

**SAFETY STATUS OF ANTIDIABETIC AGENTS - AVANDIA[®] (ROSIGLITAZONE),
AVANDAMET[®] (COMBINATION OF ROSIGLITAZONE/METFORMIN) AND
AVANDARYL[®] (COMBINATION OF ROSIGLITAZONE/GLIMEPIRIDE)**

The European Medicines Agency (EMA) on 23 September 2010 had issued a statement regarding their recommendation to suspend the use of rosiglitazone (Avandia[®]) and rosiglitazone containing antidiabetes medicines Avandamet[®] (combination of rosiglitazone/metformin) and Avaglim[®] (combination of rosiglitazone/glimepiride). This is following the review by *Committee for Medicinal Products for Human Use* (CHMP) on data related to increased risk of cardiovascular events following the use of this medicine. Rosiglitazone is approved as an adjunct to diet and exercise for improving glycaemic control in patients with type 2 diabetes mellitus. It works by increasing the sensitivity of cells to insulin resulting in better control of blood sugar levels.

The United States Food and Drug Administration (USFDA) on the same date announced that it will significantly restrict the use of rosiglitazone to patients with Type II diabetes who cannot be controlled with other medications. USFDA also ordered GlaxoSmithKline (GSK) to convene an independent group of scientists to review key aspects of the company's clinical trial known as *RECORD (Rosiglitazone Evaluated for Cardiac Outcomes and Regulation of Glycaemia in Diabetes)*. USFDA may take additional actions once the independent re-analysis of RECORD is completed.

In light of current regulatory actions taken by USFDA and EMA, the Drug Control Authority (DCA) would like to recommend that prescribers restrict the use of rosiglitazone and not initiate this medicine on any new patients. Diabetic patients who are currently on rosiglitazone should seek advice from their doctors on whether they need to continue taking rosiglitazone or otherwise. The DCA will continue to monitor and review any new safety information regarding this product for further regulatory action if necessary.

Director General of Health
As DCA Chairman
Ministry of Health Malaysia

24 September 2010