



Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of
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[MHRA Website](https://www.mhra.gov.uk)

Our Ref: **FOI2025/00033**

6 February 2025

Dear [REDACTED]

Thank you for your Freedom of Information (FoI) request received on 9 January. You wrote:

Dear Medicines and Healthcare Products Regulatory Agency, with reference to the UKHSA's recent announcement of the purchase of more than 5 million doses of H5 influenza vaccine from CSL Seqirus UK Ltd, I have asked UKHSA some questions. They replied that you are the competent authority to answer them. So here are my questions:

- 1. What is the effectiveness profile of the H5 vaccine/platform?*
- 2. What is the harm profile of the H5 vaccine/platform?*
- 3. What is the field effectiveness of the vaccine/platform?*
- 4. Please provide me with a copy of the risk-benefit assessment.*

MHRA Response

We can confirm that the Agency holds this information. However, the information is exempt under Section 21(1) of the Freedom of Information Act because the information is reasonably accessible to you, as it is already in the public domain.

We have understood the influenza vaccine you are referring to in your request is Adjuvanted Zoonotic Influenza Vaccine Seqirus suspension for injection in pre-filled syringe (PLGB 47991/0013). This is a national abridged application submitted under Regulation 56 of Human Medicines Regulations (HMR) 2012, as amended).

The cross-reference product is Aflunov, which was licensed in the UK based on its European Union (EU) approval, at the point when United Kingdom left the EU on 1 January 2021. ([Converting Centrally Authorised Products \(CAPs\) to UK Marketing Authorisations \(MAs\), 'grandfathering' and managing lifecycle changes - GOV.UK](#)).

The European Medicines Agency (EMA) originally authorised Aflunov on 28 November 2010, and a European Public Assessment Report (EPAR) is available online which describes the basis for that decision.

To be helpful you can find the information you seek at [H-2094-en6](#)

Additionally, the current published Summary of Product Characteristics (SmPC) and Patient Information Leaflet (PIL) can be found using the following links:

[Microsoft Word - 8257875480003350236_spc-doc.doc
4499a1cdfdbca012359186baf5e1d35cccdb4701](#)

The safety information is monitored throughout the product lifecycle. The EMA page includes updates.

This concludes our response to your request.

If you have any queries about this letter, please contact us quoting the reference number above.

Yours sincerely,

MHRA Central Freedom of Information Team
Medicines & Healthcare products Regulatory Agency

Your right to complain under the Freedom of Information Act

If you are not happy with this response you may request an internal review by e-mailing foi.request@mhra.gov.uk or by writing to: MHRA Central Freedom of Information Team, 10 South, Colonnade, Canary Wharf, London, E14 4PU

Any request for an internal review must be received by us within 40 working days of the date of this letter. Please note we are not obliged to provide a review if it is requested after more than 40 working days.

If you are not content with the outcome of the internal review, you may apply directly to the Information Commissioner's Office for a decision. Generally, the Commissioner cannot make a decision unless you have exhausted our own complaints procedure. The Information Commissioner can be contacted at: The Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF.

Website: [ICO FOI and EIR complaints](#) or telephone 0303 123 1113

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