Pfizer/BioNTech bivalent COVID-19 booster approved by UK medicines regulator

Press release

The adapted COVID-19 vaccine targets both the original virus and the Omicron variant

A second, “bivalent” vaccine has today been approved as a booster 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 updated booster vaccine made by Pfizer/BioNTech, targeting two coronavirus variants, has been approved for use in individuals aged 12 years and above. This decision has been endorsed by the Commission on Human Medicines, after a careful review of the evidence.

In each dose of the booster vaccine, ‘Comirnaty bivalent Original/Omicron’, half of the vaccine (15 micrograms) targets the original virus strain and the other half (15 micrograms) targets Omicron (BA.1).

The MHRA’s decision is based on data from a clinical trial which showed that a booster dose with the bivalent Pfizer/BioNTech vaccine triggers a strong immune response against both Omicron and the original strain. Safety monitoring showed that the side effects observed were the same as those seen for the original Pfizer/BioNTech booster dose and were typically mild and self-resolving, and no new serious safety concerns were identified.

Dr June Raine, MHRA Chief Executive said:

> I am pleased to announce that we now have a second approved vaccine for the UK Autumn booster programme. The clinical trial of the Pfizer/BioNTech bivalent vaccine showed a strong immune response against the Omicron BA.1 variant as well as the original strain.

> Bivalent vaccines are helping us to meet the challenge of an ever-evolving virus, to help protect people against COVID-19 variants.
>
> We have in place a comprehensive safety surveillance strategy for all UK-approved COVID-19 vaccines, and this will include the updated booster we approved today.

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

> Following an independent review of the safety, quality and effectiveness of the vaccine, the Commission on Human Medicines and its COVID-19 Vaccines Expert Working Group supports the MHRA's decision.
>
> As with any medicinal product, including vaccines, it is important to continually monitor effectiveness and safety when it is deployed, and we have the relevant processes and expertise in this country to do that.
>
> 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.
- This new authorisation to the Conditional Marketing Authorisation (CMA) granted by the MHRA is valid in Great Britain only and was approved via the European Commission (EC) Decision Reliance Route. This is when the marketing authorisation application made by the company references the decision made by the EMA's Committee for Medicinal Products for Human Use (CHMP). In such cases, the MHRA considers the application together with due consideration of the EC decision, before making an independent decision on the quality, safety, and effectiveness of the vaccine.
- More information can be found in product information for the Pfizer/BioNTech bivalent vaccine.
- 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.

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