Dear Healthcare Professionals,

European Union: EMA restricts use of Keytruda and Tecentriq in bladder cancer: Data show lower survival in some patients with low levels of cancer protein PD-L1

Your attention is drawn to the European Medicines Agency (EMA) recommendation on the restricted use of Keytruda and Tecentriq in bladder cancer.

Early data from two clinical trials show reduced survival with Keytruda (pembrolizumab) and Tecentriq (atezolizumab) when used as first-line treatments for urothelial cancer (cancer of the bladder and urinary tract) in patients with low levels of a protein called PD-L1. The data indicate that Keytruda and Tecentriq may not work as well as chemotherapy medicines in this group of patients. As a result, the EMA has recommended restricting the use of these medicines as first line-treatments for urothelial cancer.

Keytruda and Tecentriq should now only be used for first-line treatment of urothelial cancer in patients with high levels of PD-L1. There are no changes to how these medicines should be used in patients with urothelial cancer who have had chemotherapy or in patients with other cancers for which these medicines are approved.

The two clinical trials are continuing but no new patients with low levels of PD-L1 will be given only Keytruda or Tecentriq. Patients in the trials who have any questions should speak to the doctor treating them.

Please refer to the following website in EMA for details: http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2018/05/news_detail_002964.jsp&mid=WC0b01ac058004d5c1

In Hong Kong, Keytruda Solution for Injection 100mg/4ml (HK- 64228) and Keytruda Powder for Injection 50mg (HK- 64229) are pharmaceutical products registered by Merck Sharp & Dohme (Asia) Ltd. while Tecentriq Concentrate for Solution for Infusion 1200mg/20ml (HK-65567) is a pharmaceutical product registered by Roche Hong Kong Limited. All three products are prescription-only medicines and are indicated for urothelial carcinoma. In view of the EMA announcement on the restriction, the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board.

Please report any adverse events caused by drugs to the Pharmacovigilance Unit of Department of Health (tel. no.: 2319 2920, fax: 2319 6319 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 digest of drug safety news and information issued by Drug Office.

Yours faithfully,

(Joseph LEE)
for Assistant Director (Drug)

We build a healthy Hong Kong and aspire to be an internationally renowned public health authority