FOI 23-073 – Inventory of items submitted in support of Vaxzevria's Temporary and Conditional Marketing Authorisations

REQUEST
27 January 2023

Inventory of items submitted in support of Vaxzevria's Temporary and Conditional Marketing Authorisations

Pending release of the full set of data on quality, safety and efficacy reviewed by MHRA, would you please provide me with:

1. A full list, inventory, or manifest of the documents, packages, and data sets *submitted to MHRA in support of the Temporary Authorisation under Regulation 174*.

2. A further list, inventory or manifest of the additional documents, packages, and data sets *submitted to MHRA in support of the Conditional Marketing Authorisation*.

3. A further list, inventory or manifest of additional documents, packages, and data sets that have been *submitted to MHRA in compliance with the post-authorisation measures and obligations specified alongside the CMA*.

4. A further list, inventory or manifest of still outstanding documents, packages, and data sets specified in conjunction with the CMA as *post-authorisation measures and obligations, yet to be submitted to MHRA*.

For each listed document, package, or data set, please supply, where possible, Unique reference number or identifier; Short title; Longer description where retrievable; Version number/Date; Number of pages (as shown on first page).

For documents in list 4 above, please supply an anticipated/expected date of delivery instead of Version number/date and Number of pages.

Should there be a problem with producing one or more of the above lists, please provide what you can as well as an explanation of why some of the information cannot be provided. In any event, please confirm that MHRA holds all the above information.

MHRA RESPONSE
24 May 2023

Thank you for your request of 27 January 2023, we apologise for the long delay in reply.

We have been looking into your request for an inventory of documents (split into four separate listings), 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. We estimate that it will take us at least 35 hours to comply with your request, though potentially longer.

The data which we hold on the AstraZeneca vaccine (or indeed any licensed medicine) is not held in such a way that an inventory can easily be extracted. In the case of your request, our technical support team have determined that it would take them at least 35 hours to perform these extraction activities. Please note, this does not take account of the time that would then be required to sort through the extracted inventory into the four areas which you have asked about. Further, this estimate only covers one of our platforms, we also have another software for document management, we have made a similar for a time estimate to produce an inventory for this software to our technical support team and this is pending. However, as the 24 hour limit has already been exceeded, and we do not wish to further delay this response by waiting on that estimate.

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 also note the EMA 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.

We apologise once more for the delay in response.
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
10 South Colonnade, Canary Wharf, London E14 4PU