European Medicines Agency gives further interim recommendations on dealing with shortcomings in quality assurance at Ben Venue Laboratories

Your attention is drawn to that the European Medicines Agency (EMA) gives further interim recommendations on dealing with shortcomings in quality assurance at Ben Venue Laboratories subsequent to its press release on 22 November 2011.

The EMA has recommended a precautionary recall of the anti-fungal medicine Ecalta used to treat invasive candidiasis, and the diagnostic medicine Luminity which was already quarantined at the level of the marketing authorisation holder. For the two anti-cancer medicines Torisel and Cepeline, the EMA advised that healthcare professionals should visually inspect the vials for the presence of particles before administration.

The EMA’s Committee for Medicinal Products for Human Use (CHMP) considered whether supply from Ben Venue remained essential to meet clinical needs, whether alternative treatment options were available, current EU stock levels and the possibility of sourcing the product from alternative manufacturing sites. For details, please refer to the following link:

In Hong Kong, Luminity and Cepeline are not registered pharmaceutical products. Ecalta is registered under the product name of Eraxis for Inj 100mg (HK-57097) and Eraxis Powder for Inj 100mg (HK-59270) which are registered by Pfizer Corporation HK Limited. The only current supply of Eraxis is Eraxis Powder for Injection (HK-59270) which is not manufactured by Ben Venue Lab. For Torisel Inj Kit 25mg/ml (HK-58079), it is registered by Wyeth (HK) Ltd and the manufacturing source for the diluent is Ben Venue Lab.

The quality assurance problems at Ben Venue Lab. have been released by many drug regulatory agencies before and the news were posted on the website of Drug Office. A letter to inform healthcare professionals and press release were also issued on 23 November 2011. We would therefore like to provide you the update recommendations released by EMA.

Please remind your members to report any adverse events caused by the drugs to the Adverse Drug Reaction Monitoring 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: http://www.drugoffice.gov.hk at Drug Office under “Reporting an Adverse Drug Reaction”.

Yours sincerely,

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for AD(D)