Modified COVID-19 vaccines for variants to be fast-tracked, says MHRA and other regulators

Authorised COVID-19 vaccines that are modified in response to new variants will not need a brand new approval or "lengthy" clinical studies, according to new guidance from the ACCESS Consortium – a coalition of regulatory authorities from the UK, Australia, Canada, Singapore and Switzerland. The guidance, developed by the MHRA and its ACCESS partners, lays out what information the medicines regulators would need to approve any modifications to authorised COVID-19 vaccines, should virus mutations make them less effective at preventing the disease.

According to the guidance, vaccine manufacturers would need to provide robust evidence that the modified vaccine produces an immune response, but time-consuming clinical studies that do not add to the regulatory understanding of a vaccines safety, quality or effectiveness would not be needed. This is because researchers are now better able to measure protection by looking at antibodies in the blood following vaccination, reducing the need to wait and see whether or not people in a trial become infected with the disease. This would significantly reduce the length of time taken for the modified vaccine to be ready for use.

Alongside data on the immune response, the vaccine manufacturer would also be expected to provide evidence showing the modified vaccine is safe and is of the expected quality. In addition, data from the original robust clinical trials and the ongoing studies on real-world use in millions of people could be used to support any decision by the regulators.

This approach is based on the tried and tested regulatory process used for seasonal flu vaccines, for which annual modifications are needed to match the strains circulating each year.

MHRA Chief Scientific Officer, Dr Christian Schneider said:

"Our priority is to get effective vaccines to the public in as short a time as possible, without compromising on safety. Should any modifications to authorised COVID-19 vaccines be necessary, this regulatory approach should help to do just that.

"The announcement today also demonstrates the strength of our international partnerships with other regulators and how our global work can help ensure faster access to life-saving vaccines in the UK and around the world.

"The public should be confident that no vaccine would be approved unless the expected high standards of safety, quality and effectiveness are met."

Notes

The MHRA joined the Access consortium in October 2020. The consortium’s goal is to maximise international co-operation between partners in the consortium, reduce duplication, and increase each agency’s capacity to ensure patients have timely access to high quality, safe and effective therapeutic products.