

FOI 23/952

Dear

Thank you for your email of 5 December.

Please find below answers to the questions you have raised.

Question 1

Please can you disclose how many people in the UK are prescribed Isotretinoin and the demographic specifics of this group of people e.g. by age, gender and ethnicity, also specifically how many adults are prescribed Isotretinoin and if a different number, how many adults are prescribed Isotretinoin by the NHS in the UK.

Answer

The MHRA do not hold information on the number of people prescribed isotretinoin within the UK. Whilst we consider medicine usage as part of our analysis of the safety of medicines, information on the number of individuals prescribed a given medicines is not held by the MHRA. This information is held by the UK Health Security Agency (UKHSA), who can be contacted at enquiries@ukhsa.gov.uk.

Question 2

Also, what the incidence of different Isotretinoin side effects reported via the yellow card scheme is in the UK? And if possible the incidence of Isotretinoin side effects reported by adults in the UK?

Answer

It is 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 medicines. 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 about a drug. 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 are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date you receive this response and addressed to: info@mhra.gov.uk

Please remember to quote the reference number above in any future communications.

If you were to remain dissatisfied with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at:

Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Or online via: <https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/>

Yours sincerely

MHRA Customer Experience Centre
Communications and engagement team
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU