Communication from the President of the Office of 1 July 2022 on a meeting of global regulatory authorities (EMA, FDA, ICMRA) to discuss emerging evidence in support of adaptation of COVID-19 vaccines in relation to virus evolution.

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Urzędu Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych

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On 30 June, regulators from around the world discussed emerging evidence to support adaptation of COVID-19 vaccines as the SARS-COV-2 virus continues to evolve during a workshop co-chaired by the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA) under the umbrella of the International Coalition of Medicines Regulatory Authorities (ICMRA). The meeting focused on identifying key principles to support the adaption of COVID-19 vaccines to better match Omicron variants of concern, and on ensuring global regulatory alignment.

Participants from 18 members and the World Health Organization (WHO), including the vice-chair of the WHO Technical Advisory Group on COVID-19 Vaccine Composition (TAG-CO-VAC), engaged in the scientific discussions.

ICMRA members and WHO agreed that authorised COVID-19 vaccines continue to offer protection against severe disease, hospitalisation and death and encouraged their use, where available, both as primary series and as booster doses.

Global regulators also acknowledged that the continuous evolution of SARS-CoV-2 reduces the protection offered by the approved vaccines against infection and mild disease.

Although the Omicron BA.4 and BA.5 subvariants seem to be taking over in many parts of the world, experience has shown that new variants may emerge rapidly and replace the currently circulating ones after short-lived waves.

Preliminary data indicate that adapted mRNA vaccines, which incorporate an Omicron variant strain, can increase and extend protection, when used as a booster.

Additionally, according to emerging data, a bivalent mRNA vaccine targeting two strains of SARS-CoV-2, one of which should be an Omicron strain, may provide some advantages in widening the immune response. Bivalent vaccines could be considered initially for use as boosters. Their use for primary vaccination might be supported in the future when further data become available.

Vaccines which include other variants, for example the beta variant, might also be considered for use as boosters if clinical trial data demonstrate an adequate level of neutralisation against Omicron and other variants of concern.

Evidence is still being collected and the workshop participants stressed the need to carefully review emerging clinical data from the ongoing clinical trials to determine the suitability of the adapted vaccines.

The global regulators also highlighted the importance of planning effectiveness studies with the adapted vaccines to determine the level of protection conferred from infection, hospitalisation and death in real-life conditions.

The workshop was co-chaired by Peter Marks, Director of the Center for Biologics Evaluation and Research (CBER) at US FDA, and Marco Cavaleri, Head of Health Threats and Vaccines Strategy at EMA.

It was the fourth in a series of workshops on COVID-19 vaccine development and virus variants held by ICMRA.

These workshops underline the power of ICMRA's leadership in achieving alignment between regulators to expedite and streamline global development and authorisation of new or adapted COVID-19 vaccines against emerging coronavirus variants. More details on the discussions and the outcomes of the meeting will be posted on the ICMRA website in the coming days.

Compiled from the information available on the website:
https://www.ema.europa.eu/en/news/global-regulators-agree-key-principles-adapting-vaccines-tackle-virus-variants [1]

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President
of the Office for Registration of Medicinal Products,
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