



Medicines & Healthcare products  
Regulatory Agency

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Our Ref: **FOI2025/00678**

01 August 2025

Dear [REDACTED]

Thank you for your Freedom of Information (FOI) request received on 3 July. You wrote:

*During our initial application for PLPI 20636/2654 we applied for a parallel import licence for Flagyl 40mg/ml oral suspension/mitkstur from Norway under ECMA. 6929 and this was granted as per the enclosed grant letter.*

*We understand that an assessment would have been carried out by the MHRA (PLPI unit) to prove equivalency of this product against PL 17780/0275 Flagyl S 200mg/ml Oral Suspension of Winthrop Pharmaceuticals which has then undergone a change of ownership to Aventis Pharma under PL04425/0747 (Our renewal letter is enclosed for reference).*

*Please may we request a copy of the documents and information obtained during the initial assessment of our parallel import licence application which shows equivalency of the Norwegian product to the UK reference product, and any other supporting information that you may have on file.*

## **MHRA Response**

We confirm that we hold the information you have requested.

The information is provided, as an annex (Annex A), in the attached extract from the initial assessment report generated for the initial application for Flagyl 40mg/ml oral suspension (PLPI 20636/2654). The MHRA assessment established that the product to be imported from Norway and which was granted a parallel import licence Flagyl S 200 mg/5ml Oral Suspension (PLPI 20636/2654), has no differences with the potential to have therapeutic effect compared to the existing UK product and is marketed or manufactured by a company linked to the existing UK licence holder.

We consider that some information is exempt from disclosure. Under section 17(1) of the FOIA, when we refuse any part of the requested information, we must specify the relevant exemption and explain why the exemption applies.

Redactions have been made under the following Sections of the FOIA:

**Section 40** – Disclosure of information subject to Section 40 would be an infringement of personal data. Section 40 is an absolute exemption, and no consideration of the public interest is required.

**Section 41 – (1)** Information is exempt information if — (a) it was obtained by the public authority from any other person (including another public authority), and, (b) the disclosure of the information to the public (otherwise than under this Act) by the public authority holding it would constitute a breach of confidence actionable by that or any other person.

**Section 43** –

**(1)** Information is exempt information if it constitutes a trade secret.

**(2)** Information is exempt information if its disclosure under this Act would, or would be likely to, prejudice the commercial interests of any person (including the public authority holding it).

### **Public interest test**

Section 17(3) of the Act requires us to conduct a Public Interest Test (PIT) when applying of a qualified exemption. In applying this exemption, we are required to consider whether, in all the circumstances of the case, the public interest in withholding the information outweighs the public interest in releasing the information held. The 'public interest' is not the same as what interests the public. In carrying out a PIT, we consider the greater good or benefit to the community as a whole in withholding. The 'right to know' must be balanced against the need to enable effective procedural governance and to serve the best interests of the public. The FOI Act is 'applicant blind'. This means that we cannot, and do not, ask about the motives of anyone who asks for information. In providing a response to one person, we are expressing a willingness to provide the same response to anyone.

### **Considerations in favour of releasing the information**

To release this information would benefit in general by showing transparency in MHRA's day-to-day work for the public to see assessment reports produced by MHRA in an unredacted form.

### **Considerations in favour withholding the information**

Information redacted under Section 43 constitutes trade secrets and know-how on how these products were developed. The marketing authorisation holders have spent time and resources in developing the products, in order to meet the regulatory guidelines.

The redacted information can be used by rival companies to overcome regulatory hurdles at the expense of the marketing authorisation holders (Winthrop Pharmaceuticals UK Limited and Sanofi-aventis Norge AS) in submitting similar marketing authorisation applications.

In applying this exemption, the agency has balanced the public interest in withholding the information against the public interest in disclosing the information and on balance we find that withholding the information from release outweighs our obligation to release.

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](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/>