
From: MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>

To:

Sent: 11/01/2023 16:12

Subject: FOI 22/1002 - RE: Human Medicine Regulations - Delegations to MHRA and One Year Reviews of the Temporary Authorisations of the Covid Vaccines

Our Ref: FOI 22/1002

Dear

Thank you for your Freedom of Information request; please accept our apologies for the delay in reply.

We include your original questions in blue italicised text, and our responses in black text.

The Human Medicines Regulations define the Licensing Authority as the Secretary of State for Health & Social Care. Please can you send me the MHRA document describing the flow of delegation from the SoFS to posts/people in MHRA who can authorise medicines for public use.

All the Covid vaccines and therapeutics authorisation decisions were taken by the Licensing Minister and were not delegated. The MHRA does not hold a document describing the flow of delegation from the Secretary of State to posts/people in MHRA who can authorise medicines for public use.

Regulation 174 of the Human Medicines Regulations allows the temporary authorisation of medicines. Please can you send me a copy of the instruction to MHRA that Regulation 174 applied to the Covid vaccines.

We attach copies of the letters that DHSC sent to MHRA regarding Regulation 174 and the Covid vaccines. Please note, these letters do not denote instructions to authorise; rather the letters from DHSC seek on a case-by-case the view of MHRA on the suitability of the product concerned.

Please can you tell me which post/person in MHRA signed the temporary authorisations for public use of the Covid vaccines.

The licensing minister signs the Regulation 174 letter.

Please can you send me copies of the MHRA's one year reviews of the temporary authorisation for each of the Covid vaccines.

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 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