## Recommendations for additional vaccine doses following primary vaccination with COVID-19 Vaccine Janssen

Analyses of Austrian data highlighted an unexpectedly low protection resulting from a single vaccine dose and a relatively low effectiveness of primary vaccination with COVID-19 Vaccine Janssen. The latter was shown to maximally reach 50% compared to VE following two-dose-schedules (AstraZeneca, BioNTech/Pfizer, Moderna) ranging from 75-90%<sup>1</sup>. Thereupon, the Austrian NITAG issued a recommendation to administer a second vaccine dose (preferably an mRNA-vaccine) at least 28 days after first vaccination to individuals having received one dose of COVID-19 Vaccine Janssen. This decision is supported by recommendations and evidence from other countries:

France's HAS issued a similar recommendation in August. Their analyses also showed low VE of COVID-19 Vaccine Janssen, especially against Delta-variant, which led to the conclusion of insufficient protection and the recommendation for administration of a second dose (preferably mRNA)<sup>2</sup>.

In October Germany's STIKO followed with the same recommendation. According to RKI (Robert-Koch-Institut) most breakthrough infections in relation to administered vaccine doses in Germany occur after vaccination with COVID-19 Vaccine Janssen. Moreover, VE against Delta-variant was shown to be relatively low for COVID-19 Vaccine Janssen compared to other vaccines<sup>3</sup>.

Also Belgian authorities recently included persons primarily vaccinated with COVID-19 Vaccine Janssen to their booster strategies. According to them Belgian data show a slightly higher proportion of breakthrough infections among those vaccinated with COVID-19 Vaccine Janssen. Yet, they state that the significance of their findings is limited due to low absolute numbers. Nevertheless, they issued the recommendation taking into account internationally available evidence like the study conducted by Cohn et al. in the US<sup>4</sup>. Authors showed that protection against infection conferred by COVID-19 Vaccine Janssen declined most during the surge of Delta-variant compared to other vaccines. Moreover, they found that COVID-19 Vaccine Janssen's VE against death was about 50% lower compared to the RCT<sup>5</sup>.

The United States' CDC have also issued a recommendation for booster shots following a single dose of COVID-19 Vaccine Janssen. These should be administered at least 2 months after first vaccination and are explained by the lower VE of a single dose compared to two doses<sup>6</sup>.

<sup>&</sup>lt;sup>1</sup> Bicher M et al. (2021). Modell & (gemessene) Wirklichkeit: Aktuelle Inzidenz nach Immunisierungsgradund was wir daraus lernen können. 27.09.2021, available from: http://www.dexhelpp.at/de/modellvalidierung-auf-basis-immunitatsbezogener-positiver-testzahlen/, date accessed: 22.11.2021

<sup>&</sup>lt;sup>2</sup> HAS. COVID-19: la HAS precise les populations éligibles à une dose de rappel de vaccin. 24.08.2021, available from: <u>https://www.has-sante.fr/jcms/p\_3283153/fr/covid-19-la-has-precise-les-populations-eligibles-a-une-dose-de-rappel-de-vaccin</u>, date accessed: 22.11.2021

<sup>&</sup>lt;sup>3</sup> RKI. Pressemitteilung der STIKO zur COVID-19-Auffrischimpfung und zur Optimierung der Janssen-Grundimmunisierung (7.10.2021), available from:

https://www.rki.de/DE/Content/Kommissionen/STIKO/Empfehlungen/PM 2021-10-07.html, date accessed: 22.11.2021

<sup>&</sup>lt;sup>4</sup> Belgium's presentation in HSC-Meeting on 17.11.2021

 <sup>&</sup>lt;sup>5</sup> Cohn BA et al. (2021). SARS-CoV-2 vaccine protection and deaths among US veterans during 2021. Science (New York, N.Y.), eabm0620. Advance online publication. https://doi.org/10.1126/science.abm0620
<sup>6</sup> CDC. COVID-19 Vaccine Booster Shots. Available from:

https://www.cdc.gov/mmwr/volumes/70/wr/mm7038e1.htm, date accessed: 22.11.2021