EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 February 2021
EMA/114493/2021
Media and Public Relations

News announcement

Adapting COVID-19 vaccines to SARS-CoV-2 variants: guidance for vaccine manufacturers

EMA has issued guidance outlining the requirements for manufacturers planning to modify their COVID-19 vaccines in order to address coronavirus (SARS-CoV-2) variants.

Currently, three vaccines are authorised for use in the EU: Comirnaty, COVID-19 Vaccine Moderna and COVID-19 Vaccine AstraZeneca. Viruses typically mutate and several variant strains of SARS-CoV-2 have already been identified worldwide. The three authorised vaccines provide protection against the variants that are currently prevalent across Europe. However, it appears that with continued mutations and new variants emerging, authorised vaccines may need to be adapted, in time to ensure continued protection. Initial data indicates that some of these variants may have an impact on the level of protection provided by COVID-19 vaccines against infection and disease.

Therefore, it is an urgent public health priority to define an expedited regulatory process for the adaptation of vaccines to protect against current or future variants. There are ongoing discussions at international level on how to approach variants and vaccines in a coordinated way.

EMA's human medicines committee (CHMP) has adopted a reflection paper which details the laboratory (non-clinical), clinical, quality and manufacturing data needed to support the approval of such 'variant' vaccines.

The assumption behind the CHMP's guidance is that a new variant vaccine would largely rely on the same technology and platform as the 'parent' vaccine - a vaccine already approved in the EU for the prevention of COVID-19. The difference would be in the specific structure (antigen) selected to trigger the immune response in the body.

In its guidance, the CHMP sets out the following requirements for the different types of data needed:

- Clinical data

Large-scale safety and efficacy studies are not needed and moreover would present feasibility constraints. The efficacy of variant vaccines should therefore be demonstrated in immunogenicity studies that are designed to investigate the immune response triggered by the variant vaccine against the variant virus.

EMA recommends that at least one clinical trial is conducted in subjects that have not been vaccinated and have never been infected with SARS-CoV-2.

A small group of subjects should be randomly selected to receive either the parent or the variant vaccine. This 'bridging study' is intended to gather evidence to demonstrate that the immune response, measured as neutralising antibodies, triggered by the variant vaccine against the variant virus is of the same magnitude as the immune response elicited by the parent vaccine against the parent virus.

Should vaccination with the parent vaccine be no longer feasible, e.g. because of ethical considerations, a comparison between immune responses triggered by vaccination with the variant vaccine against the variant strain and prior data on the immune response with the parent vaccine against the parent strain, could suffice.

Manufacturers should also study the efficacy of the variant vaccine when given as a single dose, as a booster, to subjects previously vaccinated with the parent vaccine. The immune response induced by one dose of the variant vaccine against the variant strain should be compared with the immune response recorded during clinical trials with the parent vaccine against the parent strain of the virus.

Post-authorisation studies will be set up to monitor the long-term safety and effectiveness of variant COVID-19 vaccines.

- Laboratory studies (nonclinical data)

No further laboratory studies are required to support the development of variant vaccines. However, should the applicant conduct such studies, the results will be evaluated by CHMP together with clinical data.

- Quality and manufacturing

The variant vaccine is expected to be produced by the same manufacturer, and in line with processes and controls used for the parent vaccine. The manufacturer will need to generate data that show that the quality of the variant vaccine complies with the standards set for the parent vaccine. In the case of a multivalent vaccine - one that contains different viral variant strains - additional evidence may be required to ensure the quality of the active substances and the finished product.

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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