EUROPEAN MEDICINES AGENCY (EMA) RECOMMENDATION FOR SUSPENSION OF SIBUTRAMINE

The Drug Control Authority (DCA), Ministry of Health Malaysia has received information regarding suspension of products containing Sibutramine by the European Medicines Agency (EMA). This was based on a review of results from the SCOUT study (Sibutramine Cardiovascular OUTcome Trial) which was conducted by Abbott for its product Reductil® to evaluate cardiovascular safety in high-risk patients with a history of cardiovascular disease. SCOUT interim report showed higher rates of cardiovascular events such as non-fatal heart attack and stroke in patients using Sibutramine as compared to those receiving placebo.

Sibutramine is contraindicated in patients with a history of coronary artery disease, congestive heart failure, tachycardia, peripheral arterial occlusive disease, arrhythmia or cerebrovascular disease and inadequately controlled hypertension. Currently there are 9 products containing Sibutramine registered in Malaysia and all products carry this contraindication/warning and precautions in their product inserts as directed by DCA.

Through the National Adverse Drug Monitoring Programme, Ministry of Health has received a total of 35 adverse drug reports for Sibutramine to date out of which four (4) reports were related to cardiovascular events such as palpitation (3 reports) involving one patient with hypertension and 1 report of myocardial infarction (non- fatal).

DCA will instruct all Sibutramine product registration holders to circulate a `Dear Health Care Professional' letter to all prescribers in Malaysia regarding this new information as well as adding the description of the SCOUT study in the product insert, to further strengthen its safety information.

DCA will continue to monitor this situation and assess any new information regarding Sibutramine for further regulatory action.

Director General of Health
As Chairman of DCA
Ministry of Health Malaysia
25 January 2010