Summary of the workshop on Review of Periodic Safety Update Report (PSUR) organized by Central Drugs Standard Control Organization (CDSCO) on 18th 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 1st day was attended by representative from vaccine manufacturers responsible for pharmacovigilance planning, safety monitoring, the reviewers / Drug Inspectors from Biological division and QA Division, the PvPI division, IPC and AEFI division of Immunization Programme of India.

The representatives from vaccine manufacturers gave presentation on pharmacovigilance planning and review of PMS/ PSUR data.

Further to the presentation and subsequent discussion following points were summarized:

1. Salient features of the drafted guidance for industry: Pharmacovigilance Requirements for Biological products was discussed in the workshop for comments and suggestions.

2. 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.

3. It was proposed to share the Adverse Drug Reaction (ADR) received by PvPI centre, NCC, IPC on vaccines and the FIR received after Adverse events following immunization by Immunization division with the vaccines manufacturers to aid in investigation by the vaccine manufacturers and to ensure that there is no duplication of data in data compilation, analysis and detection.

4. The Public Sector Units (PSUs) was encouraged to have pharmacovigilance planning and for collection of safety data of vaccines supplied to the immunization programme.

It was stated by Drugs Controller General (India) that Public Sector Units (PSUs) are strength of the country and it was important for the PSUs to adopt current practices in areas like GMP, pharmacovigilance to fulfil the demand of the country. It was also conveyed to CRI, Kasauli to expedite the production in the new facility after completion of the validation activities as per the provisions of Drugs and Cosmetic Act and rules thereunder.