INDIAN PHARMACOPOEIA COMMISSION
National Coordination Centre- Pharmacovigilance Programme of India (PvPI)
MINISTRY OF HEALTH & FAMILY WELFARE, GOVERNMENT OF INDIA
SECTOR-23, RAJ NAGAR, GHAZIABAD- 201 002.

Tel No: 0120- 2783392, 2783400, 2783401 Fax: 0120-2783311
e-mail: pvpi@ipcindia.net, ipclab@vsnl.net, Web: www.ipc.gov.in

Minutes of Meeting

Title: "3rd Interactive Session on Participating of Marketing Authorization Holders in PvPI: A way forward"

Date: 07th October 2016

Venue: Seminar Hall, Indian Pharmacopoeia Commission, Ghaziabad

Attendance: Enclosed as Annexure I

Background and Objective: - As per the recent Gazette notification (G.S.R. 287 (E)), issued by Ministry of Health & Family Welfare, New Delhi, dated 8th March, 2016, Pharmacovigilance setup is mandatory for the Marketing Authorization Holders (MAHs) in India. In order to ensure the effective implementation, there is an urgent need to deliberate the issues and challenges for the MAHs as well as PvPI in terms of managing the Adverse Drugs Reactions (ADRs).

Item 0: Opening of the Meeting

Welcome Address

Dr. G. N Singh, DCG (I) and Secretary-cum-Scientific Director, Indian Pharmacopoeia Commission, extended his warm welcome to all the participants from Pharmaceutical Industries. He stated that, as you know India is the Pharmacy hub to the world and we are contributing in a big way. Therefore, our responsibility is enhanced towards the medicine safety. He also stated that this is the starting of our journey towards excellence in Pharmacovigilance and, we have to go a long way.

Dr. Jai Prakash, Sr. Principal Scientific Officer emphasised on the importance of Post Marketing Surveillance and how the Pharmacovigilance team of Pharmaceutical Industries and PvPI can collaborate for the patient safety in India.

Dr. V. Kalaiselvan, Principal Scientific Officer, In-Charge PvPI, IPC Ghaziabad, welcomed all the participants and highlighted recommendations of the previous meeting which was held on 29th April 2016 at IPC, Ghaziabad and shared the action taken. He briefed about the agenda of the meeting. He also conveyed DCG (I) message to the house stating that industries involvement in PvPI is very important to secure comprehensive patient safety data in Indian population.

Item 01: Opening Remark

Dr. Naresh Sharma, ADC (I), CDSCO, New Delhi, expressed his gratitude to Indian Pharmacopoeia Commission, NCC-PvPI for organizing such type of meeting/session for the MAHs to provide regular updates on Pharmacovigilance and regulatory activities. He briefed the gathering about the history of Pharmacovigilance in India. He discussed the difference between PSUR and Pharmacovigilance for a marketed pharmaceutical product. He directed MAHs to develop the Pharmacovigilance system as per the notification issued by Govt. of India.

Item 02: Technical Session

Quantitative & Qualitative analysis of MAHs ICSRs received at NCC-PvPI

Dr. Prasad Thota, briefed the gathering about the Quantitative and Qualitative analysis of ICSRs received at NCC-PvPI from MAHs. He presented analysis in a very lucid manner and expressed his concern about the completeness of data in ICSRs submitted by MAHs. He also pointed out the lacunas in ICSRs reports received at NCC-PvPI.

Demo to import E2B XML ADRs report in to VigiFlow database

Mr. Vipin Kumar, Pharmacovigilance Associate PvPI demonstrated import of E2B XML format to VigiFlow software and discussed various technical issues related to importing the E2B XML format to VigiFlow with examples. He also expressed his concern that most of the MAHs are reporting ICSRs to NCC-PvPI in E2B XML format but some of them are still submitting ICSRs in CIOMS pdf format that need to be converted in E2B XML format to harmonize and expedite the processing of ICSRs at NCC-PvPI.

Comparison of patient information leaflet/prescribed information leaflet (PILs) of the products marketed in India with other countries

Dr. Naresh Sharma, ADC (I), CSCO and Member of Quality Review Panel, PvPI very nicely presented regarding lack of information in patient information leaflet/prescribed information leaflet of pharmaceutical products marketed in India as compared to products marketed in other countries. He emphasized that MAHs should take a proactive action to update their Indian PILs. He also clarified the doubts of the participants on various regulatory related issues including the legality of PIL as per Schedule Y of Drugs & Cosmetic Act 1940, rules 1945.

The recommendations and proposed action plan is appended below:

Recommendations and proposed action plan

Sr. No.	Recommendations	Action Plan		Time Line
		For MAHs	For NCC-PvPI	
1.	MAHs shall have to make available their updated Package Insert leaflets on company website. Harmonization of PILs among all the MAHs in India.	MAHs should comply		December 2016
2.	MAHs shall start sending of ICSRs in E2b, xml format to NCC-PvPI, IPC who are reporting in CIOMS format.	MAHs should comply		December 2016
3.	Development of the Medication Error module for PvPI with technical support from Lupin Pharmaceutical Ltd.	Lupin Pharmaceutical Ltd	NCC-PvPI	January 2017
4.	MAH is responsible for ADR reporting of their products manufactured by contract manufacturer	MAH should comply		November 2016
5.	MAHs are instructed to report all ADRs to PvPI including the unlisted AE/ADRs.	MAHs should comply		November 2016
6.	Quality of ICSRs sent to PvPI need to be improved and emphasize on causality assessment	MAHs should comply		November 2016
7.	Training required for Medical representatives of MAHs to improve quality of ICSRs.	MAHs should comply		December 2016
8.	Helpline no. of PvPI to be promoted by MAHs (by printing in the last page of PIL of pharmaceutical product).	MAHs should comply		December 2016
9.	Draft version of Pv Guidelines for MAHs in India may be share with all participants to get their suggestions/comments.		NCC-PvPI should provide	October 2016

The meeting ended with vote of thanks by Dr. V. Kalaiselvan, Principal Scientific Officer, and officer In-charge PvPI