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.)

12 May 2023

Dear Healthcare Professionals,

FDA updating warnings to improve safe use of prescription stimulants used to treat ADHD and other conditions

Your attention is drawn to the United States Food and Drug Administration's (FDA) announcement that, to address continuing concerns of misuse, abuse, addiction and overdose of prescription stimulants, FDA is requiring updates to the Boxed Warning and other information to ensure the prescribing information is made consistent across the entire class of these medicines.

Prescription stimulants are used to treat attention deficit/hyperactivity disorder (ADHD), binge-eating disorder and uncontrollable episodes of deep sleep called narcolepsy. Examples of common prescription stimulants include Adderall (amphetamine/dextroamphetamine), Concerta (methylphenidate), Dexedrine (dextroamphetamine) and Ritalin (methylphenidate).

The current prescribing information for some prescription stimulants does not provide up to date warnings about the harms of misuse and abuse, and particularly that most individuals who misuse prescription stimulants get their drugs from other family members or peers. Further, individuals who are prescribed stimulants are often faced with requests to share their medication. Sharing these medicines with others can lead to development of substance use disorder and addiction in those with whom these drugs are shared.

Prescription stimulants can be an important treatment option for disorders for which they are indicated. However, even when prescribed to treat an indicated disorder, their use can lead to misuse or abuse. Misuse and abuse, also called nonmedical use, can include taking your own medicine differently than prescribed or using someone else's medicine. For this reason, sharing prescription stimulants with those for whom they are not prescribed is an important concern and a major contributor to nonmedical use and addiction. Misuse and abuse of prescription stimulants can result in overdose and death, and this risk is increased with higher doses or unapproved methods of taking the medicine such as snorting or

injecting.

FDA is requiring the Boxed Warning, FDA's most prominent warning, to be updated and FDA is adding other information to the prescribing information for all prescription stimulants. FDA is adding information that patients should never share their prescription stimulants with anyone, and the Boxed Warning information will describe the risks of misuse, abuse, addiction and overdose consistently across all medicines in the class. The Boxed Warning also will advise heathcare professionals to monitor patients closely for signs and symptoms of misuse, abuse and addiction. FDA is also requiring updates to the existing patient Medication Guides to help educate patients and caregivers about these risks.

Healthcare professionals should assess patient risk of misuse, abuse and addiction before prescribing stimulant medicines. Counsel patients not to share their prescribed stimulant with anyone else. Educate patients and their families on these serious risks, proper storage of the medicine and proper disposal of any unused medicine. Throughout treatment, regularly assess and monitor them for signs and symptoms of nonmedical use, addiction and potential diversion, which may be evidenced by more frequent renewal requests than warranted by the prescribed dosage.

FDA reviewed the medical literature published from Jan 2006 to May 2020 on misuse and abuse, also called nonmedical use, of prescription stimulants and associated adverse events. Overall, the most common source of prescription stimulants for nonmedical use in the general population came from friends or family members, with estimates generally ranging from 56 percent to 80 percent, usually provided for free. Nonmedical use from their own prescription accounted for approximately 10 percent to 20 percent of people who report having used stimulants nonmedically in the past year. Less commonly reported sources included drug dealers or strangers accounting for 4 percent to 7 percent of people who report having used stimulants nonmedically in the past year, and the internet accounting for 1 percent to 2 percent.

FDA review found that nonmedical use has remained relatively stable over the past two decades, despite the increasing number of prescription stimulants dispensed. However, the past-year prevalence of nonmedical use of these medicines varies across specific subpopulations and is highest in the following groups: young adults ages 18 to 25 (estimates ranged from 4.1 percent to 7.5 percent), college students (4.3 percent), and adolescents and young adults diagnosed with ADHD (estimates ranged from 14 percent to 32 percent). According to the available data, people who use prescription stimulants for nonmedical reasons have a higher risk of developing a substance use disorder than those who do not. The most serious harms were more commonly observed with nonmedical use by a non-oral route such as snorting or injecting.

Please refer to the following website in FDA for details:
https://www.fda.gov/drugs/drug-safety-and-availability/fda-updating-warnings-improve-safe-use-

prescription-stimulants-used-treat-adhd-and-other-conditions

In Hong Kong, there are registered pharmaceutical products containing methylphenidate (25 products) and lisdexamfetamine (3 products). All products are prescription-only medicines. There is no registered pharmaceutical product containing amphetamine or dextroamphetamine. So far, the Department of Health (DH) has received 2 cases of adverse drug reaction related to methylphenidate, of which one case was related to intentional overdose. The DH has not received any case of adverse drug reaction related to lisdexamfetamine. 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,

(Sheila CHUNG)
for Assistant Director (Drug)