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(IN REPLY PLEASE QUOTE THIS FILE REF.)

15 Jun 2021

Dear Healthcare Professionals,

PRAC concludes review of signal of increased risk of major cardiovascular events and cancer with Xeljanz

Your attention is drawn to the European Medicines Agency (EMA)'s announcement that the Pharmacovigilance Risk Assessment Committee (PRAC) has recommended an update to the product information for Xeljanz (tofacitinib) to include a new recommendation for its use. The committee has concluded its review of a safety signal regarding major adverse cardiovascular events and cancer (excluding non-melanoma skin cancer). The evidence is gathered from a recent study (A3921133) on this medicine conducted in patients who were 50 years of age or older with at least one additional cardiovascular risk factor. The PRAC is reminding healthcare professionals to carefully evaluate a patient's individual benefit-risk profile when deciding to prescribe or continue the treatment with Xeljanz (tofacitinib).

Xeljanz (tofacitinib) is used to treat adults with moderate to severe rheumatoid arthritis (inflammation of the joints), psoriatic arthritis (red, scaly patches on the skin with inflammation of the joints) and ulcerative colitis (inflammation and ulcers of the colon and rectum).

Final results from a recently completed study (A3921133) showed an increased risk of major adverse cardiovascular events and cancer in some patients, compared with TNF-alpha inhibitors (other medicines for rheumatoid arthritis). The PRAC is therefore advising healthcare professionals that Xeljanz (tofacitinib) should only be used in patients over 65 years of age, patients who are current or past smokers, patients with other cardiovascular risk factors, and patients with other malignancy risk factors, if no suitable treatment alternative is available.

Please refer to the following website in EMA for details: https://www.ema.europa.eu/en/news/meeting-highlights-pharmacovigilance-risk-assessment-committee-prac-7-10-june-2021

In Hong Kong, there are 3 registered pharmaceutical products containing tofacitinib, namely Xeljanz Tablets 5mg (HK-63303), Xeljanz XR Extended Release Tablets 11mg (HK-66141) and Xeljanz Tablets 10mg (HK-66833). All products are registered by Pfizer Corporation Hong Kong Limited, and are prescription-only medicines. So far, the Department of Health (DH) has received 8 cases of adverse drug reaction related to tofacitinib, of which one case is related to lung cancer.

Related news on the risk of serious heart-related problems and cancer of tofacitinib was previously issued by various overseas drug regulatory authorities, and was posted on the Drug Office website since 5 Feb 2021, with the latest update posted on 7 Apr 2021. In light of the above EMA's announcement, the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board. 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,

(Joseph LEE)
for Assistant Director (Drug)