FOI 22/1210 – Astra-Zeneca one year report

REQUEST
23 December 2022

The report I require is the one referenced and highlighted by me in this quote below ie the one year report on the Oxford Astra Zeneca vaccine after one years usage.

The Human Medicines Regulations 2012

(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.**]

MHRA RESPONSE
19 January 2023

Dear

Thank you for your email of x where you have asked

"The report I require is the one referenced and highlighted by me in this quote below ie the one year report on the Oxford Astra Zeneca vaccine after one years usage."

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. New 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

If you disagree with how we have interpreted the Freedom of Information Act 2000 with regards to your request, you can ask for the decision to be reviewed. The review will be carried out by a senior member of the Agency who was not involved with the original decision.

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

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