

衛生署藥物辦公室
藥物註冊及進出口管制部

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DEPARTMENT OF HEALTH
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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,

**Lapatinib (Tykerb[®]) based regimens shown to be less effective than Trastuzumab (Herceptin[®])
based regimens in certain settings**

Your attention is drawn to Singapore Health Sciences Authority's (HSA) announcement with respect to the important study results concerning the efficacy of lapatinib.

Two recent trials have shown statistically significant superior efficacy of trastuzumab in combination with chemotherapy as compared to lapatinib in combination with chemotherapy. This effect was observed in patients with HER2 positive metastatic breast cancer regardless of whether they had previously received trastuzumab; however, the effect was more pronounced in the patients who had no prior exposure to trastuzumab.

Healthcare professionals are reminded that lapatinib in combination with capecitabine is to be used in patients with advanced or metastatic disease with progression following prior therapy which must have included trastuzumab in the metastatic setting.

Please refer to HSA's website for details:

http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/safety_information/DH_CPL.html

In Hong Kong, Tykerb Tab 250mg (HK-56194) containing lapatinib is registered by GlaxoSmithKline Limited (GSK), and there are three Herceptin products containing trastuzumab registered by Roche Hong Kong Limited [Herceptin Powder for Inj 440mg (HK-50617), 150mg (HK-50618) and 150mg (Germany) (HK-56694)]. All of the products are prescription-only medicines. Regarding this issue, GSK has submitted the application to change the package insert by including the details of the clinical trial and updating the indications. The application is under evaluation and process. The Department of Health will keep vigilant on the above issue.

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 "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 drug safety digest of drug safety news and information issued by Drug Office.

Yours sincerely,

(Ms. Pamela LI)

for Assistant Director (Drug)