11 December 2020

Exemption request for COVID-19 mRNA Vaccine Comirnaty

BioNTech Manufacturing GmbH is asking to be temporarily exempted from the provision of the safety (serialisation) features on the outer packaging (label of the 195 vials containing carton) as demanded in Article 54 of Directive 2001/83/EC.

The applicant is requesting a temporary permission to supply the COVID-19 mRNA Vaccine Comirnaty concentrate for dispersion for injection in all European Economic Area (EEA) member states initially without the full national safety (serialisation) features on the outer packaging enabling verification of authenticity of the vaccine and identification of individual packs until July 2021.

The request is based on Article 63(3) of Directive 2001/83/EC and the guideline "Recommendations for the implementation of the exemptions to the labelling and package leaflet obligations in the centralised procedure Quality Review of Documents (QRD) group" (EMA/135540/2019 rev.4*) [1, 2].

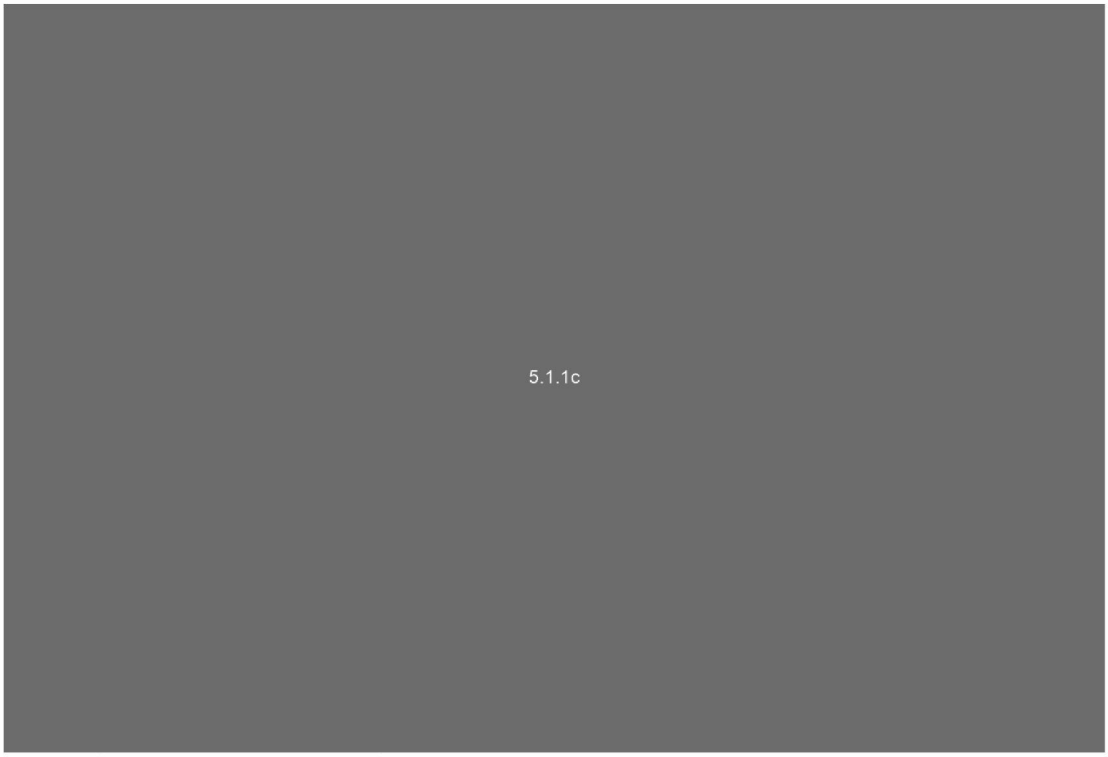
Article 63(3) of Directive 2001/83/EC clarifies "Where the medicinal product is **not intended to be delivered directly to the patient**, or where there are **severe problems in respect of the availability** of the medicinal product, the competent authorities may, subject to measures they consider necessary to safeguard human health, grant an exemption to the obligation that certain particulars should appear on the labelling and in the package leaflet." [1].

Each handling step - dilution and administration, including storage - will be performed by healthcare professionals only; never by patients or any other laypersons and the vaccine will **not be delivered directly to patients**.

