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HSA UPDATES

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HSA UPDATES NO 1/2010

HSA REVIEWS BENEFIT-RISK PROFILE OF SIBUTRAMINE

The Health Sciences Authority (HSA) has been closely monitoring the safety profile, concerns and developments involving sibutramine and is already in the process of reviewing the benefit-risk profile of sibutramine, so that appropriate regulatory action is taken.

2 As part of this process, HSA has consulted with experts in metabolic diseases, cardiologists and experts from its Pharmacovigilance Advisory Committee. 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. A regulatory decision will be announced upon completion of this review.

Local Situation

3 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).

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

5 In January 2010, HSA updated healthcare professionals 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 problems. This message was reinforced in April 2010 when it was published in the HSA Adverse Drug Reaction News Bulletin which is distributed to local doctors, pharmacists and dentists.

6 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.

Consumer advisory

7 Patients who have been prescribed sibutramine are advised to consult their doctors should they have concerns about their drug therapy or if they are experiencing cardiac-related side effects like increased heart rate, irregular heartbeat, or any other discomforts after taking sibutramine.

*** The SCOUT study was a randomised, double-blind, placebo-controlled, multi-centre study conducted in approximately 10,000 obese and overweight patients with a history of cardiovascular (CV) disease and/or type 2 diabetes treated over a six year period. Analysis of this study reported a moderate increase in cardiovascular (CV) risk in patients taking sibutramine as compared to patients not taking the drug.*

HEALTH SCIENCES AUTHORITY 8 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.

▪ About HSA Updates

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