



## Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of  
Information Team  
10 South Colonnade  
Canary Wharf  
London  
E14 4PU

[foi.request@mhra.gov.uk](mailto:foi.request@mhra.gov.uk).

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

Our Ref: **FOI2025/00320**

29 April 2025

Dear [REDACTED]

Thank you for your Freedom of Information (FOI) request received on 29 March 2025. You wrote:

*'On the 7th of March you kindly informed me that Aflunov licensed in November 2010 is the predicate vaccine for Incellipan, Adjuvanted Zoonotic Influenza Vaccine Seqirus and Celldemic.*

*According to Regulation 56 of Human Medicines Regulations, you must have licensed the 3 newer vaccines as bioequivalents to ensure "the same qualitative and quantitative composition". You must have done this on the basis of their bioequivalence given the different composition and production process of each vaccine.*

*Please point me to or send me the bioequivalence studies.'*

### MHRA Response

On the 7 March 2025, in the response to the Internal Review IR2025/00104 we stated:

*'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](#)*

Bioequivalence studies are required when applying for some types of generic medicinal products. These may also be called abridged applications as the applicants are not required to provide full tests and trials because the application claims similarity to a suitable cross-reference product.

The MHRA website provides further guidance on bioequivalence studies and the types of applications for which they may be required.

*'The following types of abridged applications are commonly supported by BE [Bioequivalence] or TE [Therapeutic equivalence] studies and are within the scope of this guidance:*

- *applications relating to generic medicinal products (regulation 51B<sup>1</sup> HMRs)*
- *applications relating to hybrid medicinal products (that do not qualify as generics; submitted under regulation 52B<sup>2</sup> HMRs)*
- *applications relating to new combinations of active substances (regulation 55(iii)(b) HMRs)*
- *variations requiring demonstration of BE to the RMP [Reference Medicinal Product] (for example, for modified release solid oral dosage forms) (regulation 65C HMRs)*
- *extension applications (regulation 65C HMRs)*

<sup>1</sup>*Also applies to Regulation 51A until 1 January 2025.*

<sup>2</sup>*Also applies to Regulation 52A until 1 January 2025.'*

The products concerned in this FOI Request were not authorised under the legal bases outlined above that may require bioequivalence studies.

The routes and legal bases that Aflunov, Incellipan, Adjuvanted Zoonotic Influenza Vaccine and Celldemic were authorised by are outlined in the table below. Links to the Public Assessment Reports that provide further information on these authorisations are also included.

Product	Authorisation Route/Legal basis	Public Assessment Report
AFLUNOV suspension for injection in pre-filled syringe. Zoonotic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted)  PLGB 47991/0004	Originally authorised by the European Commission (EC) on 29 November 2010, following a centralised procedure done through the European Medicines Agency (EMA).	EMA (EU): <a href="https://www.ema.europa.eu/en/documents/assessment-report/aflunov-epar-public-assessment-report_en.pdf">https://www.ema.europa.eu/en/documents/assessment-report/aflunov-epar-public-assessment-report_en.pdf</a>  As the authorisation of this medicinal product by the EC predates the UK leaving the EU, no PAR was prepared by MHRA.
Incellipan suspension for injection in pre-filled syringe Pandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted, prepared in cell cultures).  PLGB 47991/0016	Authorised via International Recognition Procedure Route B with EMA as the reference regulator (UK Regulation 50).	MHRA (UK): <a href="https://mhraproducts4853.blob.core.windows.net/docs/9530d99b2d2d6d656091553ff341d0a167eb936d">https://mhraproducts4853.blob.core.windows.net/docs/9530d99b2d2d6d656091553ff341d0a167eb936d</a>  EMA (EU): <a href="https://www.ema.europa.eu/en/documents/assessment-report/incellipan-epar-public-assessment-report_en.pdf">https://www.ema.europa.eu/en/documents/assessment-report/incellipan-epar-public-assessment-report_en.pdf</a>
Adjuvanted Zoonotic Influenza Vaccine (Surface Antigen, Inactivated) Seqirus suspension for injection in pre-filled syringe  PLGB 47991/0013	Authorised via the National Procedure (UK Regulation 56).  This initial authorisation was an informed consent procedure to create a duplicate unbranded licence of Aflunov.	MHRA (UK): <a href="https://mhraproducts4853.blob.core.windows.net/docs/ecc067fd9fa881390f6913f349148cb898e77432">https://mhraproducts4853.blob.core.windows.net/docs/ecc067fd9fa881390f6913f349148cb898e77432</a>  Please see further information on the following page regarding a strain change diverging the licence from Aflunov.
Celldemic suspension for injection in pre-filled syringe Zoonotic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted, prepared in cell cultures)  PLGB 47991/0017	Authorised via International Recognition Procedure Route A with the EMA as reference regulator (UK Regulation 50).	MHRA (UK): <a href="https://mhraproducts4853.blob.core.windows.net/docs/89f89da76a239e5c7e4c459439b1e634f4d300c7">https://mhraproducts4853.blob.core.windows.net/docs/89f89da76a239e5c7e4c459439b1e634f4d300c7</a>  EMA (EU): <a href="https://www.ema.europa.eu/en/documents/assessment-report/celldemic-epar-public-assessment-report_en.pdf">https://www.ema.europa.eu/en/documents/assessment-report/celldemic-epar-public-assessment-report_en.pdf</a>

To be as helpful as possible, each product and the reasons that bioequivalence studies were not required are discussed in turn below.

- Aflunov

This was not a generic medicine application. As the original centralised application was a full dossier application, the results of clinical and non-clinical tests were provided to the EMA. Bioequivalence tests were not conducted or required.

- Incellipan

This was not a generic medicine application. As a full dossier application under Regulation 50 through the International Recognition Route, no bioequivalence studies were required. The EMA public assessment report states:

*'As is routine in vaccine applications, studies on bioavailability, relative bioavailability and bioequivalence are not pertinent to formulation development; therefore, these types of study were not performed.'*

- Adjuvanted Zoonotic Influenza Vaccine

As a Regulation 56 Informed Consent application, this product was a duplication of the Aflunov licence and as previously stated, used Aflunov as the cross-reference product. No bioequivalence studies were conducted, and bioequivalence studies are not usually required for this type of application. It should be noted that a later variation in the product lifecycle registered a zoonotic strain change from A/turkey/Turkey/1/2005 (H5N1) like strain to A/Astrakhan/3212/2020 (H5N8)-like strain and thus this vaccine is no longer a duplicate of Aflunov.

For more information, please see the Summaries of Product Characteristics available on the MHRA products website.

- Celldemic

This was not a generic medicine application. As a full dossier application under Regulation 50 through the International Recognition Route, no bioequivalence studies were required. The Reference Regulator was the EMA and their Public Assessment Report states:

*'As is routine in vaccine applications, studies on bioavailability, relative bioavailability and bioequivalence are not pertinent to formulation development; therefore, these types of study were not performed.'*

In conclusion, the MHRA does not hold the information requested. Thus, we are upholding the decision in our original response to IR2025/00104.

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](mailto: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.

### **Re-use of our information**

The MHRA information supplied in response to your request is subject to Crown copyright. Information created by the MHRA which is disclosed under the Freedom of Information Act is made available for re-use under the Open Government Licence (OGL) v3.0, except where this is otherwise stated. There are some restrictions on re-use under the OGL and these can be viewed here:

<https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/>