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本署檔號 OUR REF.: DH DO PRIE/7-30/15

BY FAX

28 Oct 2013

(來函請註明此檔案號碼)
(IN REPLY PLEASE QUOTE THIS FILE REF.)

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

Dear Dr. LI,

Short-acting beta-agonists: Restrictions on use in obstetric indications

Your attention is drawn to the latest European Medicines Agency (EMA) announcement regarding the restrictions on use of short-acting beta-agonists in obstetric indications. The Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh) has endorsed by consensus new recommendations to restrict the use of medicines called 'short-acting beta-agonists'. These medicines should no longer be used in oral or suppository forms in obstetric indications (for the care of pregnant women), such as for suppressing premature labour or excessive labour contractions. However, injectable forms of these medicines can still be given for short-term obstetric use under specific conditions.

These recommendations follow a review by the EMA's Pharmacovigilance Risk Assessment Committee (PRAC), which looked into the available cardiovascular safety data on short-acting beta-agonists (fenoterol, hexoprenaline, isoxsuprine, ritodrine, salbutamol and terbutaline) when used in obstetric indications. There was a risk of serious cardiovascular side effects to both the mother and and unborn baby when high-dose short-acting beta-agonists are used in obstetric indications, with the data suggesting these mostly occur with prolonged use. Given the cardiovascular risk and the very limited data on the effectiveness of the oral and suppository forms of these medicines, the PRAC concluded that their benefit-risk balance is not favourable and these medicines should no longer be used in obstetric indications.

In addition to oral medicines and suppositories, this review also covered injectable short-acting beta-agonists used as tocolytics. The PRAC concluded that the benefits of injectable forms of these medicines continue to outweigh their risks when used under specific conditions: these medicines should only be used to suppress premature labour for up to 48 hours, between the 22nd and the 37th weeks of pregnancy and under specialist supervision with continuous monitoring of the mother and the unborn baby. In countries where injectable forms are also authorised for external cephalic version (a method for moving the baby into the right position for birth) and emergency use in specific conditions, the PRAC recommended that they remain authorised in these indications with their prescribing information changed to reinforce warnings on the cardiovascular risks.

Please refer to the following website in EMA for details:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2013/10/news_detail_001931.jsp&mid=WC0b01ac058004d5c1

In Hong Kong, there are 86 registered pharmaceutical products containing fenoterol, hexoprenaline, ritodrine, salbutamol or terbutaline in oral and/or injectable forms. In view of EMA action, the matter will be discussed in the meeting of the Registration Committee of the Pharmacy and Poisons Board. 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,

(Pamela LI)
for Assistant Director (Drug)