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DEPARTMENT OF HEALTH
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BY FAX

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(IN REPLY PLEASE QUOTE THIS FILE REF.)

Dr. Donald LI
President
Hong Kong Academy of Medicine
(Fax Number: 2505 5577)

Dear Dr. LI,

Safety alerts on intravenous iron-containing medicines and ergot derivatives medicines announced by EMA

Your attention is drawn to the following drug safety alerts announced by the European Medicines Agency (EMA):

1. New recommendations to manage risk of allergic reactions with intravenous iron-containing medicines

European Medicines Agency's Committee on Medicinal Products for Human Use (CHMP) completed its review of intravenous iron-containing medicines used to treat iron deficiency and anaemia associated with low iron levels and concluded that the benefits of these medicines are greater than their risks, provided that adequate measures are taken to minimise the risk of allergic reactions.

Intravenous iron medicines are used when iron supplements given by mouth cannot be used or do not work. All intravenous iron medicines have a small risk of causing allergic reactions which can be life-threatening if not treated promptly. The Committee therefore concluded that measures should be put in place to ensure the early detection and effective management of allergic reactions that may occur. Iron preparations should only be given in an environment where resuscitation facilities are available, so that patients who develop an allergic reaction can be treated immediately. In addition, the CHMP considered that the current practice of first giving the patient a small test dose is not a reliable way to predict how the patient will respond when the full dose is given. A test dose is therefore no longer recommended but instead caution is warranted with every dose of intravenous iron that is given, even if previous administrations have been well tolerated.

The CHMP also considered that, during pregnancy, allergic reactions are of particular concern as they can put both the mother and unborn child at risk. Intravenous iron medicines should therefore not be used during pregnancy unless clearly necessary. Treatment should be confined to the second or third trimester, provided the benefits of treatment clearly outweigh the risks to the unborn baby. The Committee also recommended further activities, including yearly reviews of allergic reaction reports and a study to confirm the safety of intravenous iron medicines.

Detailed recommendations for patients and healthcare professional are available at the link below.
http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2013/06/news_detail_001833.jsp&mid=WC0b01ac058004d5c1

In Hong Kong, there are 6 registered intravenous iron-containing pharmaceutical products indicated to treat iron deficiency or anaemia associated with low iron levels. In view of the findings by EMA, the matter will be discussed in the meeting of the Registration Committee of the Pharmacy and Poisons Board. The Drug Office of Department of Health will remain vigilant on new safety information related to intravenous iron-containing medicines issued by other regulatory authorities.

2. New restrictions on use of medicines containing ergot derivatives

CHMP recommended restricting the use of medicines containing ergot derivatives. These medicines should no longer be used to treat several conditions involving blood circulation problems or problems with memory and sensation, or to prevent migraine headaches, since the risks are greater than the benefits in these indications. This is based on a review of data showing an increased risk of fibrosis and ergotism with symptoms of ergot poisoning, such as spasms and obstructed blood circulation, in patients taking these medicines.

Ergot derivatives that are only indicated for these conditions will have their marketing authorisations suspended across the EU. In some EU Member States, ergot derivatives are also authorised for other indications such as treatment of dementia, including Alzheimer's disease, and treatment (as opposed to prevention) of acute migraine headache. They will remain authorised for use by patients in those indications.

Fibrosis can be a serious, sometimes fatal disease, which is often difficult to diagnose because of delayed symptoms and may be irreversible. The CHMP noted that there is a plausible mechanism by which ergot-derivatives could cause fibrosis and ergotism. Given that the evidence for these medicines' benefits in these indications was very limited, the CHMP concluded that the benefits in the concerned indications did not outweigh the risk of fibrosis and ergotism.

Detailed recommendations for patients and healthcare professional are available at the link below.
http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2013/06/news_detail_001832.jsp&mid=WC0b01ac058004d5c1

In Hong Kong, there are 16 registered pharmaceutical products containing ergot derivatives, of ingredients nicergoline, codergocrine (dihydroergotoxine) or dihydroergocryptin, that are indicated for blood circulations problems or problems with memory and sensation, or to prevent migraine headaches. In view of the findings by EMA, the matter will be discussed in the meeting of the Registration Committee of the Pharmacy and Poisons Board. The Drug Office of Department of Health will remain vigilant on new safety information related to ergot derivatives issued by other regulatory authorities.

Healthcare professionals are advised to balance the risk of possible adverse effects against the benefit of treatment. Please encourage your members to 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 sincerely,

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