First bivalent COVID-19 booster vaccine approved by UK medicines regulator

An updated version of the COVID-19 vaccine made by Moderna that targets two coronavirus variants (known as a “bivalent” vaccine) has today been approved for adult booster doses by the Medicines and Healthcare products Regulatory Agency (MHRA) after it was found to meet the UK regulator’s standards of safety, quality and effectiveness.

The decision to grant approval for this booster vaccine in the UK was endorsed by the government’s independent expert scientific advisory body, the Commission on Human Medicines, after carefully reviewing the evidence.

In each dose of the booster vaccine, ‘Spikevax bivalent Original/Omicron’, half of the vaccine (25 micrograms) targets the original virus strain from 2020 and the other half (25 micrograms) targets Omicron.

The MHRA’s decision is based on data from a clinical trial which showed that a booster with the bivalent Moderna vaccine triggers a strong immune response against both Omicron (BA.1) and the original 2020 strain. In an exploratory analysis the bivalent vaccine was also found to generate a good immune response against the Omicron sub-variants BA.4 and BA.5.

Safety monitoring showed that the side effects observed were the same as those seen for the original Moderna booster dose and were typically mild and self-resolving, and no serious safety concerns were identified.

Dr June Raine, MHRA Chief Executive said:

“I am pleased to announce the approval of the Moderna bivalent booster vaccine, which was found in the clinical trial to provide a strong immune response against the Omicron BA.1 variant as well as the original 2020 strain.

“The first generation of COVID-19 vaccines being used in the UK continue to provide important protection against the disease and save lives. What this bivalent vaccine gives us is a sharpened tool in our armoury to help protect us against this disease as the virus continues to evolve.

“We have in place a comprehensive safety surveillance strategy for monitoring the safety of all UK-approved COVID-19 vaccines and this will include the vaccine approved today.”

Professor Sir Munir Pirmohamed, Chair of the Commission on Human Medicines said:

“The Commission on Human Medicines and its COVID-19 Vaccines Expert Working Group has independently reviewed the data on safety, quality and

effectiveness and agrees with the MHRA’s decision.”

“The virus, SARS-CoV-2, is continually evolving in order to evade the immunity provided by vaccines. This novel bivalent vaccine represents the next step in the development of vaccines to combat the virus, with its ability to lead to a broader immune response than the original vaccine.”

The Joint Committee on Vaccination and Immunisation (JCVI) will advise on how this vaccine should be offered as part of the deployment programme.

Notes to editors

- The Commission on Human Medicines (CHM) advises ministers on the safety, efficacy and quality of medicinal products. The CHM is an advisory non-departmental public body, sponsored by the Department of Health and Social Care.
- The MHRA’s Conditional Marketing Authorisation for the Moderna bivalent booster vaccine is valid in Great Britain only. An emergency use authorisation has been granted for Northern Ireland to ensure access across the whole of the United Kingdom. Both authorisations were made on the basis of the same rigorous evaluation of data.
- More information can be found in the product information
- A recent paper in a Lancet journal suggested that COVID-19 vaccines have prevented up to 20 million deaths in the first year of use