EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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News announcement

Update on assessment of marketing authorisation application for Moderna's mRNA-1273 COVID-19 vaccine

Over the last few weeks, EMA has made good progress on the assessment of the marketing authorisation application for Moderna's mRNA-1273 COVID-19 vaccine. A continuous dialogue with the company has ensured that questions that arose during the evaluation were swiftly followed up and addressed by the company.

The rate of progress of the further evaluation will depend on the robustness of these data as well as availability of additional information from the company to respond to questions raised during the evaluation. The CHMP will conclude its assessment at the earliest possible timepoint, but only if the evidence shows convincingly that the benefits of the vaccine are greater than any potential risks.

Today, ahead of schedule, the company has submitted the last outstanding data package needed for the assessment of the application. This contains information that is specific to the manufacturing of the vaccine for the EU market.

Taking due account of the progress made, the Committee has scheduled an extraordinary meeting on 6 January 2021 to conclude its assessment, if possible. The meeting planned for 12 January 2021 will be maintained if needed. These two meetings will be virtual, as the EMA premises are closed for external visitors and staff are currently working remotely due to the pandemic.

"We have been able to revise the timetables for the evaluation of the COVID-19 vaccines due to the incredible efforts of everybody involved in these assessments: the chairs of the scientific committees, the rapporteurs and their assessment teams, scientific experts in all EU Member States and my staff at EMA," said Emer Cooke, EMA Executive Director, who also stressed that these timetables, as for any medicine, are set provisionally. "We have constantly revised our planning to further streamline all the procedural aspects that need to be in place for a robust scientific assessment that leads to a marketing authorisation in all EU countries. The number of infections is increasing across Europe and we are aware of the huge responsibility we have to get a vaccine to the market as quickly as is feasible, whilst maintaining the robustness of our scientific review."

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.

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

EMA, its European experts and the European Commission are working towards a marketing authorisation of a COVID-19 vaccine, immediately valid in all EU Member States, with all the safeguards, controls and obligations that this 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.

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.

The role of EMA is the independent regulatory assessment of evidence generated for COVID-19 vaccines and to make recommendations on their authorisation and use in EU citizens.

The scientific assessment recommending approval of vaccines will be independent and driven by patient and public health needs. The recommendation will be based on the strength of the scientific evidence on a vaccine's safety, quality and efficacy, and nothing else.

Notes

1. This press release, together with all related documents, is available on the Agency's website;
2. 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