

**FOI 23/719**

Dear

Thank you for your query regarding covid vaccines attached and below.

*"I would also like to know if either Pfizer or Astra Zeneca were required to obtain a GMO license for their covid vaccine?"*

*If so, please state the relevant legislation requiring such a license and whether one was granted to either company."*

The AstraZeneca vaccine, Vaxzevria, contains a genetically modified organism (GMO). However, a GMO licence was not required for this to be supplied as a medicinal product because of legislation exempting covid vaccines from such. This was approved by the European Parliament on 15 July 2020 as Regulation 2020/1043 as can be seen at this link: <https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32020R1043>. At that time, the UK was in the European Union and therefore this was applied to Vaxzevria.

Pfizer were not required to obtain a GMO licence for their mRNA vaccine, Comirnaty, as it does not contain a GMO.

The MHRA is responsible for determining applications for clinical trials and for marketing authorisations for medicinal products. However, it is not the responsible regulatory authority for release of a GMO into the environment: for more information on that issue, you are advised to consult this link: <https://www.gov.uk/guidance/developing-genetically-modified-organisms>.

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.

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**

Communications and engagement team

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