EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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News announcement

Update on assessment of the BioNTech and Pfizer BNT162b2 vaccine marketing authorisation application

EMA's human medicines committee (CHMP) and its experts have been working intensively over the past weeks to evaluate data submitted by BioNTech and Pfizer in the context of the conditional marketing authorisation (CMA) application for BNT162b2), a COVID-19 mRNA vaccine.

The rate of progress is reliant on a robust and complete assessment of the quality, safety and efficacy and is determined by availability of additional information from the company to respond to questions raised during evaluation.

Following receipt yesterday evening of additional data requested by CHMP from the company and pending the outcome of its evaluation, an exceptional meeting of CHMP has now been scheduled for 21 December to conclude if possible. The meeting planned for 29 December will be maintained if needed.

CHMP will conclude its assessment at the earliest possible timepoint and only once the data on the quality, safety and effectiveness of the vaccine are sufficiently robust and complete to determine whether the vaccine's benefits outweigh its risks.

Once the CHMP recommends a marketing authorisation, the European Commission will then fast track its decision-making process with a view to granting a marketing authorisation valid in all EU and EEA Member States within days.

EMA, its European experts and the European Commission are working towards the first marketing authorisation of a COVID-19 vaccine, with all the safeguards, controls and obligations that a CMA imposes, including:

- full prescribing information and package leaflet with detailed instructions for safe use;
- a robust risk-management and safety monitoring plan;
- manufacturing controls including batch controls for vaccines and conditions for storage;
- an investigation plan for use in children;
- legally binding post-approval obligations (i.e. conditions) and a clear legal framework for evaluation of emerging efficacy and safety data.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

A marketing authorisation ensures that COVID-19 vaccines meet the same high EU standards as for all vaccines and medicines. It will be valid in all EU Member States at the same time enabling all Member States to benefit from the joint work done at EU level and allowing them to start rolling out their vaccination campaigns at the same time.

Notes

1. This press release, together with all related documents, is available on the Agency's website at: <LINK>
2. <Note>.
3. <Note>.
4. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

Contact our press officers

Tel. +31 (0)88 781 8427
E-mail: press@ema.europa.eu
Follow us on Twitter @EMA_News