



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: 4th Interactive Session on Participation of Marketing Authorization Holders (MAHs) in PvPI

Date: April 28, 2017

Venue: Seminar Hall, Indian Pharmacopoeia Commission, Ghaziabad

Background and Objective: The Interactive session on Participation of Marketing Authorization Holders (MAHs) at PvPI was planned to ensure the effective implementation of Pharmacovigilance system at MAH-level as per the "Gazette notification (G.S.R. 287 (E)), issued by Ministry of Health & Family Welfare, New Delhi, dated March 8, 2016". The primary objective was to delve upon draft Pharmacovigilance Guidelines for MAHs in India as also the present status and challenges for Periodic Safety Update Report (PSUR)-reporting. The session also focussed on the quality of Individual Case Safety Reports (ICSRs) received from MAHs.

Item 0: Opening of the Meeting

Welcome Address:

Dr V Kalaiselvan, Principal Scientific Officer & Officer in-Charge PvPI, Indian Pharmacopoeia Commission, Ghaziabad, welcomed all participants to the 4th Interactive session, highlighting the implementation of recommendations made at the previous meeting. He said that ICSR-reporting had increased quantitatively and improved qualitatively by regular interactive sessions with MAHs. He briefed about the agenda of the meeting and presented the glimpses of PvPI's delightful journey into the future

Opening Remarks:

Shri A K Pradhan, DDC (I), CDSCO (NZ), welcomed Dr P Das Gupta, Former DCG(I), and Dr GN Singh, DCG (I) and Secretary-cum-Scientific Director, Indian Pharmacopoeia

Commission, for their valuable support before addressing the audience. He recalled how PvPI was conceptualized in 2010. He also appreciated the successful achievement of NCC-PvPI in the WHO-NRA Assessment for 2017. He stressed the need for the pharmaceutical industry to be proactive for promotion of patient-safety and building a robust Pv system at MAH-level. He emphasized that MAHs should be equally involved with PvPI to secure comprehensive patient-safety data in India.

Remarks:

Dr P Das Gupta, shared his reminiscences and exhorted the CDSCO to ensure effective implementation of Pharmacovigilance set-up by MAHs as per the recently issued Gazette notification. He gave a brief overview of the Indian pharmaceutical industry and generic drugs. He discussed the key principles for regulation of prices in the National Pharmaceutical Pricing, 2012 and ANDA approval process in USA.

Special Remarks:

Dr G N Singh, expressed his gratitude to Dr P Das Gupta. He welcomed all participants from the pharmaceutical industry. He elaborated upon the essence of, and urgency for, promoting patient safety across the country. He urged Shri A K Pradhan and Dr V Kalaiselvan to strengthen the regulatory system in eastern UP and other states such as the Northeast, Telangana, etc, where people continued to suffer due to lack of awareness for medicine safety.

Item 01: Technical Session

Quality grading of ICSRs reported by MAHs

Mr Naveen Chandu G, Senior Pharmacovigilance Associate, made a presentation on the quality grading of ICSRs reported by MAHs which included:

- * Statistical contribution of India to global drug safety in 2016
- * ICSRs reporting status to PvPI
- * Documentation grading by NCC-PvPI
- * Lack of information in the ICSRs received from MAHs
- * 16 in-house quality parameters were defined with weightage given to each
- * Compared the quality of the ICSRs of AMCs with those of MAHs based on the Completeness score

It was unanimously decided that a serious effort should be made to make an attempt for performing causality assessment of generic drugs, too while it is mandatory for new drugs.

Item 02: Panel Discussion I

The first panel discussion was on **“Pharmacovigilance system set-up at MAHs”** as per the *Gazette notification (G.S.R. 287 (E))*. Dr P Das Gupta, Shri AK Pradhan and Dr V Kalaiselvan chaired the session and welcomed the participants for their valuable inputs/suggestions. Shri A K Pradhan focussed on ‘Schedule Y’ of the Drugs and Cosmetics Act, Rules 1945. He said that MAHs have to be serious in respect of promoting patient safety.

Dr P Das Gupta initiated the next panel discussion on **“PSUR Reporting: Current Status and Challenges”**

Participants expressed their concern for PSUR submission: whether it ought to be from the date of approval or date of marketing. Shri A K Pradhan suggested that date of marketing be considered for first PSUR submission. The PSURs submitted by MAHs to the regulatory authority comprises only global data while Indian data is generally neglected, he added. He urged MAHs to focus on Indian data. MAHs explained that they were making efforts to collect Indian data through their channel of ADR-reporting but only a few cases were being reported. MAHs suggested that PvPI share their product data with them to increase the PSUR data. The chair instructed the MAHs to have a strong system at their end.

Item 03: Panel Discussion II

Dr P Das Gupta, Ms Rubina Bose, DDC(I), CDSCO HQ, and Dr V Kalaiselvan chaired the panel discussion on **“Effective Implementation of PvPI: Comments and Suggestions from MAHs”**. The panel invited the participants for an open discussion on draft Pharmacovigilance guidelines for MAHs in India. Participants expressed their views on the following sections of guidance document:

1. Section 7.1 of PSUR line listing should be elaborated.
2. PSURs submission period should be extended from 30 days to 60 days after data lock point.
3. 6 months time period should be given after finalization for implementation of guidance document at MAHs.

Participants expressed their concern over non-cooperation by doctors on reporting ADRs. Dr P Das Gupta suggested MAHs to approach Indian Medical Association (IMA) to sensitize the reporting of adverse events by Healthcare Professionals (HCPs). NCC-PvPI has already signed a MoU with IMA, HQ, to sensitize the HCPs, Dr V Kalaiselvan added.

Item 04: 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.	Weightage adopted by NCC-PvPI for quality scoring of ICSRs to be shared with MAHs.		NCC-PvPI	May 2017
2.	Awareness regarding system and procedure for ADR-reporting under PvPI to be included in training module of Medical Representatives by MAHs.	MAHs to comply		To be effective immediately
3.	Participation of Medical Representatives in PvPI skill-development programme	MAHs to comply		To be effective immediately
4.	Pv Guidelines for MAHs in India to be shared with all participants for their final suggestions/comments	MAHs to comply		Uploaded on PvPI website for 45 days
5.	Causality assessment should be attempted for generic drugs by MAHs	MAHs to comply		To be effective immediately
6.	PSURs' submission period should be extended from 30 days to 60 days after data lock point		NCC-PvPI will propose to CDSCO	May 2017
7.	MAH is responsible for ADR-reporting of their products manufactured by contract manufacturer	MAHs to comply		To be effective immediately
8.	Quality of ICSRs sent to PvPI need to be improved and emphasis be on causality assessment	MAHs to comply		To be effective immediately


9.	To create awareness by Public-Private Partnership mode	MAHs to comply	NCC-PvPI	May 2017
10.	DCG (I) may authorize to display the PvPI toll-free helpline number on the MAHs website		NCC-PvPI	May 2017

Item 05: Closing remarks

In the closing remarks, Ms Rubina Bose emphasized that MAHs will have to adhere to the Pv guidance document when it comes to the public domain. Regulatory compliance, she added, should be done by MAHs to promote patient-safety.

Dr P Das Gupta thanked the DCG (I) and all organizers for the interactive session. Sharing his experiences and wisdom, he asked the MAHs to recommend their most-suited medical representatives to be trained at NCC-PvPI.

The meeting ended with a vote of thanks by Dr V Kalaiselvan to all dignitaries and participants.


(Dr G N Singh)

Secretary-cum-Scientific Director