衛生署

藥物註冊組

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(IN REPLY PLEASE QUOTE THIS FILE REF.)

Professor Raymond LIANG, President, Hong Kong Academy of Medicine, 99 Wong Chuk Hang Road, Hong Kong.

Dear Professor LIANG

European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) recommended restriction on use of Tygacil (tigecycline)

Your attention is drawn to the recommendation on restriction on use of Tygacil (tigecycline) issued by European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP).

The CHMP recommended that the product information for Tygacil (tigecycline) should be amended to ensure that the medicine is used appropriately, by making prescribers aware that the medicine has been associated with an increased mortality in clinical studies. The medicine should only be used in its approved therapeutic indications, namely in the treatment of complicated skin and soft tissue infections and complicated intra-abdominal infections, and only when other antibiotics are not suitable.

Tygacil is registered in Hong Kong. In light of the new information, the issue will be discussed in the coming meeting of Registration Committee of the Pharmacy and Poisons Board.

Please remind your members to report any adverse events caused by the drug to the Adverse Drug Reaction Monitoring Unit of Department of Health (tel. no.: 2319 8633, fax: 2147 0457 or email: adr@dh.gov.hk). For details, please refer to the website: http://www.psdh.gov.hk at Pharmaceutical Service under "Reporting an Adverse Drug Reaction".

Yours faithfully,

(Ms Pamela LI) for Chief Pharmacist