FOR IMMEDIATE RELEASE

HEALTH SCIENCES AUTHORITY
PRESS RELEASE

11 OCTOBER 2010

HSA SUSPENDS SALES OF SIBUTRAMINE PRODUCTS WITH IMMEDIATE EFFECT

The Health Sciences Authority (HSA) is suspending the sales of sibutramine products in Singapore with effect from today, after consulting its Pharmacovigilance Advisory Committee (PVAC) and a panel of external experts in metabolic diseases and cardiology. This decision was made following a benefit-risk assessment of sibutramine, which concluded that the increased cardiovascular risk of sibutramine outweighed the modest weight loss seen in patients. The deliberations have taken into consideration the findings from the Sibutramine Cardiovascular Outcomes (SCOUT) study, the use of the product locally, and developments in other international jurisdictions.

2 Sibutramine is licensed for use in Singapore since 2001 as an adjunctive therapy to diet and exercise for obesity and for overweight patients with obesity-related risk factors such as Type 2 diabetes or disorders in lipid metabolism. It is marketed under four different brands in Singapore - Reductil®, Ectiva®, Reduxade® (all by Abbott) and Slenfig® (Apotheca Marketing).

Overview of the SCOUT Study

3 The SCOUT study was a large study designed to evaluate the cardiovascular (CV) safety after the long-term use of sibutramine in patients who had a history of CV disease and/or type 2 Diabetes Mellitus (DM) with at least one CV-related risk factor such as high blood pressure and high lipid levels. Approximately 10,000 patients who were overweight and obese, aged 55 years and older were recruited in the study and treated up to six years. This study has shown a moderate increased risk of serious CV events associated with sibutramine use in patients with pre-existing CV disease.

International Regulatory Actions

4 The US Food and Drug Administration (FDA) has recently in October 2010 recommended against the continued use of sibutramine following deliberations of its Advisory Committee meeting as this drug may pose unnecessary cardiovascular risks to patients.

5 The European Medicines Agency (EMA) completed its review of sibutramine, including the preliminary results of the SCOUT study earlier this year and had decided

to suspend the marketing of sibutramine throughout Europe until additional data becomes available.

Local situation

6 Following the preliminary results of the SCOUT study in early 2010, HSA had updated healthcare professionals in January 2010 on the CV risks associated with the use of sibutramine and advised healthcare professionals not to prescribe the drug to patients with a history of CV disease. This message was reinforced in April 2010 in the HSA Adverse Drug Reaction News Bulletin, which was distributed to all healthcare professionals. Since then, HSA has been closely monitoring the safety profile, concerns and developments involving sibutramine.

7 In Singapore, all four sibutramine products are already contraindicated (not allowed for use) in patients with a history of CV problems such as coronary artery disease, congestive heart failure, tachycardia, peripheral arterial occlusive disease, arrhythmia, stroke and inadequately controlled hypertension (>145/90 mmHg) since it was approved for use locally.

8 To date, HSA has received three non-serious CV-related adverse reaction reports that were associated with the use of sibutramine. In the reports, patients either had a slight elevation in blood pressure or palpitation following the consumption of sibutramine. All three patients had recovered following the discontinuation of the use of sibutramine products.

HSA's Assessment and Recommendations

9 The availability of the SCOUT study results has added to the knowledge about sibutramine and has demonstrated that the increased CV risk of sibutramine outweighed the modest efficacy seen. The mean weight loss achieved with sibutramine treatment was modest, with patients losing up to 2.4kg in comparison with non-drug treatment (placebo). The study did not clearly demonstrate that weight loss was maintained when sibutramine treatment had stopped. It was also not shown that there was a reasonable benefit to offset the attributable risk for CV events.

10 Based on these findings and the overall assessment, HSA has concluded that the risks outweigh the benefits of sibutramine products and has recommended that the sales of sibutramine be suspended immediately.

HSA's Advisory

11 With the suspension of sales of sibutramine which takes effect today, doctors have been advised not to prescribe sibutramine to new patients. Patients who have been prescribed sibutramine are advised to consult their doctors for a review of their therapy. Patients should also consult their doctors if they experience CV-related side effects like increased heart rate, irregular heartbeat, or any other discomforts after taking sibutramine.

12 Abbott Laboratories (Singapore) Pte Ltd has set up a telephone hotline to handle any enquiries related to this suspension of sales at Tel: 6277 6310 from 9am to 5pm (Monday to Sunday).

HEALTH SCIENCES AUTHORITY
11 OCTOBER 2010

- **About the Health Sciences Authority (HSA)**

The Health Sciences Authority (HSA) is a multidisciplinary agency that applies medical, pharmaceutical and scientific expertise through its three professional groups, Health Products Regulation, Blood Services, Applied Sciences, to protect and advance national health and safety. It serves as the national regulator for health products, ensuring they are wisely regulated to meet standards of safety, quality and efficacy. It operates the national blood bank, Bloodbank@HSA, securing the nation's blood supply. It also applies specialised scientific, forensic, investigative and analytical capabilities in serving the administration of justice. For more details, visit www.hsa.gov.sg.

- **About HSA's Health Products Regulation Group**

The Health Products Regulation Group (HPRG) of HSA contributes to the development of biomedical sciences in Singapore by administering a robust, scientific and responsive regulatory framework. It ensures that drugs, innovative therapeutics, medical devices and health-related products are wisely regulated and meet appropriate safety, quality and efficacy standards.