衞生署藥物辦公室
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DEPARTMENT OF HEALTH
DRUG OFFICE
DRUG REGISTRATION AND IMPORT/EXPORT CONTROL DIVISION
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(IN REPLY PLEASE QUOTE THIS FILE REF.)

Dr. Donald LI
President
Hong Kong Academy of Medicine
(Fax Number: 2505 5577)

Dear Dr. LI,

Toxic Epidermal Necrolysis and Stevens-Johnson Syndrome Reported with MabThera® (Rituximab)

Your attention is drawn to Singapore Health Sciences Authority's (HSA) announcement with respect to post-marketing cases of severe skin reactions such as Toxic Epidermal Necrolysis (TEN) and Stevens-Johnson Syndrome (SJS) associated with the use of MabThera®. Rituximab is indicated in adults for non-Hodgkin's lymphoma, chronic lymphocytic leukaemia and rheumatoid arthritis.

In Singapore, rare post-marketing cases of TEN and SJS, with fatal outcomes, have been reported in patients with autoimmune diseases and haematological malignancies following MabThera® infusions. A total of 67 cases of TEN and SJS occurring in patients treated with MabThera® were received by Roche for the period since product approval to 11 June 2012. The package insert for MabThera® would be updated to include the safety information on the occurrence of TEN and SJS, with fatal outcomes, following MabThera® administration. Healthcare professionals are advised to discontinue MabThera® treatment in case of the occurrence of severe skin reactions and to carefully assess the decision to re-administer MabThera® based on the individual patient's benefit-risk profile.

For details, please refer to HSA's website:
http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/safety_information/DHCPL.html

In Hong Kong, MabThera Inj 100mg/10ml (HK-46232), MabThera Inj 500mg/50ml (HK-46231), MabThera Concentrate for Solution for Infusion 100mg/10ml (Germany) (HK-59248) and MabThera Concentrate for Solution for Infusion 500mg/50ml (Germany) (HK-59249) are registered by Roche HK Ltd and are prescription-only medicines. The Drug Office has not received any adverse drug reaction reports in connection with the products. In view of HSA's recommendation, the Department of Health will keep vigilant on any safety updates of the drug and actions taken by other overseas regulatory authorities for consideration of any action deemed necessary.

Please encourage your members to report any adverse events caused by the drugs to the Pharmacovigilance Unit of Department of Health (tel. no.: 2319 2920, fax: 2186 9845 or email: adr@dh.gov.hk). For details, please refer to the website at Drug Office under "Reporting an Adverse Drug Reaction": 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 drug safety digest of drug safety news and information issued by Drug Office.

Yours sincerely,

(Ms Pamela LI)
for Assistant Director (Drug)