Pfizer B.V.
5.1.2e
5.1.2e
Nederland

Uw brief
December 11, 2020

Uw kenmerk
-

Utrecht,
December 28, 2020

Zaaknummer
835545

Ons kenmerk
5.1.2e

Behandeld door
5.1.2e

Doorkiesnummer
+31 5.1.2e

Onderwerp
Serialisation exemption request

Dear Mr. 5.1.2e

In reference to the letter from BioNTech Manufacturing GmbH regarding the serialisation exemption request for the vaccine

Comirnaty, concentraat voor dispersie voor injectie

I hereby inform you that last week the EMA has communicated to BioNTech Manufacturing GmbH that the Member states have considered, under Art. 63.3 of the Directive 2001/83, the request for an exemption from the obligation of serialisation for the EU pack of the BioNTech/Pfizer vaccine and have decided the following:

- All EU Member States have accepted a temporary derogation from serialisation for your EU pack until **the end of March 2021**.

- The company must provide two progress reports on the serialisation: a first by 1st of February 2021 and a second by 1st of March 2021 referring to details on the progress achieved in terms of ensuring compliance, e.g. proof of acquiring the relevant equipment, the date for the validation, the proof of contract to connect to the European Medicines Verification Organisation.

- The company should also consider technical solutions to the serialisation due to the risk of falsification, e.g. use stickers on the outer packaging.

- The company should provide additional mitigating measures, e.g. immediate reporting of any stolen product during the period of exemption, reporting of any counterfeit or falsified vaccine in the EU or third countries in the legal supply or internet, reconciliation of product distributed and used in the respective territory.

In addition, in the Netherlands the following is applicable for the Risk Mitigation Measures mentioned in the letter from BioNTech Manufacturing GmbH:

- It seems that the company is under the impression that in the initial distribution phase the product will be distributed directly from the manufacturer to the dosing site, without involvement of wholesalers. Although this might be the case for some other EU countries, this is not the case for the Netherlands. Nevertheless, in case the supply chain for the Netherlands is strictly regulated, we do consider this to be a mitigating measure. **For the Netherlands the product may only be transported to specific locations of the logistics service provider contracted by our governmental organisation 'RIVM'.**

If you need any additional information, please let me know.

On behalf of the Medicines Evaluation Board in the Netherlands,

5.1.2e

- Enclosure: Letter from BioNTech Manufacturing GmbH, dated December 11, 2020.
- A copy of the letter will be send to the Inspectie Gezondheidszorg en Jeugd (IGJ) and the RIVM.