Medicines & Healthcare products Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
gov.uk/mhra

[redacted]

24 May 2024

MHRA reference: **FOI2024/00061**

Dear [redacted],

Thank you for your information request, which we received on **25 April**. You asked for:

> *"I am requesting the information that Pfizer and Moderna have been granted a provisional licence from our Gene Technology Regulator which I presume is the MHRA.*
>
> *I would like copies of all the licences given for both Pfizer and Moderna for each Province England, Scotland, Wales and Northern Ireland.*
>
> *I have attached a solicitors letter to the Regulator in Australia for your perusal, although I have not gone down the legal route just yet, I am asking for the same under the Freedom of Information Act 2000 personally."*

We have dealt with your request under the Freedom of Information Act 2000 (FOIA).

Please find our response below:

In the UK there is no 'Gene Technology Regulator' organisation. The MHRA regulates medicines, medical devices and blood components for transfusion in the UK, which includes vaccines for human use. Further details of what and how the MHRA regulates, and also the remit of the independent advisory bodies such as the Commission on Human Medicines, can be found here: https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/about

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I confirm that MHRA holds this information, but your request for 'copies of all the licences given for both Pfizer and Moderna for each Province England, Scotland, Wales and Northern Ireland', the release of this information is exempt under Section 21 (S21 – Information accessible by other means) of the FOIA. Section 21 is an absolute exemption and states that there is no right of access to information via FOI if it is reasonably available to the applicant by another route. Information on marketing authorisations (also known as licences) for medicinal products issued by the MHRA can be found here: MHRA Products | Search results

There are a very large number of Pfizer medical products listed, and a smaller but still substantial number of Moderna products listed. Although you do not specify in your request which licences you are interested in, from your attached letter you appear to be interested in the Comirnaty range of products from Pfizer/BioNTech and the Spikevax range of products from Moderna.

Please note that under the current Northern Ireland protocol, the European Medicines Agency and the European Commission authorise marketing authorisations for certain categories of medicinal products (e.g. medicines derived from biotechnology processes) in Northern Ireland and not the MHRA. The MHRA authorises medicinal products for Great Britain consisting of England, Scotland, and Wales. Information on products that have a European licence are available at the European Medicines Agency website https://www.ema.europa.eu/en.

In both the MHRA and the EMA links above you will find Public Assessment Reports for the various products that explain how each product was assessed. You can also find Summaries of Product Characteristics and Patient Information Leaflets, which outline the conditions under which the medicine should be used and information on its known safety.

The Health and Safety Executive (HSE) are the competent authority responsible for regulating the use of GMO's. GMO classification also falls under the remit of the HSE. Further information which you may find useful can be found using the following links:
Genetically Modified Organisms (GMOs) (hse.gov.uk)
GMOs The Public Register (hse.gov.uk)

This concludes our response to your request.

If you have a query about this response, please contact us at foi.request@mhra.gov.uk.

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Please remember to quote the reference number at the top of this letter in any future communications. Details of your appeal rights are below.

Yours sincerely,

Healthcare, Quality and Access Group

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Appeal rights

If you are dissatisfied with the handling of your request, you can ask us to conduct an internal review. Internal review requests should be submitted within two months of the date you receive this response and addressed to: foi.request@mhra.gov.uk

If you remain dissatisfied with the outcome of the internal review, you 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 a request unless the requester has first asked us to conduct an internal review.

The Information Commissioner can be contacted through their online webform at: 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

Re-use of our information