FOI 23/047

12th February 2023

Dear

Thank you for your request under the Freedom of Information Act (FOIA).

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 required 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.

There is no reluctance by MHRA to withdraw marketing authorisations for products where there is no positive benefit/risk. The vaccines are safe for use and have been shown to be efficacious for the proposed indications.

The MHRA has in place a comprehensive strategy to monitor the safety of the COVID-19 vaccines authorised in the UK. This monitoring strategy is continuous, proactive and based on a wide range of information sources. The Yellow Card scheme is one of the sources of information used in the monitoring strategy and is the UK system for healthcare professionals and patients to report suspected side effects or adverse reactions to medicines and vaccines. Further details on the

monitoring strategy including the Yellow Card Scheme can be found here: https://www.gov.uk/government/publications/report-of-the-commission-on-human-medicines-expert-working-group-on-covid-19-vaccine-safety-surveillance/report-of-the-commission-on-human-medicines-expert-working-group-on-covid-19-vaccine-safety-surveillance#proactive-vigilance-for-covid-19-vaccines

The MHRA's view is that the benefits of the vaccines in preventing serious complications associated with COVID-19 far outweigh any currently known side effects in the majority of patients. The MHRA will continue to carefully review and monitor all reports of suspected side effects submitted to us following COVID-19 vaccination. When a safety issue is confirmed the MHRA will act promptly to inform patients and healthcare professionals and take appropriate steps to mitigate any identified risk.

As the licensing authority, our authorisation of each of the vaccines has been published on our websites, along with the Public Assessment Reports, Summaries of Product Characteristics and Patient Information Leaflets. These also clearly indicate the dates of authorisation for each of the vaccines. All sites involved in the manufacture of the vaccine have been inspected to show that they comply with current Good Manufacturing Practice, as we do for all authorised medicinal products.

If you disagree with how we have interpreted the Freedom of Information Act 2000 with regards to your request, you can ask for the decision to be reviewed. The review will be carried out by a senior member of the Agency who was not involved with the original decision.

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 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 Experience Centre

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