

## **Update on drospirenone-containing birth control pills**

### **a. FDA Drug Safety Communication: Safety review update on the possible increased risk of blood clots with birth control pills containing drospirenone**

The U.S. Food and Drug Administration (FDA) is informing the public that it has not yet reached a conclusion, but remains concerned, about the potential increased risk of blood clots with the use of drospirenone-containing birth control pills. FDA has completed its review of the two 2011 studies that evaluated the risk of blood clots for women who use drospirenone-containing birth control pills, previously mentioned in FDA's Drug Safety Communication issued on May 31, 2011. FDA is continuing its review of a separate FDA-funded study that evaluated the risk of blood clots in users of several different hormonal birth control products (contraceptives). Preliminary results of the FDA-funded study suggest an approximately 1.5-fold increase in the risk of blood clots for women who use drospirenone-containing birth control pills compared to users of other hormonal contraceptives. Given the conflicting nature of the findings from six published studies evaluating this risk, as well as the preliminary data from the FDA-funded study, FDA has scheduled a joint meeting of the Reproductive Health Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee on December 8, 2011 to discuss the risks and benefits and specifically the risk of blood clots of drospirenone-containing birth control pills.

Please refer to the following website in FDA for details:

<http://www.fda.gov/Drugs/DrugSafety/ucm273021.htm#table>

### **b. Drospirenone-containing combined oral contraceptives and risk of venous thromboembolism**

Singapore Health Sciences Authority would like to update healthcare professionals on the outcome of recent studies investigating the risk of venous thromboembolism (VTE) associated with the use of drospirenone-containing combined oral contraceptives (COCs). In May 2011, the EMA's Pharmacovigilance Working Party announced that although drospirenone-containing COCs are associated with a higher VTE risk than levonorgestrel-containing COCs and that the risk may be similar to that for COCs containing desogestrel or gestodene, the absolute risk of VTE with any

COC (including those containing drospirenone) is very small. Based on the latest information available, HSA has concluded that the benefit-risk profile of Yasmin® and Yaz® remains positive when used according to its licensed indications. In its review, HSA has also considered the data from earlier observational studies conducted by academics and post-market surveillance studies undertaken by the company. Currently, Yasmin® and Yaz® are contraindicated in the presence or a history of VTE. Additional warnings on VTE, including risk factors for VTE, are in the process of being updated in the local package inserts of both products.

Please refer to the following website in HSA for details:

[http://www.hsa.gov.sg/publish/hsaportal/en/health\\_products\\_regulation/safety\\_information/product\\_safety\\_alerts/safety\\_alerts\\_2011/drospirenone-containing.html](http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/safety_information/product_safety_alerts/safety_alerts_2011/drospirenone-containing.html)

In Hong Kong, there are three registered products containing drospirenone. They are Yasmin Tab (HK-48905), Angeliq Tab (HK-53676) and Yaz Tab (HK-56563) and all are registered by Bayer Healthcare Ltd. The risk of venous thromboembolism (VTE) has already been included in the current package inserts of the three products. The above safety news has been released by the UK MHRA, the US FDA, Australia TGA and Health Canada, and was posted on the website of Pharmaceutical Service on 28 May 2011, 1 June 2011, 7 July 2011 and 16 July 2011 respectively. The issue was discussed in the meeting of the Registration Committee of the Pharmacy and Poisons Board on 15 June 2011. The Committee decided that products containing drospirenone that were used as combined oral contraceptives (COCs) should include the appropriate warnings in the sales label and/or package insert. Department of Health will keep vigilant against any updated safety issue of the drug.

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