PRESS RELEASE

SUSPENSION OF REGISTRATION OF PRODUCTS CONTAINING SIBUTRAMINE DUE TO SAFETY CONCERNS

1. The Drug Control Authority (DCA) has decided to suspend the registration of products containing sibutramine due to safety concerns. All registration holders of sibutramine products have been instructed to immediately stop import and wholesale transactions and withdraw their products from all point of sales within 30 days of suspension date.

2. This decision is based on the final results of the Sibutramine Cardiovascular OUTcomes (SCOUT) study conducted by Abbott Laboratories for their product Reductil® which confirmed increased cardiovascular risks such as heart attacks and strokes in obese and overweight patients taking sibutramine as compared to those on diet and exercise alone.

3. Sibutramine is registered in Malaysia as an adjunctive therapy to diet and exercise for the management of obesity in patients with risk factors such diabetes, hypertension and dyslipidaemia. Sibutramine is contraindicated in patients with history of coronary artery disease, congestive heart failure, tachycardia, peripheral arterial occlusive disease, arrhythmia or cerebrovascular disease (stroke or TIA) and inadequately controlled hypertension. There are 9 registered products containing sibutramine namely Reductil®, Slenfig®, Sibutramine Sandoz® , Fenslim® and Sibutrim® and all carry this safety information in their product inserts.

4. Following the preliminary results of the SCOUT study, the DCA on 25 January 2010 had directed sibutramine product registration holders to circulate a `Dear Health Care Professional' letter to all prescribers in Malaysia as well as updating the product insert to further strengthen its safety information.

5. Through the National Adverse Drug Monitoring Programme, National Pharmaceutical Control Bureau (NPCB), a total of 38 adverse drug reports for sibutramine had been received out of which five (5) reports were related to cardiovascular events such as palpitation (3 reports) and myocardial infarction non- fatal (2 reports).

6. Patients who are currently on treatment with sibutramine are advised to consult their doctors for further management.

TAN SRI DATO' SERI DR HJ MOHD ISMAIL MERICAN
Director General of Health
As Chairman of Drug Control Authority

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