Dear Dr. LIANG,

Revatio (sildenafil) – Important Safety Information

The Department of Health has been informed by Pfizer Corp. HK Ltd. on the safety information regarding the use of Revatio (sildenafil) in pediatric pulmonary arterial hypertension (PAH) involved in a clinical trial (Study A1481156). Please note Revatio is not approved in Hong Kong for this indication, and the A1481156 study is not ongoing in Hong Kong.

The Data Monitoring Committee (DMC) was convened on July 26, 2011 to review current safety data, following 4 newly reported deaths since their last meeting in Nov 2010. As of July 2011, a total of 35 deaths have been reported in this study. Of those, 5 were in the low dose group (5/55; 9%), 10 in the medium dose group (10/74; 14%) and 20 in the high dose group (20/100; 20%) according to randomized treatment assignment in study A1481156. Most deaths were assessed by the investigator as associated with disease progression and none were assessed as related to study treatment.

According to Pfizer, the DMC concluded that the high dose of sildenafil was associated with a harmful effect on survival when compared to the low dose treatment group. The DMC also expressed concern as to the apparent dose response relationship between increasing dose and mortality. Therefore, the DMC recommended immediate discontinuation of the 40 mg and 80 mg TID doses, as well as the 20 mg TID dose in children with body weight ≤ 20 kg.

In the European Union, Revatio tablets are approved for the treatment of PAH in the paediatric population. The insert is being revised to emphasize that the use of Revatio tablets at doses higher than those approved is not recommended.

In Hong Kong, Revatio Tab 20mg (HK-54170) is a prescription-only medicine. The approved indications in Hong Kong are for the treatment of pulmonary arterial hypertension, primary pulmonary hypertension and pulmonary hypertension associated with connective tissue disease in adults. You are reminded that the indication of pulmonary arterial hypertension in paediatrics has not been approved. Department of Health will keep vigilance against any updated safety issues related to the drug.

Please remind your members to report any adverse events caused by the drugs to the Adverse Drug Reaction Monitoring Unit of Department of Health (tel. no.: 2319 8633, fax: 2147-0457 or email: adr@dh.gov.hk). For details, please refer to the website: http://www.psdh.gov.hk at Drug Office under “Reporting an Adverse Drug Reaction”.

Yours sincerely,

(Ms Pamela Li)
for AD(D)

We are committed to providing quality client-oriented service