



MINISTRY OF HEALTH
Palackého náměstí 375/4, 128 01 Prague 2

Prague dated 6 April 2021

Ref. No.: MZDR 46953/2020-6/MIN/KAN

MZDRX01FDMS7

EXTRAORDINARY MEASURE

The Ministry of Health, as the competent administrative authority, pursuant to Section 80(1)(g) of Act No. 258/2000 Coll., on Public Health Protection and amendments to certain related acts, as amended, **orders** this Extraordinary Measure, proceeding pursuant to Section 69(1)(i) and (2) of Act No. 258/2000 Coll., in order to protect the population from the further spread of the COVID-19 disease caused by the new SARS-CoV-2 coronavirus:

I.

Effective from 10 April 2021, all healthcare service providers who were supplied with a medicinal product containing a substance against COVID-19 disease and purchased from state budget funds based on Commission Decision C(2020) 4192 of 18 June 2020, approving the agreement with Member States on procuring Covid-19 vaccines on behalf of the Member States and related procedures (hereinafter the "provider") are ordered to determine a deadline for administering the second dose of the medicinal product - vaccination substance as follows:

1. COMIRNATY 500MCG/ML INJ CNC DIS 195X0.45ML, Reg. No. EU/1/20/1528/001, SÚKL code 0250256 - date for administering the second dose 38 to 42 days after administering the first dose,
2. COVID-19 VACCINE MODERNA 0.2MG/ML INJ DIS 10X5ML, reg. č. EU/1/20/1507/001, SÚKL code 0250303 - date for administering the second dose 38 to 42 days after administering the first dose,
3. COVID-19 VACCINE ASTRAZENECA 2.5X10⁸INF.U/0.5ML INJ SUS 10X5ML, reg. č. EU/1/21/1529/002, SÚKL code 0250388 - date for administering the second dose 84 to 91 days after administering the first dose,

II.

This Extraordinary Measure shall take effect on the date of its issue.

Rationale:

This Extraordinary Measure has been issued in connection with the adverse development of the epidemic situation in terms of the occurrence of the COVID-19 disease, caused by the novel coronavirus designated as SARS-CoV-2 in Europe and in the Czech Republic. This measure is an important prerequisite for preventing the spread of the COVID-19 disease and is adopted with the aim of accelerating the gradual easing

of extraordinary measures adopted in connection with the epidemic spread of COVID-19 in the population.

The extraordinary measure is issued in connection with the opinion of the Czech Vaccinology Society ČLS JEP regarding the intervals between administering the first and second dose of vaccines against Covid-19 disease, dated 25 March 2021: *In accordance with its recommendation of 11 March 2021, the Czech Vaccinology Society ČLS JEP recommends extending the interval between the first and second doses of mRNA vaccines against Covid-19 to 42 days for the vaccines from Pfizer (Comirnaty) and the vaccine from Moderna (COVID-19 Vaccine Moderna). For the vector-based vaccine from AstraZeneca (COVID-19 AstraZeneca Vaccine), it recommends extending the interval to 91 days. If there is need to technically configure the vaccination dates within the Central Reservation System, we recommend not exceeding the recommended interval of 42, respectively 91 days to the greatest possible extent, and defining of the booking of dates for the second dose, for example, in the interval of 38-42 days, respectively 87-91 days.*

V In a situation where there is a general shortage of vaccines, the primary task is to ensure the administration of especially the first dose as soon as possible to the greatest possible number of people. In these situations, the extension of the intervals between vaccine doses complies fully with the opinion of the American Center for Disease Control (CDC), the World Health Organization (WHO) and the WHO Strategic Advisory Group of Experts on Immunization (SAGE). The extension of the interval also complies with the vaccines' SPC, which states that efficacy analyses included participants who received the second dose of the vaccine after 19 to 42 days from the first dose; this is also stated by the European Medicines Agency (EMA), which registered the vaccines.

V In the first phases of the vaccination strategy, the Czech Vaccinology Society considers it the most important thing to induce the swift and high efficacy of vaccination, especially to prevent hospitalization and fatalities from COVID-19. The efficacy of mRNA vaccines is more than 90% and is detectable after fourteen days from the application of the first dose. Extensive post-registration studies on millions of vaccinated patients have confirmed a high 85% efficacy of vaccination also on hospitalization after only the first dose of the vaccine.

This opinion is also supported by the Interdepartmental Group for Epidemic Situations, which in its opinion of 15 March 2021 states that *“one dose of the vaccine demonstrably reduces the risk of severe illness, hospitalization and death. The aim of extending the interval between doses is to prevent unnecessary fatalities and relieve the overburdened healthcare system. If the at-risk population groups are sufficiently vaccinated and the availability of doses increases, the interval between doses will be shortened again in the future. The same approach has already been implemented with success in Israel and Great Britain.”*



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