Medicines & Healthcare products Regulatory Agency

MHRA

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**gov.uk/mhra**

5th May 2022

FOI 22/674

Dear Annalise Beube,

Thank you for your emails of 29th April (6 in total) regarding the regulatory approval of the Covid vaccines.

We understand that data transparency is essential part of our role as the regulator of medicines and medical devices in Great Britain. Further, we appreciate that the availability of information on the safety and effectiveness of the Covid vaccines is of major importance to the public. Therefore, we have expended a great deal of effort and resource on the preparation of the public assessment reports (PARs) and into the a publishing weekly safety updates. Please note the PARs can be accessed by following the links provided in the below text.

The authorisation of the Pfizer/BioNTech, AstraZeneca and Moderna vaccines under Regulation 174 in the UK followed a rigorous scientific assessment of all the available evidence of quality, safety and effectiveness by the UK regulator, the Medicines and Healthcare products Regulatory Agency (MHRA). The MHRA expert scientists and clinicians reviewed data from the laboratory pre-clinical studies, clinical trials, manufacturing and quality controls, product sampling and testing of the final vaccine, and also considered the conditions for its safe supply and distribution. The decision was made with advice from the Commission on Human Medicines (CHM), the government's independent expert scientific advisory body. Regarding the MHRA approval of the Pfizer/BioNTech and the Oxford/AstraZeneca COVID-19 vaccines, further information (including information for physicians and recipients of the vaccine, and Public Assessment Reports [PARs] for each vaccine) are available on the MHRA website. Links to these are provided below:
https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19
https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca
https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-moderna

Please note that a marketing authorisation was granted for the Pfizer/BioNTech vaccine (Comirnaty) following a European Commission (EC) decision on 21 December 2020 (PLGB 53632/0002). Further information is available on the European Medicines Agency (EMA) website, a link to this is provided below:
https://www.ema.europa.eu/en/medicines/human/EPAR/comirnaty

Please also note that a marketing authorisation was granted for the Moderna vaccine on 31 March 2021 following an EC Reliance Procedure (PLGB 53720/0002). Further information is available on the MHRA website and the EMA website, links to these are provided below:
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

In addition, a marketing authorisation was granted for the Oxford/AstraZeneca vaccine on 24 June 2021 following an EC Reliance Procedure (PLGB 17901/0355). Further information is available on the MHRA website and the EMA website, links to these are provided below:
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

A marketing authorisation has been granted for the Janssen Covid-19 vaccine on 28 May 2021. Further information is available via the below link:
https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-janssen

A marketing authorisation has been granted for the Nuvaxovid vaccine on 03 February 2022. Further information is available via the below link:
https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-nuvaxovid

If you have a query about the information provided, please reply to this email

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

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