Medicines & Healthcare products Regulatory Agency

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

foi.request@mhra.gov.uk.

MHRA Website

Our Ref: **FOI2024/00632**

13 November 2024

Dear [redacted],

Thank you for your Freedom of Information (FoI) request received on 16 October. You wrote:

> *"[redacted] hereby submits the following Freedom of Information request with regards to the Marketing Authorisations for Revolade 25 mg, 50 mg and 75 mg film-coated tablets (PLGB 00101/1126-1128-1129) held by Novartis Pharmaceuticals UK Limited.*
>
> *The details of the request are as follows:*
>
> ** The Environmental Risk Assessment document named Revolade(r) (eltrombopag olamine) 25 and 50 mg film coated tablets Environmental Risk Assessment and associated study/chemical testing reports that are currently registered in module 1.6 for the following Product Licences (PLGB 00101/1126, PLGB 00101/1128, PLGB 00101/1129)*
>
> *In accordance with the Heads of Medicines Agencies/European Medicines Agency (HMA/EMA) guidance on transparency, the environmental risk assessment information within module 1.6 requested is considered releasable, as outlined in pages 5 and 25 of the HMA/EMA guidance."*

MHRA Response

We have dealt with your request under the Freedom of Information Act 2000 (FOIA).

We confirm that we hold the information you have asked for. In response to your request, we are providing the following Environmental Risk Assessment (ERA) reports:

- **ERA of Revolade for Severe aplastic anemia (SAA), 06 December 2018**
- **ERA of Revolade for Immune thrombocytopenia (ITP), 10 December 2021**

Please note that some redactions have been applied to these documents under the following Section of the Environmental Information Regulations (EIRs), 2004.

- Section 12(3): Exception to disclose environmental information if the information requested includes personal data of which the applicant is not the data subject, the personal data shall not be disclosed otherwise than in accordance with regulation 13.

Section 12(3)
We are unable to provide you with some of the information requested as it constitutes personal data of someone other than yourself and as such, it is being withheld in accordance with section 12(3) of the Environmental Information Regulations (EIRs), 2004. Regulation 12(3) does not require consideration of the public interest.

We do not consider that disclosing this information is necessary or justified in order to satisfy your information request and the requirements of the FoI Act. In relation to this request, we consider that there is no strong legitimate interest that would override the prejudice to the rights and freedoms of the data subject.

Personal data are subject to UK General Data Protection Regulation (UK GDPR) and the Data Protection Act 2018

MHRA maintains the following policy on disclosure of personal information:
"All personal information held in MHRA records is regarded as confidential. Information will not normally be disclosed to third parties without the consent of the person concerned. Information may normally be disclosed without consent to meet statutory requirements; to comply with a court order; to prevent duplication of payments from public funds; or where there is a compelling public interest in making the disclosure."

All disclosures made by MHRA, in order to be considered authorised must be able to demonstrate that at least one of the above criteria apply.

This concludes our response to your request.

If you have a query about this response, please contact us at foi.request@mhra.gov.uk

Please remember to quote the reference number at the top of this letter in any future communications. Details of your appeal rights are below.

Yours sincerely,

Healthcare, Quality and Access Group
Medicines and 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.

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/