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本署檔號 OUR REF.:

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

25 Jan 2024

Dear Healthcare Professionals,

Safety-related information for the product Mifegyne

Supplemented to the letter titled “含 mifepristone 成分藥品安全資訊” issued by the Drug Office on 24 Jan 2024, your attention is drawn to the Swissmedic’s announcement that the current Mifegyne (mifepristone) Tablets 200mg and 600mg packages on the Swiss market do not contain the most recently approved Patient Information Leaflet.

The new adverse event Acute Generalized exanthematous pustulosis (AGEP) is missing under section “Possible side effects” of the leaflet.

Please refer to the following website in Swissmedic for details:

<https://www.swissmedic.ch/swissmedic/en/home/humanarzneimittel/market-surveillance/health-professional-communication--hpc-/dhpc-mifegyne-mifepristonum.html>

In Hong Kong, there are 2 registered pharmaceutical products containing mifepristone. These products are prescription-only medicines. So far, the Department of Health (DH) has not received any case of adverse drug reaction related to mifepristone. The DH will remain vigilant on safety update of the drug issued by other overseas drug regulatory authorities for consideration of any action deemed necessary.

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 Clinical Trials and Pharmacovigilance 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)