Summary of the workshop on Review of Periodic Safety Update Report (PSUR) organized by Central Drugs Standard Control Organization (CDSCO) on 19th December, 2013

A two days workshop on Review of Periodic Safety Update Report (PSUR) was organized at Hotel Metropolitan, Bangla Sahib Road, New Delhi on 18th -19th December, 2013, of which the 2nd day was attended by representatives from pharmaceutical manufacturers responsible for pharmacovigilance, safety monitoring, the reviewers / Drug Inspectors from Biological division and QA Division, Medicine, Medical Device division, CDSCO(HQ) and PvPI division, IPC.
The representatives from pharmaceutical manufacturers gave presentation on pharmacovigilance planning and review of PMS/ PSUR data.
Further to the presentation and subsequent discussion following points were summarized:

1. Lack of India specific data in the PSUR data submitted by the manufacturers to CDSCO as a regulatory obligation / requirements.
2. Heath care practitioners in India should be encouraged to report ADR / AE through Continuing Medical Educations (CME), incorporating pharmacovigilance in the medical curriculum as mandatory etc.
3. It was proposed to share the Adverse Drug Reaction (ADR) received by PvPI centre, NCC, IPC with manufacturers and to aid in investigation by the manufacturers and to ensure that there is no duplication of data in collection, data compilation, analysis and detection
4. Medical Council of India (MCI) should make it mandatory for doctors to report all Adverse Drug Reaction and paramedical should be sensitized in ADR reporting as well.
5. ADR report collected by IPC should be shared with industry for review, analysis and incorporation in PSUR report.
6. Nodal safety officer to be appointed by all manufacturers for pharmacovigilance.
7. Acceptability of international birth date for PSUR.
8. It should be Corporate responsibility for industry for pharmacovigilance training.
9. Active surveillance should be used by the manufacturers to get ADR report from the Health Care professionals.
   In this context, sub-paragraph 28.2 under Heading 'Complaints and Adverse Reaction' of paragraph 28 of Schedule M was also referred which states that ' Reports of serious adverse drug reaction resulting from the use of a drug along with comments and documents shall be forthwith reported to the concerned Licensing Authority'. Requirements prescribed in Schedule M further substantiates the necessity to make it mandatory for all manufacturers to have pharmacovigilance planning and nodal safety officers for continuous ADR monitoring of marketed drugs.
10. It was proposed to submit the PSUR data in conformity with Periodic Benefit-Risk Evaluation Report (PBRER) as per ICH E2C (R2) according to the current practices of the developed countries and developing countries.
11. It was also requested by the manufacturers to extend the timeline for PSUR submission beyond 30 days for generation of quality data.

On the basis of above summary, it was decided by Drugs Controller General (India) to issue administrative order for:

i. Submitting the PSUR data in conformity with Periodic Benefit-Risk Evaluation Report (PBRER) as per ICH E2C (R2).
ii. For making it mandatory to submit pharmacovigilance plan by all the manufacturers at the time of issuance of License.
iii. For making directives to all manufacturers to appoint Nodal Safety Officer who will be in charge of pharmacovigilance and safety related issues in their respective organization.