Dear Healthcare Professionals,

**Brilinta (ticagrelor): Assessing the potential risk of central sleep apnea**

Your attention is drawn to the Health Canada’s announcement that it reviewed the potential risk of central sleep apnea (CSA) in patients treated with Brilinta (ticagrelor). The safety review was triggered by the publication, in the British Journal of Clinical Pharmacology, of 2 confirmed cases of CSA after starting treatment with Brilinta. CSA is a condition in which breathing repeatedly stops and starts during sleep.

Health Canada reviewed the available information from searches of the Canada Vigilance database, international databases, and published literature. At the time of the review, Health Canada had received 2 Canadian reports of CSA related to Brilinta use. These 2 reports did not have enough information to be assessed. Literature and adverse reaction database searches found 9 case reports (none Canadian, 9 international) that included enough information for review. Four of the 9 cases were from the Canada Vigilance database. In 8 of these reports, a link between Brilinta use and CSA could not be ruled out; 4 reports were found to be probably linked to the use of Brilinta, 4 reports were possibly linked and one report was not likely to be linked. Health Canada also looked at additional information available from 2 studies in published literature. Both studies had a number of weaknesses in their design and reported conflicting results. There is not enough information in these studies to establish a link between Brilinta use and CSA at this time.

Health Canada's review concluded that there may be a link between the use of Brilinta and the risk of CSA. Health Canada will work with the manufacturer to update the Canadian product safety information for Brilinta to add a warning about this potential safety issue.

Please refer to the following website in Health Canada for details:

*We build a healthy Hong Kong and aspire to be an internationally renowned public health authority*
In Hong Kong, there are 2 registered pharmaceutical products containing ticagrelor, namely Brilinta Tab 90mg (HK-61187) and Brilinta Tablets 60mg (HK-64706). Both products are registered by AstraZeneca Hong Kong Ltd, and are prescription-only medicines. So far, the Department of Health (DH) has received 6 cases of adverse drug reaction related to ticagrelor, but these cases are not related to central sleep apnea. In light of the above Health Canada’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)