Due to the extremely urgent and global-wide need for the vaccine, BioNTech and its partner Pfizer have already manufactured vaccine batches using the labelling approved by the FDA for Emergency Use Authorisation (EUA) without the unique identifier (serialisation).

However, the second safety feature required by the Delegated Regulation (EU) 2016/161 [1], which is the anti-tamper device provided on each unit of sale through application of the seal label across the opening of the 195 vial-containing carton to provide clear evidence of opening prior to delivery, is being applied. This is also the case for batches with labels approved by the EMA for the first months of 2021.

Given the compressed timeline towards earliest possible delivery, the manufacturing sites are not in a position to establish a fully automated packaging line with serialisation for the 31 different EEA countries earlier than July 2021.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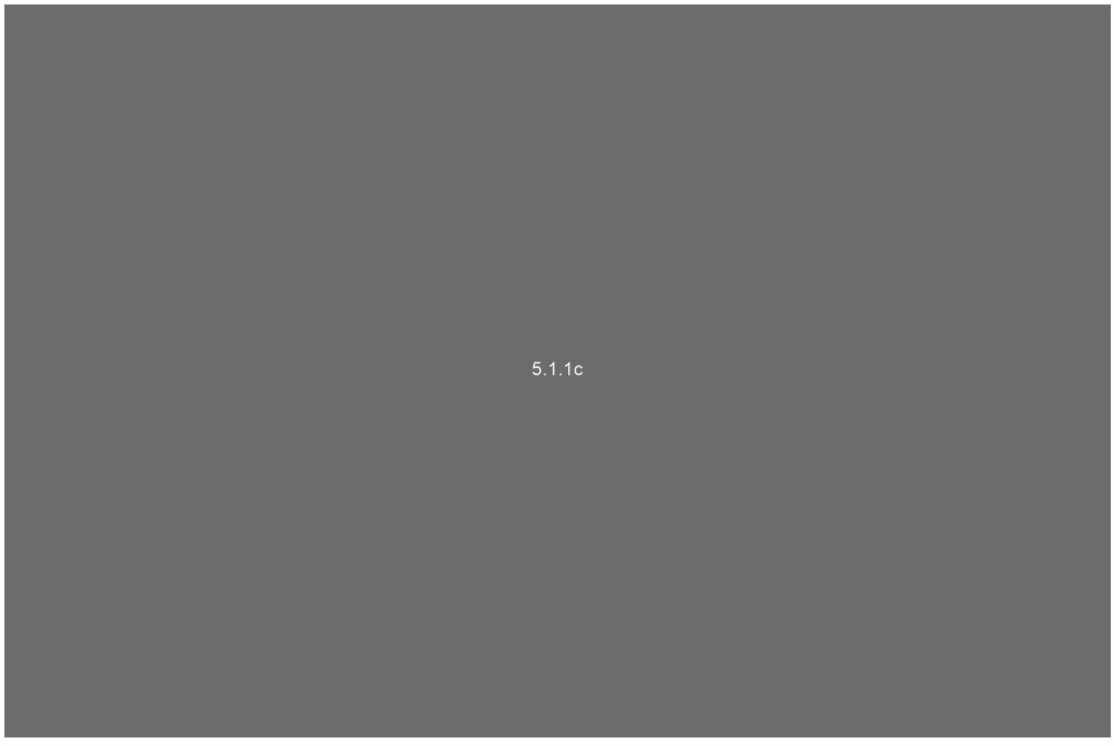
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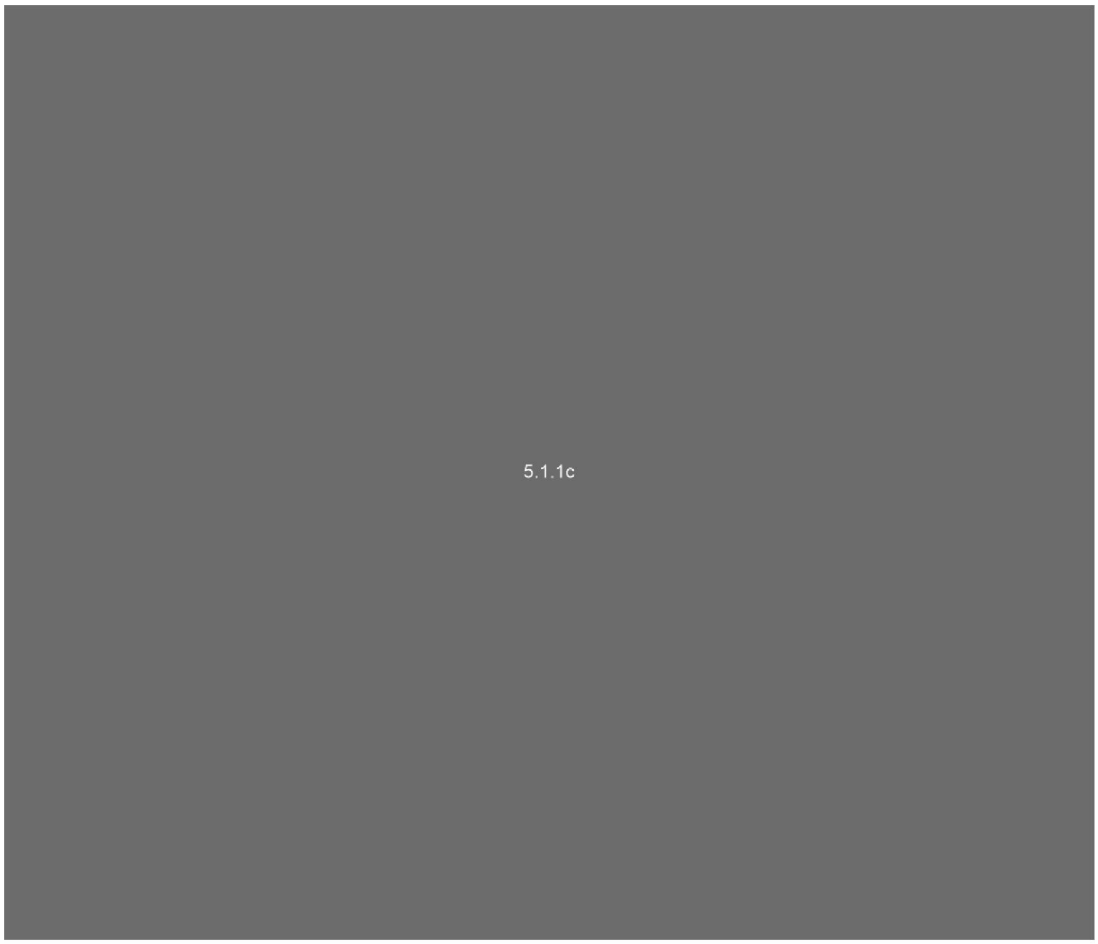
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References

