衞生署藥物辦公室
藥物註冊及進出口管制部

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BY FAX

31 August 2012

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

Dr. Raymond LIANG
President
Hong Kong Academy of Medicine
(Fax Number: 2505 5577)

Dear Dr. LIANG,

FDA: Recommendation against use of Revatio in children with pulmonary hypertension

Your attention is drawn to that the U.S. Food and Drug Administration (FDA) is recommending that Revatio (sildenafil) should not be prescribed to children (ages 1 through 17) for pulmonary arterial hypertension (PAH).

This recommendation against use is based on a recent long-term clinical pediatric trial showing that: (1) children taking a high dose of Revatio had a higher risk of death than children taking a low dose and (2) the low doses of Revatio are not effective in improving exercise ability. Most deaths were caused by pulmonary hypertension and heart failure, which are the most common causes of death in children with PAH.

In US, Revatio has never been approved for the treatment of PAH in children, and in light of the new clinical trial information, off-label use of the drug in pediatric patients is not recommended by FDA. A new warning, stating the use of Revatio is not recommended in pediatric patients and the results of the Revatio trial in padiatric patients have been added to the Revatio labeling. And Revatio is approved to improve exercise ability and delay clinical worsening of PAH in adult patients. The current Revatio label recommends avoiding doses higher than 20 mg, given three times a day. The effect of Revatio on the risk of death with long-term use in adults is unknown; FDA is requiring the manufacturer of Revatio (Pfizer) to evaluate Revatio's effect on the risk of death in adults with PAH.

FDA reminded healthcare professionals that use of this product, particularly chronic use, is not recommended in children. And an unexpectedly higher risk of mortality was found in pediatric patients taking a high dose of Revatio when compared to pediatric patients taking a low dose. Besides, the maximum recommended dose of Revatio for adult patients with PAH is 20 mg three times a day.

Please refer to FDA's website for details: http://www.fda.gov/Drugs/DrugSafety/ucm317123.htm

In Hong Kong, Revatio Tab 20mg (HK-54170), containing sildenafil, is registered by Pfizer Corporation Hong Kong Limited. It is a prescription-only medicine. Revatio is indicated for the treatment of pulmonary arterial hypertension in adult patients (≥ 18 years) and the recommended dose is 20mg three times a day. Healthcare professionals are reminded that the indication of pulmonary arterial hypertension in children and adolescents (< 18 years) has not been approved and are advised to balance the risk of possible adverse effects against the benefit of treatment.

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: 2147 0457 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. Christine CHEUNG)
for AD(D)

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