



Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of
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[MHRA Website](#)

Our Ref: **FOI2026/01076**

2 October 2026

Dear [REDACTED]

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

We hereby request any information you hold and can provide regarding the adverse effects of Roaccutane, in particular in relation to mental health, including depression, mood and suicide, including reports regarding same from 2016 onwards.

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. Further information can be found on [ICO Section 21 Guidance](#)

However, to be helpful you can find the information you seek at: <https://yellowcard.mhra.gov.uk/idaps>, searching for isotretinoin. Interactive Drug Analysis Profiles (iDAPs) contain complete listings for all medicines and vaccines of all UK spontaneous suspected adverse reactions received by the MHRA and are available to view on this website. On this platform, you will be able to search for the specified medicine or vaccine and find the reported suspected adverse reactions associated with them. The graphs and tables within the 'Total Report Profile' and 'Total Reaction Profile' tabs are dynamic for all products. The filters on the left-hand side allow you to interact and filter the data as you wish. The platform also provides other searches which you can filter by, including "Year Received" such as 2016 onwards, "Age Group" and "Seriousness".

The MHRA uses the Medical Dictionary for Regulatory Activities ([MedDRA](#)) to code suspected adverse drug reactions reported by patients and healthcare professionals via the Yellow Card scheme. MedDRA is an international, clinically validated medical terminology used by regulatory authorities and the biopharmaceutical industry throughout the entire regulatory process, from pre-marketing to post-marketing safety monitoring. The reactions you requested relating to mental health, including depression, mood and suicide, can be found under the Psychiatric Disorders System Organ Class (SOC) within the Reactions by System Organ Class table on the Total Reaction Profile tab.

When considering spontaneous data for medicinal products, it is important to be aware of the following points:

- A reported reaction does not necessarily mean it has been caused by the medicine, only that the reporter had a suspicion it may have. The fact that symptoms occur after use of a medicine, and are reported via the Yellow Card scheme, does not in itself mean that they are proven to have been caused by it. Underlying or concurrent illnesses may be responsible and such events can also be coincidental.
- It is also important to note that the number of reports received via the Yellow Card scheme does not directly equate to the number of people who suffer adverse reactions and therefore cannot be used to determine the incidence of a reaction or compare the safety profile of different medicinal products. ADR reporting rates are influenced by the seriousness of ADRs, their ease of recognition, the extent of use of a particular medicine, and may be stimulated by promotion and publicity. Reporting tends to be highest for newly introduced medicines during the first one to two years on the market and then falls over time.

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