EUROPEAN MEDICINES AGENCY
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Media and Public Relations

News announcement

EMA recommends standard marketing authorisations for Comirnaty and Spikevax COVID-19 vaccines

EMA's human medicines committee (CHMP) has recommended converting the conditional marketing authorisations of the COVID-19 vaccines Comirnaty (BioNTech/Pfizer's vaccine) and Spikevax (Moderna's vaccine) into standard marketing authorisations. These no longer need to be renewed annually. All other obligations for the companies remain in place.

Both vaccines were granted a conditional marketing authorisation at the time of their authorisation[1]. This imposed obligations on the companies to submit results from the ongoing clinical trials and to provide additional data on the pharmaceutical quality of the vaccine in light of the planned manufacturing scale-up.

These trials and additional studies, including observational studies, have provided reassuring data on key aspects such as how well the vaccines prevent severe COVID-19. In addition, the companies have provided all requested additional data on the pharmaceutical quality of the vaccines.

Taking into account the totality of the available efficacy and safety data resulting from the large utilisation of these vaccines, the specific obligations are no longer considered key to the benefit-risk (of the products), which has cleared the way to move from a conditional to a standard marketing authorisation.

Conditional marketing authorisations are reviewed annually. The CHMP recommended their conversion to standard marketing authorisations as an outcome of the second annual renewal procedure. This recommendation covers all existing and upcoming adapted Comirnaty and Spikevax vaccines, including the recently-approved adapted Comirnaty Original/Omicron BA.1, Comirnaty Original/Omicron BA.4/5 and Spikevax bivalent Original/Omicron BA.1.

As for any medicine, Comirnaty and Spikevax continue to be closely monitored. EMA will continue to assess any new data promptly and take action to protect patients as needed.

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Notes

1. The conditional marketing authorisations were granted based on i) a positive benefit-risk balance, ii) the fact that the vaccines addressed an unmet medical and were to be used in the context of a public health emergency, and iii) the likelihood that the applicants would be able to provide more comprehensive clinical and quality data post-authorisation, which were deemed necessary considering the vaccines' novel mode of action and their very large anticipated use.

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