FOI 23/137

26th February 2023

Dear

Thank you for your email of 10th February where you have asked "Please provide me with copies of the Ministerial reports on Reg 174a authorisation of vaccines authorised for temporary use and not marketing authorisations for 2021 and 2022"

We understand that you are referring to the one year review of regulations 174A and 247A, which were included in The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020. Regulation 174A states:

> (5) As soon as is reasonably practical after the end of one year beginning on the day on which the first conditions are attached in accordance with paragraph (1), the Secretary of State must—
>
> (a)review the operation of this regulation with a view to evaluating whether there have been any adverse consequences for the market in medicines or for patient safety as a consequence of the operation of this regulation;
>
> (b)set out the conclusions of the review in a report; and
>
> (c)publish the report.".

The commitment made in the regulations (above) was to produce a review of how the regulations had been used, rather than individual reports on the vaccines authorised by the 174 route. This report is published on gov.uk and can be found at the link below:

https://www.gov.uk/government/publications/changes-to-human-medicine-regulations-to-support-the-rollout-of-vaccines-one-year-review/regulations-174a-and-247a-one-year-review

We hope you find this information helpful.

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