衞生署藥物辦公室
藥物註冊及進出口管制部

香港九龍南昌街 382 號公共衞生檢測中心三樓

電話號碼 Tel. No.: 2319 8458
詢問處 Enquiries (852) 2319 8458
傳真號碼 Faxline No. (852) 2803 4962
本署檔號 OUR REF.: DH DO PRIE/7-30/15

(來函請敍明此檔案號碼)
(IN REPLY PLEASE QUOTE THIS FILE REF.)

**DEPARTMENT OF HEALTH**
**DRUG OFFICE**
**DRUG REGISTRATION AND IMPORT/EXPORT CONTROL DIVISION**
3/F., Public Health Laboratory Centre,
382 Nam Cheong Street, Kowloon, Hong Kong

31 March 2016

Dear Healthcare Professionals,

**Glivec® (imatinib) - Need to screen patients for hepatitis B virus (HBV) infection before treatment due to risk of HBV reactivation**

Your attention is drawn to Singapore Health Sciences Authority's (HSA) announcement regarding risk of hepatitis B (HBV) reactivation associated with the use of Glivec® (imatinib) in patients who are chronic HBV carriers. The package inserts for Glivec® products in Singapore have been updated with the new information.

Cases of reactivation of HBV can occur in patients who are chronic carriers of this virus after receiving BCR-ABL tyrosine kinase inhibitors (TKIs), such as imatinib. Case reports indicate that HBV reactivation may occur at any time during BCR-ABL TKIs treatment. Some of these cases resulted in acute hepatic failure or fulminant hepatitis leading to liver transplantation or a fatal outcome.

Healthcare professionals are advised of the following:

- Patients should be tested for HBV infection before initiating treatment with imatinib.
- Patients currently on imatinib should have baseline testing for HBV infection in order to identify chronic carriers of the virus.
- Experts in liver disease and in the treatment of HBV should be consulted before treatment is initiated in patients with positive HBV serology (including those with active disease) and for patients who test positive for HBV infection during treatment.
- Carriers of HBV who require treatment with imatinib should be closely monitored for signs and symptoms of active HBV infection throughout therapy and for several months following termination of therapy.

Please refer to the HSA's website for details:

http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Safety_Information_and_Product_Recalls/Dear_Healthcare_Professional_Letters/2016/glivec-imatinib-needtoscreenpatientsforhepatitisbvirushbvinfecti.html

In Hong Kong, Glivec Cap 100mg (HK-49431) is a registered pharmaceutical product, and is a prescription only medicine which is registered by Novartis Pharmaceuticals (HK) Limited. So far, the Department of Health (DH) has received two adverse drug reaction cases in connection with the product, but neither of them was related to HBV reactivation. In view of the HSA 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 Pharmacovigilance 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,

(Grant NG)
for Assistant Director (Drug)