

FOI 23/098

26th February 2023

Dear

Thank you for your email.

The temporary authorisations of the Pfizer/BioNTech, Oxford/AstraZeneca and Moderna vaccines was done through an expedited rolling review. A 'rolling review' can be used to complete the assessment of a promising medicine or vaccine during a public health emergency in the shortest time possible. This is done as the packages of data become available from ongoing studies on a staggered basis. The temporary authorisation under Regulation 174 permits the supply of identified vaccine batches, based on the safety, quality and efficacy data submitted to MHRA. These authorisations do not constitute a marketing authorisation.

All vaccines are tested through three phases of clinical trials to ensure they meet the gold standard. Phase 1 trials are with a small group of people to make sure there are no safety concerns and determines the appropriate dosage for the best immune response. Phase 2 trials are conducted on a larger group of people to check the vaccine works consistently and that the immune response is sufficient. Phase 3 trials test the vaccines on thousands of people for scientists to assess if the vaccine is producing immunity that will prevent disease. Usually, these phases are run in sequence, but in an effort to find a safe and effective Covid-19 vaccine as quickly as possible, once safety has been ascertained through Phase 1, Phases 2 and 3 are being run in parallel. Extensive checks and balances are required at every stage of the development of a vaccine, and this is no different for a Covid-19 vaccine. No stages in the vaccine development processes were bypassed.

The temporary authorisations for use of the COVID-19 vaccines in the UK followed a rigorous scientific assessment of all the available evidence of quality, safety and effectiveness by the UK regulator, the Medicines and Healthcare products Regulatory Agency (MHRA). The MHRA expert scientists and clinicians reviewed data from the laboratory pre-clinical studies, clinical trials, manufacturing and quality controls, product sampling and testing of the final vaccine, and also considered the conditions for its safe supply and distribution. The decision was made with advice from the Commission on Human Medicines (CHM), the government's independent expert scientific advisory body.

The MHRA approval of the Pfizer/BioNTech, Moderna and the Oxford/AstraZeneca COVID-19 vaccines, further information (including information for physicians and recipients of the vaccine, and Public Assessment Reports [PARs] for each vaccine) are available on the MHRA website. Links to these are provided below:

<https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19>

<https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca>

<https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-moderna>

Please note that a marketing authorisation was granted for the Pfizer/BioNTech vaccine (Comirnaty) following a European Commission (EC) decision on 21 December 2020 (PLGB 53632/0002). Further information is available on the European Medicines Agency (EMA) website, a link to this is provided below:
<https://www.ema.europa.eu/en/medicines/human/EPAR/comirnaty>

Please also note that a marketing authorisation was granted for the Moderna vaccine on 31 March 2021 following an EC Reliance Procedure (PLGB 53720/0002). Further information is available on the MHRA website and the EMA website, links to these are provided below:

<https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-moderna>

<https://www.ema.europa.eu/en/medicines/human/EPAR/covid-19-vaccine-moderna>

A marketing authorisation has been granted for the Janssen Covid-19 vaccine on 28 May 2021. Further information is available via the below link:

<https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-janssen>

In addition, a marketing authorisation was granted for the Oxford/AstraZeneca vaccine on 24 June 2021 following an EC Reliance Procedure (PLGB 17901/0355). Further information is available on the MHRA website and the EMA website, links to these are provided below:

<https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca>

<https://www.ema.europa.eu/en/medicines/human/EPAR/vaxzevria-previously-covid-19-vaccine-astrazeneca>

A marketing authorisation was granted for Valneva suspension for injection (PL 43185/0002) on 13 April 2022. A link to the Public Assessment Report is provided below:

<https://mhraproducts4853.blob.core.windows.net/docs/27680d2f701880f90f62740cab6adb4d939b54b4>

In response to your specific questions:

Are the covid 19 vaccines, in particular Pfizer Moderna and AstraZeneca's, subject to the same rigorous testing and safety checks as other vaccines that don't have an EUA licence ?

Also are any of the covid 19 vaccines that the MHRA have given regulatory approval listed as 'prototypes' ?

As we have explained above, all vaccines for Covid-19 have marketing authorisations granted, which means that they have undergone the same level of testing and assessment of safety and efficacy as any other medicinal product. None of these vaccines are prototypes.

If you have a query about the information provided, please reply to this email.

Please remember to quote the reference number above in any future communications.

If you disagree with how we have interpreted the Freedom of Information Act 2000 in answering your request, you can ask for an internal review. Please reply to this email, within two months of this reply, specifying that you would like an Internal Review to be carried out.

If you were to remain dissatisfied with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at:

Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Yours sincerely

MHRA Customer Service Centre

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