketing information form

Dear Dear Colleagues,

Thank you very much for having responded to the survey on the possible waiver of the marketing information form (MIF)
The outcome is as following, based the responses received from 23/27MS

- 9 MS are in favour and 6 not opposed to option 1 : to skip the MIF (option 1)
- 14 MS are in favour and 2 not opposed to option 2: to use de MIF and be ready to respond within hours. (option 2)

During the Vaccine steering Committee yesterday the company raised again the likelihood of a bottleneck and a delay in shipping resulting from the use of the MIF, certainly also on their behalf, considering the acceleration of the timetable. The Commission decision granting the marketing authorisation to the BNT/PFZ vaccine, on the basis of a positive opinion by the CHMP, should be adopted by the 22/12 in the morning and the dispatch of the products to all MS is planned on the 26th.

As the Paul-Ehrlich-Institut kindly proposed to notify EMRN, when batches are released and communicate the batch numbers to you, it might be advisable, for the first batches when the national legislation allows it, to waive the MIF in order to guarantee the **start of the vaccination campaign on 27th in all MS**

Although the MIF is in the remit of national competence, we would recommend a coordinated approach in the remit of discussions at EMRN . As the information made available by the PEI, allows each authority to check the batches released on its territory, we think that you will get the adequate information even with the waiver.

We would appreciate being informed **by Monday 10 a.m.** if anyone would not opt for a waiver. Could you please in this case also notify us the mitigating measures taken to ensure the delivery of the batches on 26 December. Please provide your replies to my colleague 5.1.2e at 5.1.2e @ec.europa.eu

Thank you

5.1.2e

5.1.2e

European Commission
Health and Food Safety Directorate General (SANTE)
Unit B5 Medicines-policy, authorisation and monitoring
5.1.2e
B-1049 Brussels, Belgium

From: 5.1.2e (SANTE) < 5.1.2e @ec.europa.eu>
Sent: Wednesday, December 16, 2020 5:52 PM
To: 5.1.2e (EMA) < 5.1.2e @ema.europa.eu>; 5.1.2e < 5.1.2e 5.1.2e @ansm.sante.fr>; 5.1.2e @phs.moh.gov.cy; 5.1.2e @sukl.cz; 5.1.2e @fimea.fi; 5.1.2e @bfarm.de; 5.1.2e @urpl.gov.pl; 5.1.2e @noma.no; 5.1.2e (EMA) < 5.1.2e @ema.europa.eu>; 5.1.2e @hpra.ie; 5.1.2e @aifa.gov.it; 5.1.2e @ms.etat.lu; 5.1.2e @ages.at; 5.1.2e @ms.etat.lu; 5.1.2e @sukl.sk; 5.1.2e (EMA) < 5.1.2e @ema.europa.eu>; 5.1.2e @dkma.dk; 5.1.2e @zva.gov.lv; 5.1.2e (EMA) < 5.1.2e @ema.europa.eu>; 5.1.2e (SANTE) < 5.1.2e @ec.europa.eu>; 5.1.2e @vvkt.lt 5.1.2e (EMA) < 5.1.2e @ema.europa.eu>; 5.1.2e @pei.de; 5.1.2e @halmed.hr; 5.1.2e @sukl.cz; 5.1.2e (SANTE) < 5.1.2e @ec.europa.eu>; 5.1.2e @ima.is; 5.1.2e @anm.ro; 5.1.2e EMA) < 5.1.2e @ema.europa.eu>; 5.1.2e EMA) < 5.1.2e @ema.europa.eu>; 5.1.2e @lakemedelsverket.se; 5.1.2e @aemps.es; 5.1.2e @llv.li; 5.1.2e @gov.mt; 5.1.2e (EMA) < 5.1.2e @ema.europa.eu>; 5.1.2e @eof.gr; 5.1.2e (EMA) < 5.1.2e @ema.europa.eu>; 5.1.2e @fagg-afmps.be; 5.1.2e @jazmp.si; 5.1.2e EMA) < 5.1.2e @ema.europa.eu>; 5.1.2e (EMA) < 5.1.2e @ema.europa.eu>; 5.1.2e @anm.ro; 5.1.2e @bda.bg; 5.1.2e @ogyei.gov.hu; 5.1.2e @cbg-meb.nl; 5.1.2e @mpa.se 5.1.2e (EMA) < 5.1.2e @ema.europa.eu>; 5.1.2e < 5.1.2e @ema.europa.eu>; 5.1.2e @pei.de; 5.1.2e @infarmed.pt; 5.1.2e @dkma.dk; 5.1.2e (SANTE) < 5.1.2e @ec.europa.eu>; 5.1.2e @ravimiamet.ee
Cc: 5.1.2e < 5.1.2e @urpl.gov.pl>; 5.1.2e @aemps.es; 5.1.2e - IMA < 5.1.2e @lyfjastofnun.is>; 5.1.2e (EMA) < 5.1.2e @ema.europa.eu>; 5.1.2e <5.1.2e @dkma.dk>; 5.1.2e . < 5.1.2e @cbg-meb.nl>; 5.1.2e < 5.1.2e @aifa.gov.it>; 5.1.2e . < 5.1.2e @cbg-meb.nl> 5.1.2e < 5.1.2e @aifa.gov.it>; 5.1.2e <5.1.2e @dkma.dk>; 5.1.2e EMA) < 5.1.2e @ema.europa.eu>; 5.1.2e (EMA) < 5.1.2e @ema.europa.eu>; 5.1.2e (EMA) < 5.1.2e @ema.europa.eu>; 5.1.2e EMA) < 5.1.2e @ema.europa.eu>
Subject: Follow-up of the ad-hoc EMRN meeting on the marketing information form

