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Dear Healthcare Professionals,

Isotretinoin (Roaccutane▼): new safety measures to be introduced in the coming months in the United Kingdom, including additional oversight on initiation of treatment for patients under 18 years

Your attention is drawn to the United Kingdom Medicines and Healthcare products Regulatory Agency's (MHRA) announcement that the Isotretinoin Expert Working Group (IEWG) of the Commission on Human Medicines (CHM) has made recommendations to strengthen the safety of isotretinoin treatment.

In Sep 2019, the CHM formed the IEWG to review the safety of isotretinoin, in particular concerns about suspected psychiatric and sexual side effects and whether, in some cases, these continue after use of isotretinoin has been stopped. The IEWG considered all the available evidence, including information from patients and their families, and concluded that gaps in the available evidence meant that it was not possible to say that isotretinoin definitively caused many of the short-term or longer-term psychiatric and sexual side effects. However, the individual experiences of patients and families continue to cause concern and the IEWG emphasised the need for patients to be informed about the risks before starting isotretinoin treatment, for there to be additional oversight of prescribing in young patients under 18, and for patients to be consistently monitored for side effects. Following the review and endorsement by the CHM, the MHRA will be introducing a number of measures to strengthen the safety of isotretinoin.

Isotretinoin should not be used for the treatment of prepubertal acne and is not recommended in children younger than 12 years of age. For patients younger than 18 years of age, there will also be a requirement for two prescribers to jointly agree that the acne is severe enough to justify treatment with isotretinoin and that other standard treatments have been sufficiently tried and were ineffective before isotretinoin is started.

The product information for isotretinoin medicines is being updated with these new requirements

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and to add new information and warnings regarding psychiatric and sexual disorders. This will include a warning that there have been reports of long-lasting sexual dysfunction where the symptoms have continued despite discontinuation of isotretinoin. The product information will state that patients, and where applicable their families, must be counselled about the risk of psychiatric side effects and sexual dysfunction prior to prescription of isotretinoin. Patients should have an assessment of their mental health and sexual function prior to treatment and should be monitored during treatment for developing psychiatric or sexual disorders.

Advice for healthcare professionals:

- Isotretinoin is indicated for severe forms of acne resistant to adequate courses of standard therapy with systemic anti-bacterials and topical therapy.
- Continue to follow strict precautions on prescribing isotretinoin, including the conditions of the isotretinoin Pregnancy Prevention Programme.
- Fully inform patients about the potential risks in addition to the expected benefits before prescribing isotretinoin.
- Assess an individual's mental health before initiation of isotretinoin and monitor regularly for developing or worsening psychiatric disorders.
- Tell patients to seek advice if they feel their mental health or sexual function is affected or is worsening. Patients with a serious side effect should be told to stop their treatment and seek urgent medical advice.

Please refer to the following website in MHRA for details:

<https://www.gov.uk/drug-safety-update/isotretinoin-roaccutan-ev-new-safety-measures-to-be-introduced-in-the-coming-months-including-additional-oversight-on-initiation-of-treatment-for-patients-under-18-years>

In Hong Kong, there are 11 registered pharmaceutical products containing isotretinoin. All products are prescription-only medicines. So far, the Department of Health (DH) has received 2 cases of adverse drug reaction related to isotretinoin, but these cases were not related to psychiatric or sexual side effects.

Related news was previously issued by MHRA, and was posted on the Drug Office website since 27 Oct 2017, with the latest update posted on 11 Nov 2020. Letters to inform local healthcare professionals were issued by the DH on 27 Oct 2017.

Currently, the sales pack or package insert of locally registered isotretinoin-containing products should include warnings on suicide, suicidal attempts and sexual dysfunction including erectile dysfunction and decreased libido.

In light of the above MHRA's announcement, the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board.

Please note that this letter serves as a means for the DH to communicate important new safety information about registered pharmaceutical products with healthcare professionals in Hong Kong and is not intended to serve as guidelines or to replace professional clinical judgement. Healthcare professionals are advised to balance the risk of possible adverse effects against the benefit of treatment.

Please report any adverse events caused by drugs to the Adverse Drug Reaction Unit of the DH (tel. no.: 2319 2920, fax: 2319 6319 or email: adr@dh.gov.hk). For details, please refer to the website at Drug Office under "ADR Reporting": <http://www.drugoffice.gov.hk/adr.html>. You may wish to visit the Drug Office's website for subscription and browsing of "Drug News" which is a monthly digest of drug safety news and information issued by Drug Office.

Yours faithfully,



PP (Terence MAN)
for Assistant Director (Drug)