

**Decision of the Chinese Medicines Board made at a meeting held under
section 7(1) of the Chinese Medicines Traders (Regulatory) Regulation**

Name of the Chinese medicines trader : Crown (International) Medicine Health Co (O/B King Crown Industries Limited)

B2 & B17, 2/F, Blk B, Sheung Shui Plaza, Fsstl
95 Po Wan Road, Sheung Shui, New Territories

Manufacturer licence in proprietary : PM-2003-00082
Chinese medicines

Date of meeting of the Chinese Medicines Board : 23 November 2020

According to information received from the Department of Health (hereinafter called “DH”), the DH found during a routine market surveillance in April 2017 that a product named **【Pak Ton Dick】** Pak Ton Dick Woo Lok Oil (hereinafter called “Pak Ton Dick”) (batch no. : 160425), with a proprietary Chinese medicine (hereinafter called “pCm”) registration number of HKP-10494 as labelled on its package, contained, upon testing, 1.9 milligrams of a Western drug ingredient “piroxicam” per gram. The batch of products was suspected to be unregistered pharmaceutical products in contravention of the Pharmacy and Poisons Ordinance (hereinafter called “PPO”).

The registration information of Pak Ton Dick (pCm registration no. : HKP-10494) revealed that its pCm registration holder was Crown (International) Medicine Health Co (O/B King Crown Industries Limited) (hereinafter called “Crown”). The DH later visited Crown for investigation and seized a stock of 3,659 bottles of Pak Ton Dick (batch no.: 160425) as well as one bottle of control sample for examination by the Government Laboratory, and they were found to contain piroxicam ranging from 1.7 to 2.2 milligrams per gram. The investigation of the DH revealed that Crown had imported the above product from the Mainland for local sale via a pCms wholesaler after external packing. According to DH’s information, Pak Ton Dick falls under the definition of a pharmaceutical product pursuant to the PPO, but was not registered as such in Hong Kong.

Subsequently, King Crown Industries Limited, which operated Crown, was prosecuted. On 31 May 2018, it was convicted on its own plea of possession of pharmaceutical product which was not registered for sale or distribution, thereby contravening section 36(1) and section 40 of the Pharmacy and Poisons Regulations made under the PPO, Chapter 138 of the Laws of Hong Kong, and was fined HK\$20,000 at the Fanling Magistrates’ Courts. Hence, the DH alleged that Crown had violated the relevant regulations of the

Practising Guidelines for Manufacturers of Proprietary Chinese Medicines (hereinafter called “the Guidelines”).

The Chinese Medicines Board considered that the allegations made by the DH against Crown were established. It was held that the company had violated the following regulations of the Guidelines:

- (i) section 3.1(3)viii, implement and comply with the prescribed codes of practices and relevant laws, namely the restrictions related to the control of medicines containing any western medicine as ingredients under the Pharmacy and Poisons Ordinance (Chapter 138 of the Laws of Hong Kong), including the provisions related to the registration of pharmaceutical products. Proprietary Chinese medicines should not contain any western medicine as ingredients; and
- (ii) section 3.1(6), properly manage the business of manufacture of proprietary Chinese medicines.

In accordance with the power specified in section 139(2)(a) of the Chinese Medicine Ordinance, the Chinese Medicines Board decided that the manufacturer licence in proprietary Chinese medicines held by Crown be suspended for one week.