FOI 22/1131 - Comirnaty full marketing authorisation

REQUEST
21 November 2022

Comirnaty was converted from Conditional Marketing Authorisation to a full Marketing Authorisation on 9th November.

Please could you:
-Confirm what triggered the conversion to full market authorisation?
-State what additional requirements the vaccines were subjected to for the conversion?
-State if all requirements of temporary authorisation were fulfilled prior to conversation?
-Explain what approval process the vaccines would have been subjected to if they went straight to full market authorisation, rather than via conditional authorisation?
--Provide a list of any requirements of full market authorisation that have been missed due to the initial temporary authorisation

MHRA RESPONSE
12 February 2023

Dear

Thank you for your request under the Freedom of Information Act (FOIA).

Apologies for the delayed response.

We are pleased to provide you with the information requested, see below.

The change from CMA to MA was done following the second annual renewal of Comirnaty, where no new data emerged that would alter the benefit/risk for these products. The CHMP concluded that the clinical safety profile, as well as the efficacy of this product, may now be considered comprehensively characterised, in the sense of the conditional marketing authorisation (CMA) legislation and the CMA converted to a full MA.

Further information is available from the EMA, see the link below:

https://www.ema.europa.eu/en/medicines/human/EPAR/comirnaty

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