FOI 23/811

Dear

Thank you for your request of 24 October 2023 where you requested the following:

Q1. Please can you send me the other AstraZeneca, Pfizer and Moderna Covid vaccine PASS studies which MHRA holds (all versions : ie Interim/Progress and Final)

Q2. For those Interim/Progress and Final PASS reports which have not yet been submitted by the MAHs, please can you tell me the corresponding planned submission dates.

Before we can process your request further, we require some clarification of the requested information.

You refer to three PASS studies concerning COVID-19 vaccines mentioned on the CPRD website:

- AstraZeneca : https://cprd.com/protocol/post-authorisation-post-marketing-observational-study-using-existing-secondary-health-data
- Pfizer : https://cprd.com/protocol/post-conditional-approval-active-surveillance-study-among-individuals-europe-receiving
- Moderna : https://cprd.com/post-authorization-active-surveillance-safety-study-using-secondary-data-monitor-real-world-safety

And also refer to the fact that interim report 1 for the COVID-19 vaccine AstraZeneca is available here: https://www.encepp.eu/encepp/viewResource.htm?id=104913

To clarify, a PASS study will comprise various documents which may include: a protocol (possibly several versions to incorporate amendments), one or more interim/progress reports (not always) and a final study report. It is not clear to us whether you are requesting interim/progress and final reports for the three studies you reference in your request, or for all PASS studies being undertaken for the Pfizer, Moderna and AstraZeneca vaccines. Please be aware that requesting all interim/progress and final reports for all PASS studies for these three vaccines would involve multiple documents requiring retrieval and review. If you are interested in PASS studies other than the three listed above, you are advised to consider reviewing the current Risk Management Plans for these vaccines, which are available on the European Medicines Agency website and include in Part III (Pharmacovigilance Plan), details of the PASS studies being undertaken by the respective companies. Here you will also find the milestones for the studies.

comirnaty-epar-risk-management-plan_en.pdf (europa.eu) (see pages 159-160, C4591021)
spikevax-previously-covid-19-vaccine-moderna-epar-risk-management-plan_en.pdf (europa.eu) (see page 117, mRNA-1273- P904)
vaxzevria-previously-covid-19-vaccine-astrazeneca-epar-risk-management-plan_en.pdf (europa.eu) (see page 62-63, D8111R00006)

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:

The Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Kind regards,

MHRA Customer Experience Centre
Communications and engagement team
Medicines and Healthcare products Regulatory Agency
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