1 The European Parliament and the Council of the European Union. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to medicinal products for human use - as amended by Directives 2002/92/EC to Directive 2019/1243/EU. (Consolidated version: 26/07/2019). https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02001L0083-20190726&from=EN (accessed October 12, 2020).

2 European Medicines Agency - Quality Review of Documents (qrd) group. Recommendations for the implementation of the exemptions to the labelling and package leaflet obligations in the centralised procedure, dated 19 March 2019 (EMA/135540/2019 rev.4*). http://www.ema.europa.eu/ema/pages/includes/document/open_document.jsp?webContentId=WC500170684 (accessed October 12, 2020).

3 World Health Organization. WHO Coronavirus Disease (COVID-19) Dashboard. https://covid19.who.int/ (accessed October 12, 2020).

4 Wu Z, McGoogan JM. Characteristics of and important lessons from the Coronavirus Disease 2019 (COVID-19) outbreak in China. JAMA 2020; doi:10.1001/jama.2020.2648.

5 European Centre for Disease Prevention and Control (ECDC). Rapid risk assessment: Novel coronavirus disease 2019 (COVID-19) pandemic: increased transmission in the EU/EEA and the UK – sixth update, 12 March 2020. Stockholm. ecdc.europa.eu/en/publications-data/rapid-risk-assessment-novel-coronavirus-disease-2019-covid-19-pandemic-increased (accessed October 12, 2020).

6 Onder G, et al. Case-fatality rate and COVID-19 death characteristics in Italy. JAMA 2020; doi:10.1001/jama.2020.4683.