衞生署藥物辦公室
藥物資訊及警戒科
香港九龍觀塘巧明街 100 號
Landmark East 友邦九龍大樓
20 樓 2002-05 室

DEPARTMENT OF HEALTH
DRUG OFFICE
DRUG INFORMATION AND PHARMACOVIGILANCE DIVISION
Suites 2002-05, 20/F, AIA Kowloon Tower,
Landmark East, 100 How Ming Street,
Kwun Tong, Kowloon, Hong Kong

電話號碼 Tel. No.: 3974 4175
詢問處 Enquiries: (852) 3974 4175
傳真號碼 Faxline No.: (852) 2803 4962
本署檔號 OUR REF.:
(來函請敍明此檔案號碼) DH DO DIMC/7-30/1
(IN REPLY PLEASE QUOTE THIS FILE REF.)

13 Jan 2022

Dear Healthcare Professionals,

FDA warns about dental problems with buprenorphine medicines dissolved in the mouth to treat opioid use disorder and pain

Your attention is drawn to the US Food and Drug Administration's (FDA) announcement that it is warning that dental problems have been reported with medicines containing buprenorphine that are dissolved in the mouth. The dental problems, including tooth decay, cavities, oral infections, and loss of teeth, can be serious and have been reported even in patients with no history of dental issues. Despite these risks, buprenorphine is an important treatment option for opioid use disorder (OUD) and pain, and the benefits of these medicines clearly outweigh the risks.

FDA is requiring a new warning about the risk of dental problems be added to the prescribing information and the patient medication guide for all buprenorphine-containing medicines dissolved in the mouth. The prescribing and patient information will also include strategies to maintain or improve oral health while undergoing treatment with these medicines. These strategies will include recommending that prescribers refer patients to dental care services and encourage them to have regular checkups while taking these products. Patients should tell the dentist about all medicines they take, including buprenorphine.

The buprenorphine medicines that are associated with dental problems are tablets and films dissolved under the tongue or placed against the inside of the cheek. There are also buprenorphine products for pain and OUD delivered by other routes such as a skin patch and injection, but FDA has not identified a concern for dental health related to these other forms.

Since buprenorphine was approved, FDA identified 305 cases of dental problems (131 cases classified as serious) with buprenorphine medicines dissolved in the mouth. These only include cases reported to FDA or published in the medical literature, so there may be additional cases about which FDA is unaware. The average age of the patients was 42 years, but those as young as 18 years were also affected. Most cases were in patients using the medicines for OUD; however, 28 cases of dental problems occurred

in patients using it to treat pain. In 26 cases, patients had no prior history of dental problems. Some cases reported dental problems occurring as soon as 2 weeks after treatment began, with the median time to diagnosis being approximately 2 years after starting treatment. Many cases were reported by health care professionals and provided documentation of extensive dental adverse events. Of the 305 cases, 113 mentioned two or more teeth were affected. The most common treatment for these dental problems was tooth extraction/removal, which was reported in 71 cases. Other cases reported requiring root canals, dental surgery, and other procedures such as crowns and implants.

Health care professionals should be aware the benefits of buprenorphine medicines clearly outweigh the risks and are an important tool to treat OUD. Ask patients about their oral health history prior to prescribing treatment with a transmucosal buprenorphine medicine. These serious dental problems have been reported even in patients with no history of dental issues, so refer them to a dentist as soon as possible after starting transmucosal buprenorphine. Counsel patients about the potential for dental problems and the importance of taking extra steps after the medicine has completely dissolved, including to gently rinse their teeth and gums with water and then swallow. Patients should be advised to wait at least 1 hour before brushing their teeth. Dentists treating someone taking a transmucosal buprenorphine product should perform a baseline dental evaluation and caries risk assessment, establish a dental caries preventive plan, and encourage regular dental checkups.

Please refer to the following website in FDA for details:
https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-about-dental-problems-buprenorphine-medicines-dissolved-mouth-treat-opioid-use-disorder

In Hong Kong, there are 8 registered pharmaceutical products containing buprenorphine, of which 3 products are sublingual tablets. All products are prescription-only medicines. So far, the Department of Health (DH) has not received any case of adverse drug reaction related to buprenorphine. In light of the above FDA's announcement, the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board.

Please note that this letter serves as a means for the DH to communicate important new safety information about registered pharmaceutical products with healthcare professionals in Hong Kong and is not intended to serve as guidelines or to replace professional clinical judgement. Healthcare professionals are advised to balance the risk of possible adverse effects against the benefit of treatment.

Please report any adverse events caused by drugs to the Adverse Drug Reaction Unit of the DH (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,

P.P. (Terence MAN)
for Assistant Director (Drug)