Medicines & Healthcare products Regulatory Agency

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

[redacted]

08 December 2023

Dear [redacted]

FOI 23/871: Fluzone HD for use as a comparator vaccine for a phase 3 flu vaccine trial

Thank you for your request dated 11 November 2023 in which you requested information concerning Fluzone HD for use as a comparator vaccine for a phase 3 flu vaccine trial. Please find below, our response to your query.

MHRA response

1. **I understand that Fluzone HD adjuvanted quadrivalent influenza vaccine isn't currently licensed by the MHRA for use or marketing in the U.K.**

We confirm that a Marketing Authorisation is not approved in the United Kingdom (UK) for Fluzone HD adjuvanted quadrivalent influenza vaccine.

2. [redacted] **I am aware that Flublok influenza vaccine was given emergency licensing by the MHRA in 2021 for use nationally due to flu vaccine shortages. Does the MHRA ever consider licensing under this scenario for clinical trial purposes and, if so, what would the process be?**

Flublok Quadrivalent (Influenza vaccine) is licensed in the USA and was authorised for temporary supply by the UK Department of Health and Social Care and the MHRA. This

medicinal product does not have a UK marketing authorisation. This route is not applicable to clinical trial supplies.

The MHRA provide scientific and regulatory advice on development of medicines and assess whether a trial proposal is acceptable to be conducted based on the benefit versus risk of an individual proposal.

The MHRA would consider a clinical trial authorisation (CTA) submission from a sponsor intending to conduct a clinical trial testing flu vaccines.

Comparators in clinical trials are considered Investigational Medicinal Products (IMPs) and the acceptability of any comparator in a clinical trial needs to be adequately justified by the sponsor of the study and supported by quality documents of the product including an acceptable Investigational Medical Product Dossier (IMPD).

While the Agency plays a leading global role in protecting and improving public health and supports innovation through scientific research and development, its remit does not include conducting our own research (or on behalf of others) or sponsoring clinical trials.
Information on how to apply for a CTA is provided in the following MHRA website:

https://www.gov.uk/guidance/clinical-trials-for-medicines-apply-for-authorisation-in-the-uk.

A sponsor may also request advice on clinical, quality or regulatory aspects of a specific clinical trial proposal in Scientific Advice Meetings as detailed in the following MHRA website:

https://www.gov.uk/guidance/medicines-get-scientific-advice-from-mhra.

We trust that you will find this reply of use.
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 2 months of the date you receive this response and addressed to: info@mhra.gov.uk.

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 online via an electronic form: https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/

or by writing to:

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

Yours sincerely,

HQA FOI Team

Email: FOILicensing@mhra.gov.uk