



# DRUG SAFETY UPDATE (DSU)

## Isotretinoin – updates to prescribing guidance and survey of services

*Specialisms: Dermatology, Dispensing GP practices, General practice, Pharmacy, Psychiatry*

### Overview of Measures

The Medicines and Healthcare products Regulatory Agency (MHRA) has reviewed the impact of the implementation of the recommendations advised by the Commission on Human Medicines (CHM) who were informed by its Isotretinoin Expert Working Group (IEWG) and Isotretinoin Implementation Advisory Expert Working Group (IIAEWG) in 2023.

The CHM has endorsed changes to the isotretinoin prescribing guidance of the IIAEWG and an addendum to the IIAEWG report has been published to amend and clarify previous advice, regarding follow-up consultations, pregnancy testing and sexual function monitoring.

In addition, the CHM agreed an effective approach is required to monitor the adherence to risk minimisation measures going forward, whilst supporting patient access to treatment across all age groups. As such, the MHRA seeks to undertake a survey of services where isotretinoin is prescribed to support its safe prescribing.

Both NHS and private services which prescribe isotretinoin for the treatment of acne will be asked to complete a baseline survey by 16 November 2025. This data will be used to inform the CHM recommendations on the regulatory requirements of isotretinoin, whilst supporting patient access to treatment across all age groups. It will also provide baseline information to monitor adherence to risk minimisation measures, to ensure the continuation of safe prescribing.

### Action and Advice for Healthcare Professionals:

#### Survey

- Clinical Service Leads for any service or clinic (NHS or private) that prescribes isotretinoin for the treatment of acne need to complete a baseline survey for their service by 16 November 2025. There should only be one survey response per service provider

- the MHRA will hold this data securely and provide a summary to the CHM in an anonymised format to support the development of a new approach to monitor the adherence to risk minimisation measures while minimising any impact on patient access to treatment across all age groups. It will also provide baseline information for comparison with future monitoring of adherence to risk minimisation materials, to ensure the continuation of safe prescribing
- the link to the survey will be sent directly to organisations through various routes, if you or your service have not received this link and you believe that you need to complete the survey, please contact [info@mhra.gov.uk](mailto:info@mhra.gov.uk)

### Changes to isotretinoin prescribing advice

- from today, updates to the IIAEWG guidance have also been published as an Addendum to the original report (see background for further information) which advise that:
  - follow-up consultations do not necessarily need to be in person (face to face) and could be remote if appropriate, however the first appointment should be in person
  - medically supervised pregnancy testing may be performed remotely with appropriate oversight to ensure tests are performed correctly and safely
  - patients should be asked about sexual function at follow up appointments, although by the third appointment, this may be brief
- new clinical guidance on these topics is available from the British Association of Dermatologists website (please see links in background section)

## Background

Following implementation of the October 2023 recommendations advised by the CHM, who were informed by its IEWG and IIAEWG, the MHRA has conducted a review of the impact of these measures and has sought advice from the CHM. The CHM considered all the available data and have advised on a number of issues as set out below.

### IIAEWG report Addendum 2025

An addendum to the IIAEWG report has been published outlining changes to the guidance.

### Follow-up consultations guidance

The CHM has endorsed changes to the IIAEWG recommendations, which now advise that follow-up consultations could be conducted remotely if appropriate. It was emphasised that this should be discussed and agreed with the patient and should take into account the clinical assessment, the patient's needs and preferences, and safeguarding considerations. Prescribers should be mindful of professional standards and best practice including General Medical Council (GMC) guidance, guidance from professional bodies, and other relevant guidelines and local policies. New clinical guidance on this topic is available on the British Association of Dermatologists' [website](#).

### Remote pregnancy testing guidance

The CHM endorsed advice that remote pregnancy testing may be regarded as a medically supervised test with appropriate guidance and oversight, to ensure tests are performed correctly and safely. This should be discussed and agreed with the patient and should take into account the clinical assessment, the patient's needs and preferences, and safeguarding considerations. New clinical guidance on this topic is available on the British Association of Dermatologists' [website](#).

### Sexual function monitoring

The CHM endorsed advice that patients should be asked about sexual function at follow up appointments, although by the third appointment, this may be brief. The CHM noted this monitoring was particularly important as the timeframe of onset of sexual function side effects is not known and has been reported to persist after treatment has completed. New clinical guidance on this topic is available on the British Association of Dermatologists' [website](#).

### Actions required to support possible options for modification to the risk minimisation measures for isotretinoin

The MHRA is requesting all services prescribing isotretinoin for acne to undertake a survey about their service (NHS and private). The MHRA will hold this data and provide anonymised summary statistics to the CHM to support its advice on possible options for further modifications to the isotretinoin risk minimisation measures. A streamlined Acknowledgement of Risk form will also be produced to incorporate the CHM's advice.

Survey information may be used to make future contact about monitoring of adherence to risk minimisation measures, to help assess good practice by services prescribing isotretinoin.

### Reporting advice

Healthcare professionals, patients, and caregivers are asked to submit reports using the Yellow Card scheme electronically using:

- the [Yellow Card website](#)
- the Yellow Card app; download from the [Apple App Store](#) or [Google Play Store](#)
- some clinical IT systems for healthcare professionals (EMIS, SystemOne, Vision, MiDatabank, and Ulysses)

When reporting suspected adverse drug reactions, please provide as much information as possible, including information about medical history, any concomitant medication, onset timing, and treatment dates.

### **Additional information**

You can [sign up](#) to receive email notifications for Drug Safety Updates.

You can [sign up](#) to receive our monthly roundup of safety communications.

For any enquiries, please contact [info@mhra.gov.uk](mailto:info@mhra.gov.uk)

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