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(IN REPLY PLEASE QUOTE THIS FILE REF.)

15 April 2013

Dear Healthcare Professionals,

Recommendation to restrict use of strontium ranelate by the European Union

Your attention is drawn to the announcement from European Medicines Agency (EMA)'s Pharmacovigilance Risk Assessment Committee (PRAC) on recommended restrictions in the use of Protelos/Osseor (strontium ranelate) based on the outcome of a routine benefit-risk assessment of the medicine, showing an increased risk of heart problems, including heart attacks.

Protelos and Osseor are identical medicines used in the treatment of osteoporosis. The data from clinical studies showed that there was an increased risk of a heart attack in post-menopausal women taking Protelos/Osseor compared with those taking placebo, although there was no increase in deaths. On the whole, the data were of concern given other serious risks (blood clots and rare serious skin reactions) that were identified in a previous EMA review in 2012. The PRAC therefore concluded that a further expedited in-depth evaluation of the benefits and risks of the medicine is needed. While this evaluation is carried out, the PRAC recommends that changes should be implemented to the prescribing information for Protelos/Osseor as follows:

- Protelos/Osseor should only be used for the treatment of severe osteoporosis in postmenopausal women at high risk for fracture and severe osteoporosis in men at increased risk of fracture.
- Protelos/Osseor should not be used in patients with current or past history of ischaemic heart disease (such as angina or a heart attack), peripheral arterial disease (obstruction of large blood vessels, often in the legs) or cerebrovascular disease (diseases affecting the blood vessels supplying the brain, such as stroke).
- Protelos/Osseor should not be used in patients with hypertension (high blood pressure) that is not adequately controlled by treatment.

This outcome of the PRAC assessment will be sent to the Agency's Committee for Medicinal Products for Human Use (CHMP), which will adopt a final opinion at the next CHMP meeting of 22 to 25 April 2013.

Please refer to the following website at EMA for details:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2013/04/news_detail_001759.jsp&mid=WC0b01ac058004d5c1

In Hong Kong, there is one registered product Protos Granules For Oral Suspension 2g (HK-53835) containing strontium ranelate and is a prescription-only medicine. Safety alerts regarding venous thromboembolism (VTE) and serious skin reactions associated with strontium had been released by HSA and EMA, and healthcare professionals letters were issued in August 2011 and March 2012 to draw their attention and to urge them to report any adverse drug reaction related to the drug. The Registration Committee of the Pharmacy and Poisons Board concluded in the meeting held in December 2012 that Strontium should no longer be indicated for use in immobilised patients or patients with VTE, and warnings in product information are updated regarding serious skin reactions. In view of this latest information, the matter will be brought up for further discussion in the meeting of Registration Committee, and Department of Health will remain vigilant on any updated news of the drug.

Please report any adverse events caused by the 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 drug safety digest of drug safety news and information issued by Drug Office.

Yours faithfully,

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(Ms. Pamela LI)
for Assistant Director (Drug)