

**FOI 23/971**

Dear

Thank you for your email.

Re 23/774:

*“The agency withheld PSUR 3 and PSUR 4 under Section 22 because the agency stated the PSURs would be published by the European Medicines Agency (EMA). Our client asks that you please provide us with the webpage where the PSURs (included 1 and 2) for Vaxzevria (previously COVID-19 Vaccine AstraZeneca) are made publicly available. Additionally, please provide us with the estimated dates PSUR 3 and 4 will be made publicly available.”*

We included a link to the EMA website in our response to 23/774 which explains what information they’re publishing for Covid-19 vaccines:

<https://www.ema.europa.eu/en/human-regulatory-overview/public-health-threats/coronavirus-disease-covid-19/covid-19-public-health-emergency-international-concern-2020-23/transparency-exceptional-measures-covid-19-medicines>

Our response to 23/774 provided PSUR 1 and 2 to you because we have not been made aware of any EMA intent to publish these PSURs.

We therefore do not hold any information about where PSUR 1 and 2 will be published.

We do not hold details of where and when the EMA will publish PSUR 3 and 4. As these are decisions taken by the EMA, we recommend that you contact the EMA directly.

To assist, we include a link to contact the EMA

here: <https://www.ema.europa.eu/en/about-us/contacts-european-medicines-agency>

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](mailto: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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