FOI 23/008

19th January 2023

Dear

Thank you for your email and information request dated 6 January where you asked about COVID-19 vaccine AstraZeneca.

All the COVID-19 vaccines used in the UK vaccination programme were approved following a rigorous review by the MHRA and the Government's independent advisory body, the Commission on Human Medicines (CHM), of their safety, quality and effectiveness. The MHRA concluded that the COVID-19 vaccines were safe and effective and that the benefits outweigh any risk.

COVID-19 vaccine AstraZeneca remains authorised in the UK. Information on the regulatory approval of COVID-19 vaccine AstraZeneca is available at https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca.The Joint Committee on Vaccination and Immunisation (JCVI) advises UK health departments on immunisation including recommendations on deployment of individual COVID-19 vaccines in the UK. JCVI advice is independent of MHRA.

No medicine or vaccine is completely risk-free and hence the MHRA continually monitors the safety of the COVID 19 vaccines through a comprehensive COVID-19 Vaccine Surveillance Strategy. This monitoring strategy is proactive and based on a wide range of information sources, with a dedicated team of scientists continually reviewing information to look for safety issues or any unexpected, rare events.

The Yellow Card scheme is one of these sources of information and is the UK system for collecting suspected side effects to medicines and vaccines from healthcare professionals and patients. We publish a summary of Yellow Card reporting for the COVID-19 vaccines which summarises information received via the Yellow Card scheme. This report now focuses on the COVID-19 vaccines administered from the beginning of the Autumn 2022 booster campaign. Please see our existing record for a summary of information received via the Yellow Card scheme on COVID-19 vaccine primary and booster vaccination campaigns up to the end of August 2022 (including COVID-19 vaccine AstraZeneca) as well as safety investigations carried out by the MHRA on these products.

For the vast majority of people, the benefits of the vaccines in preventing serious complications associated with COVID-19, far outweigh any currently known side effects. The safety of COVID-19 vaccines is continuously monitored; should a new safety issue be confirmed we will continue to act promptly to inform patients and healthcare professionals and take appropriate steps to mitigate any identified risk and protect public health.

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

If you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date you receive this response and addressed to: info@mhra.gov.uk

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