



Medicines & Healthcare products
Regulatory Agency

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Ms Catherine McKenna
HM Coroner for Coroner area of Manchester North

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[REDACTED]

03 May 2023

Dear Ms McKenna,

Report to Prevent Future deaths - John Abrahams

Thank you for your report dated 14 February 2023, received on 15 February 2023. I would like to offer my sincere condolences to Mr Abraham's family on their tragic loss.

The Medicines and Healthcare products Regulatory Agency (MHRA) monitors the safety of all medicines to ensure that up-to-date information on the benefits and risks of a medicine is available for healthcare professionals and patients.

The MHRA obtains independent advice from the Commission on Human Medicines (CHM). [The Isotretinoin Expert Working Group](#) (IEWG) was convened by the CHM to evaluate the latest data on risk of psychiatric adverse reactions and sexual dysfunction suspected to be associated with the use of isotretinoin and to consider whether regulatory action is required to minimise risks or raise awareness of the risks.

The IEWG considered oral and written evidence over 2020 and 2021. The review included a public call for information which resulted in 659 responses with views from patients, families, and other stakeholders and more than 7 hours of direct presentations, all of which were considered carefully by the IEWG in making their recommendations. The findings and recommendations of the IEWG were presented in a report to the CHM at the end of 2021. Patients and other stakeholders were invited to attend part of this meeting of the CHM to hear the presentation and discussion of the data.

The report of this review was published 26 April 2023. A link to the published report is here: [Isotretinoin: an expert review of suspected psychiatric and sexual side effects - GOV.UK \(www.gov.uk\)](#). It was accompanied by a Drug Safety Update Bulletin, sent to healthcare professionals: [Isotretinoin \(Roaccutane ▼\): new safety measures to be introduced in the coming months, including additional oversight on initiation of treatment for patients under 18 years - GOV.UK \(www.gov.uk\)](#).

The CHM further advised that, in order to ensure the safe and effective introduction of the recommendations, an Implementation Working Group should be established with representation from the wider healthcare system in addition to relevant healthcare professionals. This was due to concerns raised around the logistical implementation of the recommendations which they felt may delay treatment for those that need it.

The Implementation Working Group has had two meetings in March 2023 and is making good progress with a further meeting planned in mid-May 2023. The output of the Group's work will be made public in due course.

Should you have any further questions, I should be pleased to assist.

Yours sincerely,

[Redacted signature]

[Redacted name]

Chief Executive
Medicines and Healthcare products Regulatory Agency

[Redacted contact information]