

衛生署藥物辦公室  
藥物註冊及進出口管制部

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DEPARTMENT OF HEALTH  
DRUG OFFICE  
DRUG REGISTRATION AND  
IMPORT/EXPORT CONTROL DIVISION  
3/F., Public Health Laboratory Centre,  
382 Nam Cheong Street, Kowloon, Hong Kong

18 August 2017

The Hong Kong Veterinary Association Ltd.

Dear Mr. President,

**Tick and flea control agent Bravecto continues to be acceptably safe to use.**

**New adverse reaction to be included in package leaflet**

Your attention is drawn to the European Medicines Agency's (EMA) announcement that EMA concluded in July 2017 that Bravecto, a medicine that treats tick and flea infestations in dogs and cats, continues to have an acceptable safety profile. However, the company that markets the product will have to update the package leaflet and include convulsions as a new side effect that is reported very rarely, i.e., less than one animal out of 10,000 animals treated. Veterinarians and pet owners will also be advised to use Bravecto with caution in dogs with epilepsy.

EMA's Committee for Medicinal Products for Veterinary Use (CVMP), following a regular but inconclusive analysis of limited data on serious side effects, had requested the company to investigate all relevant reports related to various disorders such as neurological, skin and appendage diseases, hypersensitivity or immune-mediated reactions and liver diseases, some of which were fatal. The investigation had to take into account the age and breed of animals, the number of treatments, underlying disease conditions and concomitant treatments. According to the company, about 41.6 million doses had been distributed worldwide, of which approximately 18 million were in the European Union (EU) between February 2014 and December 2016. By 15 August 2017, suspected side effects had been reported electronically for 5,326 dogs, of which 2,144 were in the EU. Between February 2014 and 15 August 2017, deaths had been reported in 1,265 dogs worldwide and 342 in the EU. Each report relates to dogs under different health conditions, often receiving multiple medicines, therefore these figures may or may not be related to the use of Bravecto in dogs.

Please refer to the following website in EMA for details:

[http://www.ema.europa.eu/ema/index.jsp?curl=pages/news\\_and\\_events/news/2017/08/news\\_detail\\_002798.jsp&mid=WC0b01ac058004d5c1](http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2017/08/news_detail_002798.jsp&mid=WC0b01ac058004d5c1)

In Hong Kong, there are 5 Bravecto (fluralaner) products, including Bravecto Chewable Tablets For Very Small Dogs 112.5mg (Vet) (HK-65276), Bravecto Chewable Tablets For Small Dogs 250mg (Vet) (HK-65277), Bravecto Chewable Tablets For Very Large Dogs 1400mg (Vet) (HK-65278), Bravecto Chewable Tablets For Large Dogs 1000mg (Vet) (HK-65279) and Bravecto Chewable Tablets For Medium-sized Dogs 500mg (Vet) (HK-65280). All products are registered by Merck Sharp & Dohme (Asia) Ltd, and are prescription-only medicines. So far, the Department of Health (DH) has not received any case of adverse drug reaction related to Bravecto (fluralaner). The matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board. Healthcare professionals are advised to balance the risk of possible adverse effects against the benefit of treatment.

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

Please report any adverse events caused by drugs to the Pharmacovigilance Unit of the DH (tel. no.: 2319 2920, fax: 2319 6319 or email: [adr@dh.gov.hk](mailto: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,

A handwritten signature in black ink, appearing to be 'Joseph Lee', written in a cursive style.

(Joseph LEE)

for Assistant Director (Drug)