

Prague, 29 December 2020  
Ref. No.: MZDR 63142/2020-3/OLZP

MZDRX01DQ4AG

## DECISION

The Ministry of Health (hereinafter referred to as the “Ministry”), as the competent administrative authority pursuant to Section 11(a) of Act No. 378/2007 Coll., on pharmaceuticals and on the amendment of certain related laws (hereinafter referred to as the “Act on Pharmaceuticals”), as amended, has decided on the following measure:

In the interest of protecting public health in relation to the current spread of the originator of the disease, the SARS-CoV-2 coronavirus which causes the COVID-19 disease, and in order to ensure the availability of medicinal products important to providing medical care, the Ministry, in accordance with Section 8(6) of the Act on Pharmaceuticals,

### temporarily permits

use of the medicinal product

SÚKL code	Name of medicinal product Name supplement	Registration number	Holder of marketing registration decision
0250256	COMIRNATY 500MCG/ML INJ CNC DIS 195X0.45ML	EU/1/20/1528/001	BioNTech Manufacturing GmbH, Mainz, Germany

(hereinafter referred to as the “medicinal product COMIRNATY”)

in a manner which does not comply with the marketing registration decision: **under the strict observance of the volume of individual doses, the content of one multi-dose vial for up to 6 patients, in the case that the volume of the vaccination substance in one vial allows the drawing of the necessary volume of individual doses for each application.**

**This measure comes into effect on the date of its posting on the official bulletin of the Ministry.**

**This measure expires on 31 March 2021.**

### **Rationale:**

On 21 December 2020, the European Commission registered the medicinal product COMIRNATY.

V The summary of product characteristics, point 2 (QUALITATIVE AND QUANTITATIVE COMPOSITION) states that *“one vial (0.45 mL) contains 5 doses of 0.3 mL after dilution.”*

On 29 December 2020, the Ministry asked the State Institute for Drug Control (hereinafter referred to as the “Institute”) for an expert opinion pursuant to Section 8(6) of the Act on Pharmaceuticals, regarding the intended temporary permission to use the medicinal product COMIRNATY in a manner that does not comply with the marketing registration. On the same day, the Ministry received the Institute’s expert opinion in this matter.

In its opinion, the Institute stated that the situation, where the volume of the vial after adding a diluting substance is higher than the product of the volumes of 5 doses, is standard procedure for multi-dose injection products, where “overfill” must sometimes be anticipated. Hence, it is not possible to approve a precise number of doses in the given volume, because there is a justified risk that the last dose might not be applied whole. The requirement to overfill multi-dose injection products is given by instructions of the European Union and also the European Pharmacopoeia (chapter on multi-dose packaging 2.9.17). The application for marketing registration in the European Union is bound by the requirements of the European Pharmacopoeia, which is legally binding.

The registration documentation submitted by the marketing registration holder and the data in the approved summary of product characteristics correspond to the foregoing.

Finally, the Institute informed the Ministry that the usability of precisely 5 doses was thoroughly discussed within the European Medicines Agency during the registration procedure, specifically with respect to losses during dilution and application, and their number is affected by a range of factors, e.g. type of used needle and syringe. An inaccurately measured dose may affect the precision of post-registration safety and efficacy studies.

The Institute also provided the Ministry with references to foreign sources.

The Ministry reviewed the Institute’s expert opinion and other information at its disposal, and states the following.

From publicly available information from other countries, it follows that based on experience to date in applying the medicinal product COMIRNATY, the volume of one vial allows the application of the vaccination substance to a greater number of patients than that specified in the summary of product characteristics.

In the United States of America, the U.S. Food and Drug Administration, as the local medicinal agency, issued a publicly accessible document titled FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE (VACCINATION PROVIDERS), EMERGENCY USE AUTHORIZATION (EUA) OF THE PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19), in which it states that one vial after dilution contains up to 6 doses of 0.3 ml.

V At present, the marketing registration holder declares 5 doses in one vial, but the number of

generally usable doses in one vial is the subject of discussion in a number of countries around the world. However, in compliance with European legislation, the reflection of changes in the summary of product characteristics requires a standard process of change of registration.

Given the limited number of available packages of the medicinal product COMIRNATY for persons in the Czech Republic, the Ministry permits the use of the medicinal product COMIRNATY in a manner that does not comply with the marketing registration, meaning it allows the use of one vial of this medicinal product for up to 6 persons, in order to increase the number of persons that can be protected from the consequences of COVID-19 disease thanks to vaccination with this medicinal product.

The Ministry has stipulated a condition that this procedure may be applied only if the volume of the individual doses is observed and simultaneously that the volume of the vaccination substance in one vial allows the drawing of the required volume of individual doses for more than five applications. Guaranteeing the volume of individual doses stipulated in the summary of product characteristics is an essential condition for creating the intended immune reaction of the vaccinated person. The Ministry emphasizes that each dose must be drawn always from one vial only.

Given the expected time needed to evaluate the aforementioned facts and newly acquired findings, the Ministry has stipulated that this measure shall be in effect until 31 March 2021.

  
**doc. MUDr. Jan Blatný, Ph.D.**  
ministr zdravotnictví



Doc. MUDr. Jan Blatný, Ph.D.  
Minister of Health

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