

File No. 12-1/10-DC (Pt.18)
Directorate General of Health Services
Office of Drugs Controller General (India)

FDA Bhawan,
Kotla Road, New Delhi
Date: 07.10.10

To,

All State Drugs Controllers

**Subject: Suspension of import / manufacture of rosiglitazone in the country-
regarding**

Sir,

Rosiglitazone and its formulations as single drug or as FDC are being marketed in the country as anti-diabetic drugs. European Medicines Agency in its press release dated 23 Sept, 2010, has recommended the suspension of the marketing authorisations for the rosiglitazone-containing anti-diabetes medicines. U.S. Food and Drug Administration (USFDA) has also announced on the same day that it will significantly restrict the use of the diabetes drug rosiglitazone to patients with Type 2 diabetes who cannot control their diabetes on other medications.

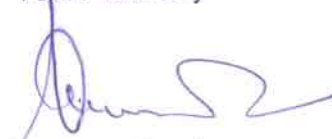
In view of above, an Expert Committee was constituted to examine safety issue and to recommend regulatory action to be taken in country in respect of continued marketing of rosiglitazone in the country.

A meeting of the Expert Committee was held on 7th October, 2010 and it recommended the suspension of import / manufacture of rosiglitazone and its fixed dose combinations in the country with immediate effect as its continued use would lead to more cardiovascular events and adverse effects on lipid profile.

In view of above, you are hereby requested to suspend all the licences granted to manufacture for sale and distribution of rosiglitazone and its fixed dose combinations with other drugs with immediate effect.

Action taken in the matter may please be intimated to this Directorate.

Yours faithfully



Dr. Surinder Singh
Drugs Controller General (India)

Copy to:

- 1) All Zonal / Sub-Zonal Offices of CDSCO