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DEPARTMENT OF HEALTH
DRUG OFFICE
DRUG REGISTRATION AND IMPORT/EXPORT CONTROL DIVISION
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(來函請註明此檔案號碼)
(IN REPLY PLEASE QUOTE THIS FILE REF.)

BY FAX

25 June 2012

Dr. Raymond LIANG
President
Hong Kong Academy of Medicine
(Fax Number: 2505 5577)

Dear Dr. LIANG,

EMA: Recommendations on the restriction use of tolperisone medicines

Please kindly note that the European Medicines Agency (EMA) has recommended restricting the use of tolperisone, as the benefit-risk profile for oral tolperisone considered positive only for adults with post-stroke spasticity and negative for injectable tolperisone.

The recommendation followed the review by the Agency's Committee for Medicinal Products for Human Use (CHMP). Taking into account that the risk of hypersensitivity reactions is more significant than previously identified and due to uncertainties in relation to its efficacy in the different indications, the Committee concluded that the benefits of tolperisone outweighed its risks only in the treatment of adults with post-stroke spasticity and only when used as an oral formulation.

EMA advised that tolperisone should not be prescribed for any other indication than post-stroke spasticity in adults and injectable tolperisone is no longer recommended. Patients should be made aware of the possibility of developing hypersensitivity reactions during treatment with tolperisone.

Please refer to EMA's website for details:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2012/06/news_detail_001540.jsp&mid=WC0b01ac058004d5c1

In Hong Kong, there are 4 registered pharmaceutical products containing tolperisone. All in oral dosage form and are prescription-only medicines. They can be used for the treatment of spasticity and muscle spasms. In view of the EMA's recommendation, the matter will be discussed in the meeting of Registration Committee of the Pharmacy and Poisons Board.

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: 2147 0457 or email: adr@dh.gov.hk). For details, please refer to the following website: http://www.drugoffice.gov.hk/eps/root/en/healthcare_providers/adr_reporting/index.html at Drug Office under "Reporting an Adverse Drug Reaction". 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. Christine CHEUNG)
for AD(D)