FOI 23/129

26th March 2023

Dear

Thank you for your email.

Please note that regarding the data submitted to MHRA for the authorisation, the quality/pharmaceutical data (Module 3) would be exempt under Section 41 & 43 and Section 21 of the Freedom of Information (FOI) Act. This is because some of the data is available in the public domain already, such as the qualitative composition in the SmPC, so is exempt under S21 (information accessible by other means). The remaining information in Module 3 is commercially sensitive information and so is exempt under S41 (information provided in confidence) and S43 (commercial interests).

Module 4 can be considered for release. However, the information is large and to collate this would take us over 24 working hours, so would be exempt under Section 12 (unreasonable use of resources) of the FOI Act.

Module 5 clinical data for the below vaccines both at authorisation and clinical data submitted since are available through the EMA clinical repository, link provided below:
https://clinicaldata.ema.europa.eu/web/cdp/home

Links to the public assessment reports published by the EMA and MHRA that provides information on how marketing authorisations are granted is available to view at the following links provided below:
https://www.ema.europa.eu/en/medicines/human/EPAR/comirnaty
https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-moderna
https://www.ema.europa.eu/en/medicines/human/EPAR/covid-19-vaccine-moderna
https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-janssen
https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca
https://www.ema.europa.eu/en/medicines/human/EPAR/vaxzevria-previously-covid-19-vaccine-astrazeneca
https://mhraproducts4853.blob.core.windows.net/docs/27680d2f701880f90f62740cab6adb4d939b54b4
https://mhraproducts4853.blob.core.windows.net/docs/27680d2f701880f90f62740cab6adb4d939b54b4

These vaccines are indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2.

Regarding the statement at the beginning of your request, “The conditional marketing authorisation was granted on less comprehensive clinical data than normally required, where the benefit of immediate availability of the medicine

outweighs the risk inherent in the fact that additional data are still required.” Can you please provide the source from which you have obtained this statement?

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
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU