



FOR IMMEDIATE RELEASE

**HEALTH SCIENCES AUTHORITY
PRESS RELEASE**

24 SEPTEMBER 2010

HSA ISSUES ADVISORY ON THE USE OF ROSIGLITAZONE

The Health Sciences Authority (HSA) announced today that it will significantly limit the use of *rosiglitazone* to selected patients who are unable to effectively control their blood sugar with the use of other anti-diabetic medications in order to minimise the potential cardiovascular risks associated with the medicine. This decision was based on the assessment conducted together with HSA's Pharmacovigilance Advisory Committee (PVAC) and a panel of diabetes and heart disease experts from the available data on the cardiovascular risks associated with rosiglitazone.

2 Rosiglitazone (Avandia®, marketed by GlaxoSmithKline (GSK) has been licensed in Singapore since 2000 for blood sugar control in patients with type 2 diabetes in addition to diet and exercise. It is also used in combination with other anti-diabetic drugs when diet, exercise, and other anti-diabetic medicines do not result in adequate blood sugar control in these patients. It is also available as combination preparations with metformin (Avandamet®) and glimepiride (Avandaryl®).

Regulatory Actions Taken Internationally

US Food and Drug Administration (FDA)

3 In July 2010, the US FDA convened an Advisory Committee meeting to review the available data on rosiglitazone and the Committee had recommended that the benefit-risk profile of rosiglitazone remained favourable although additional restrictions and warnings had to be imposed to manage the potential risks related with its use. The FDA has announced that it would significantly restrict the use of rosiglitazone to patients who cannot control their diabetes on other medications. Current users of Avandia will be able to continue using the medication if they are benefiting from the drug and they fully understand the possible cardiovascular risks associated with the use of the drug.

European Medicines Agency (EMA)

4 EMA's Committee for Medicinal Products for Human Use (CHMP) has decided to suspend the marketing of rosiglitazone following their review of the available data on the risk of heart problems associated with rosiglitazone until additional data becomes

available to help further clarify the benefit-to-risk profile of rosiglitazone. Rosiglitazone-containing products will cease to be available in Europe within the next few months.

HSA's Assessment

5 Following the review of the available scientific data and consultations with local medical experts, HSA and its PVAC have assessed that there is a small possible increased risk of heart attacks associated with rosiglitazone. However, for a group of patients who cannot effectively control their blood sugar using alternative medications, the benefits of rosiglitazone may outweigh these risks.

6 To enhance safer use of the medicine, HSA is putting in place restrictions on the use of rosiglitazone and a risk management plan will be implemented to strictly disallow the use of the drug in patients with heart problems such as acute coronary syndrome¹, ischaemic heart disease², heart failure³ and that it is not recommended for use in patients with peripheral arterial disease⁴. In addition, rosiglitazone should only be used after the patient has failed at least two other anti-diabetic therapy options. HSA is working with the company, GSK, and healthcare professionals to roll out the risk management plan. The new restrictions to the use of rosiglitazone have been communicated to healthcare professionals.

7 “The safety and well-being of patients is of utmost concern to HSA. Having carefully considered the available data and the advice of its advisory committee and medical experts, and weighing the risks versus benefits of the medicine, HSA has decided that rosiglitazone shall remain for use in the Singapore market but with strict restrictions in-place. This approach by HSA will enable doctors to very selectively prescribe rosiglitazone to a small group of patients who do not have certain heart or other conditions that may render them more susceptible to the potential adverse effects of rosiglitazone and who have not been able to adequately control their blood sugar on other oral anti-diabetic medications. To safeguard the health of our patients, HSA will continue to monitor the safety profile and usage of this medicine in Singapore,” says Ms Chan Cheng Leng⁵, Division Director, Vigilance Branch, HSA.

8 To date, HSA has received six adverse reaction reports of cardiovascular problems associated with rosiglitazone. In most of these cases, it cannot be ascertained if rosiglitazone was the direct cause of the heart problems as the patients had pre-existing heart problems. The fact that diabetic patients are usually on multiple medications or drug regimens makes it more difficult to ascertain any increase in cardiovascular risk to any specific medicine. Diabetic patients are also pre-disposed to an increased risk of cardiovascular disorders (including heart disease) due to their underlying conditions.

Consumer Advisory

9 Patients who have been prescribed rosiglitazone are advised to consult their doctors if they have concerns about their drug therapy. Patients should not stop taking their medicine unless advised by their doctors.

¹ *Acute Coronary Syndrome : Sudden blockage of an artery that supplies blood to the heart causing symptoms such as chest pressure or ache, shortness of breath, fatigue.*

² *Ischaemic heart disease : A disease characterised by reduced blood supply to the heart muscle.*

³ *Heart failure : A condition in which the heart cannot pump enough blood throughout the body to meet the needs of the body.*

⁴ *Peripheral arterial disease : Hardening and narrowing of the blood vessels in body, usually the legs due to plaque build-up. Plaque is made up of fat, cholesterol, calcium, fibrous tissue and other substances in the blood.*

⁵ *Ms Chan Cheng Leng's name & title in Chinese :*

卫生科学局

医疗保健产品管理司

警戒署

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▪ **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.