Replied - RE: FOI 23/992 - Freedom of Information Act Request

FOILicensing <FOILicensing@mhra.gov.uk>
Wed 17/01/2024 08:34

To:MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Cc [redacted] FOILicensing <FOILicensing@mhra.gov.uk> [redacted]

Dear [redacted]

Please can you send out the final response below for FOI 23/992 and mark this as closed.

Kind regards

[redacted]

Final response:

FOI 23/992

Dear [redacted]

Many thanks for your email dated 18 December 2023 in which you requested answers to the following questions:

1. Have the covid-19 vaccines been fully licensed or are they currently being administered under Emergency Use Authorisation/Temporary Authorisation under Regulation 174?

2. I understand that Regulation 174 authorisation DOES NOT constitute a marketing authorisation is that correct?

Please find our response to your questions below:

1. Have the covid-19 vaccines been fully licensed or are they currently being administered under Emergency Use Authorisation/Temporary Authorisation under Regulation 174?

Regulation 174 was used in the temporary authorisation of the Pfizer COVID-19 vaccine and the AstraZeneca COVID-19 vaccine. Each was subsequently granted a conditional marketing authorisation (CMA). The Moderna COVID-19 vaccine was also authorised under R174 on 8 January 2021, however no Moderna supply was provided under R174. Supply of the Moderna vaccine was not anticipated until early April 2021, by which time a CMA for the Moderna vaccine was in place.

The CMA for these 3 vaccines have all been converted into full MAs as follows:

Vaxzevria (AstraZeneca vaccine):
Temporary supply under regulation 174 of the Human Medicines Regulations 2012: 30 December 2020
Conditional Marketing Authorisation: 24 June 2021
Full Marketing Authorisation: 19 June 2023

Comirnaty (Pfizer/BioNTech vaccines):

Temporary supply under regulation 174 of the Human Medicines Regulations 2012: 01 December 2020
Conditional Marketing Authorisation: 21 December 2020
Full Marketing Authorisation: 09 November 2022

Spikevax (Moderna vaccines):
Conditional Marketing Authorisation: 31 March 2021
Full Marketing Authorisations: 26 February 2023

MHRA has since authorised a number of vaccines for COVID-19, none of which have been authorised on a temporary basis via Regulation 174. Further information on products that have been authorised by MHRA can be found by searching our product page: https://products.mhra.gov.uk

2. I understand that Regulation 174 authorisation DOES NOT constitute a marketing authorisation is that correct?

That is correct. Regulation 174 is the mechanism which allows for temporary authorisation of an unlicensed medicine, such as a vaccine, where such an authorisation is needed in response to certain public health threats, such as a pandemic. These authorisations do not constitute a marketing authorisation. The temporary authorisation of certain COVID-19 vaccines under Regulation 174 permitted the supply of identified vaccine batches, based on the safety, quality and efficacy data submitted to MHRA.

The Human Medicines Regulations 2012 states the following:
The prohibitions in regulation 46 (requirement for authorisation) do not apply where the sale or supply of a medicinal product is authorised by the licensing authority on a temporary basis in response to the suspected or confirmed spread of—
(a)pathogenic agents;
(b)toxins;
(c)chemical agents; or
(d)nuclear radiation,
which may cause harm to human beings.

For further information regarding regulation 174, please see 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 trust that you will find this information of use. However, if you disagree with how we have interpreted the Freedom of Information Act 2000 in answering your request, you can ask us to review our actions and decisions by writing to: info@mhra.gov.uk, and requesting an internal review.

Please note that your internal review request must be in a recordable format (email, letter, audio tape etc.), and that you have 40 working days upon receipt of this letter to ask for a review. We aim to provide a full response to your review request within 20 working days of its receipt. Please quote the reference number above in any future communications.

If you are not content 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 online via an electronic form: https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/

Or in writing to:
Information Commissioner's Office,

Wycliffe House,
Water Lane,
Wilmslow,
Cheshire,
SK9 5AF

Yours sincerely,

HQA FOI Team

From: MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Sent: Wednesday, December 20, 2023 2:22 PM
To: FOILicensing <FOILicensing@mhra.gov.uk>
Cc: [redacted]
Subject: FOI 23/992 - Freedom of Information Act Request
Importance: High

FOI 23/992

Dear All,

I hope you are safe and well.

Please see the below FOI request, which has a deadline of **19 January 2024.**

We are grateful for your help with this FOI request?

Kind regards

[redacted]

From: [redacted]
Sent: Monday, December 18, 2023 3:18 PM
To: MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Subject: FOI 23/992 - Freedom of Information Act Request

You don't often get email from [redacted]

Good afternoon

I would be grateful if you could please supply answers to the following questions:-

1. Have the covid-19 vaccines been fully licensed or are they currently being administered under Emergency Use Authorisation/Temporary Authorisation under Regulation 174?

2. I understand that Regulation 174 authorisation DOES NOT constitute a marketing authorisation is that correct?

I look forward to receiving your response within the timeframe allotted.

Kind regards.

[redacted]

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