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File No. 12-01/10-DC (Pt.11)
Directorate general of Health Services
Office of Drugs Controller General (India)

FDA Bhavan,
Kotla Road, New Delhi,
Date: 12 NOV 2010

To,

All State Drug Controllers

Subject: Suspension of import / manufacture of sibutramine & R-sibutramine and their formulations in the country – regarding.

Sir,

Formulations of Sibutramine & R-sibutramine are being marketed in the country as anti-obesity drugs. On 25th Oct, 2010, the originator of the drug M/s Abbott has stopped the marketing and distribution of the drug in India based on the results of Sibutramine Cardiovascular Outcomes Study (SCOUT). Various regulatory Authorities including those in Europe, USA, Canada & Australia have either suspended or withdrawn the marketing authorisation of Sibutramine in October, 2010.

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

A meeting of the Expert Committee was held on 12th November, 2010 and it recommended as an immediate step to suspend import / manufacture of Sibutramine & R-sibutramine and their formulations in the country as their continued use is associated with increased risk of cardiovascular events such as heart attacks and stroke.

In view of above, you are hereby requested to suspend all the licenses granted to manufacture for sale and distribution of Sibutramine & R-sibutramine and their formulations 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 with following direction:
   Not to allow import of Sibutramine & R-sibutramine and their formulations with immediate effect.