Dear Colleagues,

Following the presentation at the Ad-hoc EMRN meeting this morning and following a discussion with the BioNTech/Pfizer this afternoon, please find hereafter the request for you choice between the 2 options below.

According to the procedure : EU Administrative Procedure for Official Control Authority Batch Release, prior to placing the batch on the market, a copy of the Official Control Authority Batch Release certificate is provided by the MAH to the Member States where the batch of the product concerned will be marketed. The copy of the certificate is accompanied by a marketing information form (MIF) addressed by the marketing authorisation holder to the competent authority of the Member State(s).

According to the letter received from BioNTech/Pfizer, under normal circumstances, the MS acknowledges receipt of the MIF, within 2 days. The MAH will only hear further from the MS if there is a question about the MIF and If the MS does not object within 7 working days after sending the documents (MIF), the MAH can place the lot on the market in the member state.

Because of the possibly lengthy process (i.e requesting administrative documents to be filled in and exchanged) and given the exceptional circumstances, BioNTech/Pfizer proposes to skip the MIF procedure, at least for **the first batches** and allow an immediate formal release by MAH based on the OCABR result without any further delay.

However alternatively, it might be possible to keep the process as it is and speed it up at all steps. It would therefore require anticipation and a **rapid reaction from the MS within a few hours upon availability of MIF and the OMCL certificate i.e within 1 or 2 hours maximum. The company is expected to send the forms on 23 December 2020. Given the Christmas holidays it is important to ensure that there are available resources is MS to receive and process the form as soon as possible**. A review of the preliminary version of MIF could notably be performed in advance to support the accelerate review.

Please let me know **by tomorrow 13:00 Brussel time** if you would prefer, for the vaccine of BioNTech/Pfizer, the :

First option : Skip the marketing information form (MIF) for the first batches in order not to avoid possible delays on the availability of the product.

Second option : Keep the marketing information form (MIF) but guarantee you have in place the appropriate measures on 23 December and later to process the form and notify the company within 1-2 hours of receipt.

Thank you

With kind regards

5.1.2e

5.1.2e
Policy Officer – PHARMA
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