Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

www.gov.uk/mhra

27 July 2023

Dear [redacted]

FOI 23/469

Thank you for your email of 29 June 2023, where you requested a copy of the document referred to as the 'MHRA Core RMP for COVID-19 vaccines' in the Conditions of Authorisation for COVID-19 Vaccine Pfizer/BioNTech supplied under Regulation 174, under 'Clinical and Pharmacovigilance'. As you are requesting recorded information held by the MHRA we have treated this as a Freedom of Information request.

Please find attached a copy of the requested document. The guide was intended to to outline to applicants of authorisations for COVID-19 vaccines the UK requirements for the safety monitoring and risk management of these products.

The MHRA accepts the EU RMP format, regardless of the authorisation route of a medicinal product in the UK (e.g. GB authorisation or European Commission Decision Reliance Procedure) however the MHRA guidance document was written in advance of UK's exit from the EU on 1 January 2021 and also before it was known by which route COVID 19 manufacturers would use to apply for marketing authorisations in the UK.

We hope this information is helpful. If you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date of this response; and can be addressed to this email address.

Yours sincerely,

FOI Team,

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If you have a query about this email, please contact us. If you are unhappy with our decision, you may ask for it to be reviewed. That review will be undertaken by a senior member of the agency who has not previously been involved in your request. If you wish to pursue that option, please write to the Communications Directorate, 4-T, Medicines and Healthcare products Regulatory Agency (via this email address). After that, if you remain dissatisfied, you may ask the Information Commissioner at:

The Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF