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(來函請敍明此檔案號碼) DH DO DIMC/7-30/1
(IN REPLY PLEASE QUOTE THIS FILE REF.)

14 Nov 2022

Dear Healthcare Professionals,

EMA confirms recommendation to withdraw marketing authorisations for amfepramone medicines

Your attention is drawn to the European Medicines Agency's (EMA) announcement that the Pharmacovigilance Risk Assessment Committee (PRAC) confirmed its recommendation to withdraw the marketing authorisations for amfepramone obesity medicines on 27 Oct 2022. This follows a re-examination of its previous recommendation of Jun 2022, which was requested by the companies that market these medicines.

The recommendation follows a review which found that measures to restrict the use of these medicines for safety reasons have not been sufficiently effective. It found that the medicines were being used for longer than the recommended maximum period of 3 months, thereby potentially increasing the risk of serious side effects such as pulmonary arterial hypertension (high blood pressure in the lungs) and dependency. The medicines were also being used in patients with a history of heart disease or psychiatric disorders, increasing their risk of heart and psychiatric problems. In addition, there was evidence of use during pregnancy, which could pose risks to the unborn baby. The review considered all available information relating to these concerns, including data from two studies on the use of amfepramone medicines in Germany and in Denmark. In addition, the PRAC received advice from a group of experts, comprising endocrinologists, cardiologists and a patient representative.

The PRAC considered introducing further measures to minimise the risk of side effects but could not identify any that would be sufficiently effective. The PRAC therefore concluded that the benefits of amfepramone medicines do not outweigh their risks and recommended that the medicines be removed from the market in the European Union. The Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh) agreed with the PRAC recommendation and adopted its position by majority on 10 Nov 2022.

Information for healthcare professionals:

- EMA is recommending the withdrawal of the European Union marketing authorisations for amfepramone medicines for the treatment of obesity.
- A review of available data has found that amfepramone medicines continue to be used outside the current risk minimisation measures included in the product information.
- Inappropriate use may increase the risk of serious adverse effects, including cardiovascular disease, pulmonary arterial hypertension, dependency and psychiatric disorders, as well as harmful effects if used during pregnancy.
- A review of available data also indicates that the efficacy of amfepramone in the treatment of obesity is limited.
- Healthcare professionals should advise patients about other treatment options.

Please refer to the following website in EMA for details:
https://www.ema.europa.eu/en/news/ema-confirms-recommendation-withdraw-marketing-authorisations-amfepramone-medicines-0

In Hong Kong, there is one registered pharmaceutical product containing amfepramone, namely Dipropion Capsules 75mg (HK-64796). The product is registered by Jean-Marie Pharmacal Co Ltd. It is a prescription-only medicine. So far, the Department of Health (DH) has not received any case of adverse drug reaction related to amfepramone. Related news was previously issued by EMA, and was posted on the Drug Office website on 11 Jun 2022 and 29 Oct 2022. In light of the above EMA'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,

(Terence MAN)
for Assistant Director (Drug)