File. No 12-01/16-DC (Pt-151)
Central drugs standard control organization
Directorate General of Health Services
FDA Bhavan, New delhi
(New Drugs Division)

Date: 22.11.2016

Office Memorandum

Subject: Review/ Evaluation of PSURs data-reg.

As per requirements of Schedule Y of Drugs and Cosmetics Rules, subsequent to approval of the product, new drugs should be closely monitored for their clinical safety once they are marketed. The applicants are required to furnish Periodic Safety Update Reports (PSURs), every six months for the first two years after approval of drug is granted to the applicant, and annually for subsequent two years.

Evaluation of PSURs is a part of post marketing surveillance and overall pharmacovigilance activity and PvPI in IPC, the National Coordination Centre (NCC) is responsible for collection of spontaneous Adverse Drug Reactions (ADRs) from the ADR monitoring centres across the country and to collect, collate, analyse and identify new signals of any, for regulatory interventions by CDSCO, whenever necessary.

In view of above, it has been decided in consultation with the ministry that PSURs submitted by the marketing authorisation holders may be jointly evaluated by officials from CDSCO and PvPI at regular intervals and whenever required expert opinion may be taken from the subject experts. Finally, the divisional head of the said new drug (which is under evaluation with respect to PSUR) shall be responsible and may lead the collection, collation, analysis and final regulatory intervention/disposal of PSURs.

(Dr. G.N.Singh)
Drugs Controller General (I)

To

Pharmacovigilance Programme of India, IPC, Ghaziabad.
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AS (F&D)
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