FOI 23/019

Dear

Thank you for your request of 10 January 2023, under the Freedom of Information Act. We apologise for the long delay in reply. You requested:

> *"The index of the complete file in the possession of the MHRA concerning the AstraZeneca COVID-19 vaccine and/ or COVID-19 vaccine ChAdOx1 S [recombinant].*
>
> *Information helpful to fulfilling the request: [name] is seeking an index or other listing of all documents concerning the AstraZeneca COVID-19 vaccine in MHRA's possession and that MHRA relied upon to authorize or otherwise approve or license the AstraZeneca COVID-19 vaccine. The index should be a complete list of all documents within any existing biologic/vaccine product file."*

We have been looking into your request for a listing of all documents and our estimates to date indicate that Section 12 of the Freedom of Information Act will apply to your request. Section 12 allows public authorities to refuse requests where the cost of dealing with them would exceed the appropriate limit, which for central government is set at £600. This represents the estimated cost of one person spending 24 working hours in determining whether the department holds the information, locating, retrieving and extracting the information.

The data which we hold on the AstraZeneca vaccine (or indeed any licensed medicine) is not held in such a way that a listing can easily be extracted. We would be happy to consider a refined request if you wish to make one, however, we do not recognise any obvious means by which to propose a refinement. For example, we could suggest that you limit your request to a single regulatory procedure or update, but there are a wide range of regulatory events that occur during a product's lifecycle and we are not currently sure which regulatory procedure is of interest to you.

Please note that the European Medicines Agency include a detailed list of variations and safety updates for this vaccine on their website, these documents may be of interest to you and may assist you to refine your request.

Vaxzevria (previously COVID-19 Vaccine AstraZeneca) | European Medicines Agency (europa.eu)
Vaxzevria, COVID-19 Vaccine (ChAdOx1-S [recombinant]) (europa.eu) – procedural steps.

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
Communications and engagement team
Medicines and Healthcare products Regulatory Agency
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