Levonorgestrel and ulipristal remain suitable emergency contraceptives for all women, regardless of bodyweight.

Your attention is drawn to the European Medicines Agency’s (EMA) recommendation that emergency contraceptives containing levonorgestrel and ulipristal can continue to be used in women of all weights as the benefits are considered to outweigh the risks.

In November 2013, following a national procedure, the product information (PI) of one emergency contraceptive containing levonorgestrel, Norlevo, was updated on the basis of results from two clinical studies to state that Norlevo is less effective in women weighing 75 kg or more and not effective in women weighing more than 80 kg. An EU-wide review was then started to assess whether similar information should be included in the PI for other emergency contraceptives containing levonorgestrel and ulipristal acetate.

The EMA has assessed all the available evidence on the effectiveness of emergency contraceptives, and the Agency’s Committee for Medicinal Products for Human Use (CHMP) considered that the data available are too limited and not robust enough to conclude with certainty that contraceptive effect is reduced with increased bodyweight. For levonorgestrel-containing products, some clinical studies have suggested a reduced effectiveness in women with high bodyweight, but in others no trend for such effect was observed. Similarly, for ulipristal acetate, although limited data from clinical trials suggest a possible trend for a reduced contraceptive effect, the data are too limited to draw definite conclusions. The CHMP recommended that the results of these studies should be included in the PI of emergency contraceptives, but that the current statements on the impact of bodyweight in the PI for Norlevo should be deleted. The CHMP considered that, with side effects generally mild, the safety profile of emergency contraceptives is favourable and they can continue to be taken regardless of the woman’s bodyweight. The CHMP’s recommendation will be sent to the European Commission for a legally binding decision that will be valid throughout the EU.

Healthcare professionals are advised that emergency contraceptives can continue to be used to prevent unintended pregnancy in women of any weight or body mass index, and should remind women that emergency contraceptives should be taken as soon as possible following unprotected sexual intercourse as an occasional ‘rescue’ method but not replace a regular contraceptive method.

Please refer to the EMA’s website for details:

In Hong Kong, there are 29 registered emergency contraceptive medicines containing levonorgestrel and 2 containing ulipristal acetate. All the products are prescription-only medicines. News related to the concerns on increased bodyweight affects the effectiveness of the emergency contraceptive medicines has been released by EMA, Health Canada and Therapeutic Goods Administration (TGA), and were posted on the Drug Office website on 4 February, 1 March and 27 March 2014. Letter to healthcare professional has been issued on 27 March 2014 to draw their attention on Health Canada’s announcement on warning of reduced effectiveness of emergency contraceptives in women over a certain body weight. The matter is pending for discussion in the meeting of the Registration Committee of the Pharmacy and Poisons Board (the Committee). In view of the new
announcement concluded by the EMA that emergency contraceptives remain suitable for women regardless of bodyweight, the latest information will be provided to the Committee for consideration as well. 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 Pharmacovigilance Unit of Department of Health (tel. no.: 2319 2920, fax: 2186 9845 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 sincerely,

[Signature]

for Assistant Director (Drug)