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(IN REPLY PLEASE QUOTE THIS FILE REF.)

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

Dear Dr. LIANG,

EMA: Advice on treating patients with nosocomial pneumonia with Doribax

Please kindly note that the European Medicines Agency (EMA) has given new advice for the treatment of patients with nosocomial pneumonia, also known as hospital-acquired pneumonia, with Doribax (doripenem). Nosocomial pneumonia is caused by bacterial infection, and Doribax is one of a limited number of medicines available to treat this life-threatening disease.

The Agency's Committee for Medicinal Products for Human Use (CHMP) informed that the currently approved dose of Doribax of 500mg every 8 hours may not be sufficient to treat all patients with nosocomial pneumonia, including ventilator-associated pneumonia.

CHMP recommended that the dose of Doribax should be doubled to 1g every 8 hours for the treatment of patients with augmented renal clearance and/or with infections with non-fermenting gram-negative pathogens. The Committee advised that a longer treatment period (10-14 days) is required in patients with nosocomial pneumonia, including ventilator-associated pneumonia.

CHMP advised that caution should be exercised in patients for whom non-fermenting gram-negative pathogens such as Pseudomonas aeruginosa and Acinetobacter are suspected or confirmed as the cause of infection. In some of these patients, initiating concomitant treatment with an aminoglycoside antibiotic should be considered.

The review of Doribax was initiated following the early termination of a study in patients with ventilator-associated pneumonia. The study was stopped following a recommendation from an independent data monitoring committee. Following a review of all available data, CHMP was of the opinion that the short, fixed duration of treatment with Doribax was a major contributor to the study outcome.

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_001542.jsp&mid=WC0b01ac058004d5c1

In Hong Kong, Doribax for Inj 500mg (HK-57638) is a pharmaceutical product registered by Johnson & Johnson (Hong Kong) Ltd and is a prescription-only medicine. It is indicated for the treatment of complicated intra-abdominal infections, complicated urinary tract infections (including pyelonephritis) and nosocomial pneumonia (including ventilator-associated pneumonia). 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 website at Drug Office under "Reporting an Adverse Drug Reaction": http://www.drugoffice.gov.hk/eps/root/en/healthcare_providers/adr_reporting/index.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. Christine CHEUNG)
for AD(D)