

24 May 2011

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Dear Healthcare Professional

## **RESTRICTED ACCESS PROGRAMME FOR ROSIGLITAZONE-CONTAINING PRODUCTS**

The Health Sciences Authority (HSA) would like to update on the documentary process for the restricted access programme that has been developed for rosiglitazone-containing products. HSA had previously communicated in an advisory dated 24 September 2010 that additional restrictions on the use of rosiglitazone will be implemented to significantly limit its use to the group of patients who are unable to effectively control their blood glucose despite use of alternative anti-diabetic medications, in order to minimise any possible CV risks associated with the use of this drug.

2 A risk mitigation plan has been developed for rosiglitazone-containing products marketed in Singapore, namely Avandia™ (Rosiglitazone Maleate) and Avandamet™ (Rosiglitazone Maleate and Metformin HCl combination). The plan incorporates strengthening of package inserts to warn of the increased CV risks, the development of patient information leaflets to inform patients of the potential safety issues and a restricted access programme for these products. The key package insert changes and programme requirements are described below.

### **Labelling updates for Avandia™ and Avandamet™**

3 The package inserts of Avandia™ and Avandamet™ are currently being revised to include these new recommendations:

- a) Restriction of the indication of rosiglitazone-containing products to third-line use in mono-, dual- or triple oral hypoglycemic therapy, after considering that metformin and a sulphonylurea are inappropriate because of contraindication/s or intolerance
- b) Contraindication of the use of rosiglitazone-containing products in patients with ischaemic heart disease
- c) Contraindication of the use of rosiglitazone-containing products in patients with acute coronary syndrome (unstable angina, non-ST elevation myocardial infarction and ST elevation myocardial infarction), and all classes of heart failure (New York Heart Association class I to IV heart failure) and
- d) Recommendation that rosiglitazone-containing products is not for use in patients with peripheral arterial disease.

### **Restricted access programme requirements (Date of commencement: 1 June 2011)**

4 As part of a risk mitigation plan, the prescription of rosiglitazone will be restricted to selected patients who have been assessed by their doctors to be suitable for treatment with rosiglitazone. These patients should also be clearly informed of the benefits and risks associated with their medication.

5 Pharmacists should be aware of the potential risks, including cardiovascular risks, associated with rosiglitazone-containing products and to counsel patients receiving these products accordingly.

6 Details of the restricted access programme will be distributed by GSK. As adherence to the requirements of the restricted access programme is essential for the mitigation of CV risks in patients taking rosiglitazone, HSA seeks your co-operation in ensuring the successful implementation of the restricted access programme for rosiglitazone for its continued marketing in the Singapore market.

### Contact information and Reporting

7 For any clarifications on the above, please contact GSK at Tel: 6232 8340.

8 Please report any serious adverse events suspected to be related to rosiglitazone to HSA's Vigilance Branch at Tel: 6866-3538, Fax: 6478-6069 or report online at [http://www.hsa.gov.sg/ae\\_online](http://www.hsa.gov.sg/ae_online), as well as to GSK at Tel: 6232 8373, Fax: 6293 9646 or email [vishnu-shyamal.p.purushothaman@gsk.com](mailto:vishnu-shyamal.p.purushothaman@gsk.com) within 24 hours of initial notification of the adverse event.

Thank you.

Yours sincerely



MS DOROTHY TOH  
DIRECTOR (VIGILANCE BRANCH)  
HEALTH PRODUCTS REGULATION GROUP  
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cc Director of Medical Services, Ministry of Health  
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