

File no-NewDrug/PSUR/2011-DCG(I)
Directorate General of Health Services
Office of Drugs Controller General (India)
(PMS-PSUR/ SAE Division)

FDA Bhawan, Kotla Road, New Delhi

Dated: 28 AUG 2014

OFFICE ORDER

Subject: Submission of Periodic Safety Update Reports (PSURs) --- Regarding.

As per the requirements of Schedule "Y" of the Drugs and Cosmetics Rules, Periodic Safety Update Reports (PSURs) of new drugs are required to be submitted to the office of DCG(I) every six months for the first two years and for subsequent two years; the PSUR shall be submitted annually. The PSURs due for a period must be submitted within 30 calendar days of the last day of the reporting period.


The PSURs should be structured as per clause 4, sub clause (v) of Schedule "Y" which is as under and the report should be India specific:

- a) A title page stating: Periodic Safety Update Report for the product, applicant's name, period covered by the report, date of approval of new drug, approved indication, date of marketing of new drug and date of reporting.
- b) Introduction,
- c) Current world wide market authorization status,
- d) Update of actions taken for safety reasons,
- e) Changes to reference safety information,
- f) Estimated patient exposure,
- g) Presentation of individual case histories,
- h) Studies,
- i) Other information,
- j) Overall safety evaluation,
- k) Conclusion,
- l) Appendix providing material relating to indications, dosing, pharmacology and other related information.

It has been observed that some of the manufacturers/ Importers are not adhering into this critical requirements in totality which have been viewed seriously by the office of DCG(I).

In view of above, it is hereby directed that the manufacturers/ importers who have not updated the PSUR as per the above requirements, shall submit the same to the office of DCG(I) within 03 weeks from the date of this letter. Otherwise it will lead to suspension / cancellation of the respective new drug permission for which they will be held responsible.

For compliance of all concerned.


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