

FOI 23/030

12th March 2023

Dear

Thank you for your email.

In response to questions 1 to 6, the Oxford/AstraZeneca COVID-19 vaccine (now known as Vaxzevria) was originally authorised for use under Regulation 174 on 30 December 2020. It was granted a marketing authorisation in Great Britain (GB) on 24 June 2021. Authorisation in Northern Ireland through the European Medicines Agency was in effect from 29 January 2021. Further information is available via the below link:

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

This vaccine is currently authorised by MHRA.

In response to question 7, please note that the risks considered to be associated with the COVID-19 vaccine AstraZeneca are listed in the product information [Regulatory approval of COVID-19 Vaccine AstraZeneca - GOV.UK \(www.gov.uk\)](#) and that the risks added to the product information since first authorisation of this vaccine can be found at the bottom of the page.

Further details of the MHRA's assessments of safety issues associated with the AstraZeneca vaccine can be found in the MHRA's summary of coronavirus vaccine Yellow Card reporting [Coronavirus \(COVID-19\) vaccines adverse reactions - GOV.UK \(www.gov.uk\)](#)

The MHRA's position is that the benefits outweigh the risks identified so far for COVID-19 vaccine AstraZeneca, and this vaccine remains authorised in the UK.

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

If you remain dissatisfied following any internal review, you may ask the Information Commissioner (ICO) to decide on whether or not we have interpreted the FOIA correctly in dealing with the request and subsequent internal review. 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 ICO's address is:

The Information Commissioner's Office
Wycliffe House
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Yours sincerely

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