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Dear Healthcare Professionals,

Studies show increased risk of heart rhythm problems with seizure and mental health medicine lamotrigine (Lamictal) in patients with heart disease

Your attention is drawn to the United States Food and Drug Administration's (FDA) announcement that a FDA review of study findings showed a potential increased risk of heart rhythm problems, called arrhythmias, in patients with heart disease who are taking the seizure and mental health medicine lamotrigine (Lamictal). FDA wants to evaluate whether other medicines in the same drug class have similar effects on the heart and is requiring safety studies on those also. FDA will update the public when additional information from these studies becomes available.

FDA required these studies, called in vitro studies, to further investigate Lamictal's effects on the heart after FDA received reports of abnormal electrocardiographic (ECG) findings and some other serious problems. In some cases, problems including chest pain, loss of consciousness, and cardiac arrest occurred. In vitro studies are studies done in test tubes or petri dishes and not in people or animals. FDA first added information about this risk to the lamotrigine prescribing information and Medication Guides in Oct 2020, which FDA has updated.

Patients should not stop taking their medicine without first talking to their prescriber because stopping lamotrigine can lead to uncontrolled seizures, or new or worsening mental health problems. Contact their health care professional right away or go to an emergency room if they experience an abnormal heart rate or irregular rhythm, or symptoms such as a racing heartbeat, skipped or slow heartbeat, shortness of breath, dizziness, or fainting.

Health care professionals should assess whether the potential benefits of lamotrigine outweigh the potential risk of arrhythmias for each patient. Laboratory testing performed at therapeutically relevant concentrations has shown that lamotrigine can increase the risk of serious arrhythmias, which can be life-

threatening, in patients with clinically important structural or functional heart disorders. Clinically important structural and functional heart disorders include heart failure, valvular heart disease, congenital heart disease, conduction system disease, ventricular arrhythmias, cardiac channelopathies such as Brugada syndrome, clinically important ischemic heart disease, or multiple risk factors for coronary artery disease. The risk of arrhythmias may increase further if used in combination with other medicines that block sodium channels in the heart. Other sodium channel blockers approved for epilepsy, bipolar disorder, and other indications should not be considered safer alternatives to lamotrigine in the absence of additional information.

Please refer to the following website in FDA for details:
https://www.fda.gov/drugs/studies-show-increased-risk-heart-rhythm-problems-seizure-and-mental-health-medicine-lamotrigine

In Hong Kong, there are 26 registered pharmaceutical products containing lamotrigine. All products are prescription-only medicines. So far, the Department of Health (DH) has received 2 cases of adverse drug reaction related to lamotrigine, but these cases are not related to arrhythmias. In light of the above FDA's announcement, 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.

Please report any adverse events caused by drugs to the Undesirable Medical Advertisements and 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,

(Joseph LEE)
for Assistant Director (Drug)