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News announcement

Update on rolling review of AstraZeneca's COVID-19 vaccine

EMA's assessment of the COVID-19 vaccine being developed by AstraZeneca and Oxford University has been progressing over the past weeks. The Agency is currently assessing data on the vaccine as part of a rolling review.

So far, some evidence has been assessed on safety and efficacy coming from a pooled analysis of interim clinical data from four ongoing clinical trials in the UK, Brazil and South Africa. The latest clinical package was received on the 21 December and is currently being assessed. CHMP has already assessed data from laboratory studies (non-clinical data) and is currently assessing data on the vaccine's quality (on its ingredients and the way it is manufactured).

Additional scientific information on issues related to quality, safety and efficacy of the vaccine is deemed necessary to support the rigour required for a conditional marketing authorisation and this has been requested from the company.

Further information from the ongoing clinical trials is also expected from January. Interim data from a large trial ongoing in the USA are expected in Q1 2021.

EMA is aware that the UK MHRA has granted a temporary authorisation of supply of the vaccine in the emergency use setting, which is distinct from a marketing authorisation. EMA, its European experts and the European Commission are working towards conditional marketing authorisation of COVID-19 vaccines, with all the safeguards, controls and obligations that this imposes. It guarantees that the vaccine meets rigorous EU standards for safety, efficacy and quality and comes with:

- 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.

EMA will complete its assessment according to its usual standards for quality, safety and effectiveness. A marketing authorisation ensures that COVID-19 vaccines meet the same high EU standards as for all vaccines and medicines.

More about the vaccine

The vaccine, called COVID-19 Vaccine AstraZeneca, is expected to work by preparing the body to defend itself against infection with the coronavirus SARS-CoV-2. This virus uses proteins on its outer surface, called spike proteins, to enter the body's cells and cause disease. COVID-19 Vaccine AstraZeneca is made up of another virus (of the adenovirus family) that has been modified to contain the gene for making the SARS-CoV-2 spike protein. The adenovirus itself cannot reproduce and does not cause disease. Once it has been given, the vaccine delivers the SARS-CoV-2 gene into cells in the body. The cells will use the gene to produce the spike protein. The person's immune system will treat this spike protein as foreign and produce natural defences – antibodies and T cells – against this protein. If, later on, the vaccinated person comes into contact with SARS-CoV-2, the immune system will recognise the virus and be prepared to attack it: antibodies and T cells can work together to kill the virus, prevent its entry into the body's cells and destroy infected cells, thus helping to protect against COVID-19.

More about rolling review

A rolling review is one of the regulatory tools that EMA uses to speed up the assessment of a promising medicine or vaccine during a public health emergency. Normally, all data on a medicine's effectiveness, safety and quality and all required documents must be submitted at the start of the evaluation in a formal application for marketing authorisation. In the case of a rolling review, EMA's human medicines committee (CHMP) reviews data as they become available from ongoing studies, before a formal application is submitted. Once the CHMP decides that sufficient data are available, the formal application should be submitted by the company. By reviewing the data as they become available, the CHMP can reach its opinion sooner on whether or not the medicine or vaccine should be authorised.

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

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