"WORKSHOP ON REVIEW ON PERIODIC SAFETY UPDATE REPORT (PSUR)" (PHARMACEUTICALS) FOR

OFFICERS OF CENTRAL DRUGS STANDARD CONTROL ORGANIZATION

ON

19th DECEMBER, 2013

"Workshop on Review of Periodic Safety Update Report (PSUR)" for pharmaceuticals was organized by Quality Assurance Division of Central Drugs Standard Control Organization (CDSCO) on 19th December, 2013 to impart the knowledge on review of Periodic Safety Update Report (PSUR) and Post Marketing Surveillance (PMS) to Officers of CDSCO.

The participants for the workshop include representatives from pharmaceutical manufacturers responsible for Pharmacovigilance, safety monitoring and the reviewers /Drugs Inspectors, who are involved in the review of PMS/PSUR in CDSCO (HQ) and representatives from pharmacovigilance division (PvPI) IPC.

The objective of this workshop is to improve the understanding and reviewing capacity of PMS/PSUR data submitted by the pharmaceutical manufacturers by CDSCO reviewers.

Agenda of the workshop

TIME	TITLE OF ACTIVITY	SPEAKER/ PARTICIPANTS
09:30 HR – 10:00 HR	Registration	
10:00 HR – 10:30 HR	Inaugural Session	CDSCO
10:30 HR – 10:40 HR	Tea Break	
10:40 HR – 10:50 HR	Introduction to the Workshop	CDSCO
10:50 HR – 11:30 HR	Need for Adverse Drug Reaction (ADR) monitoring and Post Marketing Surveillance (PMS)	Dr. S.K. Gupta, Dean and Director General of the Institute of Clinical Research in India
11:30 HR – 12:00 HR	Presentation from IPC	IPC
12:00 HR – 12:45 HR	Presentation from Manufacturer	Representatives from Manufacturers.
12:45 HR – 13:30 HR	Lunch Break	
13:30 HR – 15:30 HR	Presentation from Manufacturer	Representatives from Manufacturer.
15:45 HR – 16:15 HR	Presentation from Manufacturer	Representatives from Manufacturer.
16:15 HR – 17:00 HR	Open House Discussion	Plenary

List of Participants in the workshop on "Review On Periodic Safety Update Report (PSUR)"

Sr. No.	Name of the Participant	Designation	Office Address
1.	Dr. K. Bangarurajan	Deputy Drugs Controller (India)	CDSCO, HQ
2.	Mr. A. K. Pradhan	Deputy Drugs Controller (India)	CDSCO, HQ
3.	Dr. A. Ramkishan	Deputy Drugs Controller (India)	CDSCO, HQ
4.	Mr. A. Sahu	Deputy Drugs Controller (India)	CDSCO, HQ
5.	Dr. Madhur Gupta	Technical Officer	WHO Country Office
6.	Ms. Rubina Bose	Assistant Drugs Controller (India)	CDSCO, HQ
7.	Ms. Swati Srivastava	Assistant Drugs Controller (India)	CDSCO, HQ
8.	Mr. Somnath Basu	Assistant Drugs Controller (India)	CDSCO, HQ
9.	Mr. Gulshan Taneja	Assistant Drugs Controller (India)	CDSCO, HQ
10.	Mr. Jayant Gangakhedkar	Assistant Drugs Controller	CDSCO, HQ

Sr. No.	Name of the Participant	Designation	Office Address
11.	Dr. Ravikant Sharma	Assistant Drugs Controller (India)	CDSCO, HQ
12.	Mr. Sanjeev Kumar	Assistant Drugs Controller (India)	CDSCO, HQ
13.	Mr. Sunil Joshi	Assistant Drugs Controller (India)	CDSCO, HQ
14.	Mr. Gaurav Kumar	Assistant Drugs Controller (India)	CDSCO, HQ
15.	Mr. Shashi Paul	Drugs Inspector	CDSCO, HQ
16.	Ms. Shraddha Srivastava	Drugs Inspector	CDSCO, HQ
17.	Mr. Yogesh Shelar	Drugs Inspector	CDSCO, HQ
18.	Mr. Rajesh Kumar Verma	Drugs Inspector	CDSCO, HQ
19.	Ms. Nisha Shankhawar	Drugs Inspector	CDSCO, HQ
20.	Mr. Ankur Bansal	Drugs Inspector	CDSCO, HQ
21.	Mr. Rahul Panwar	Drugs Inspector	CDSCO, HQ
22.	Mr. Fahim Khan	Drugs Inspector	CDSCO, HQ

Sr. No.	Name of the Participant	Designation	Office Address
23.	Mr. Saurabh Garg	Drugs Inspector	CDSCO, HQ
24.	Mr. Sourabh Mittal	Drugs Inspector	CDSCO, HQ
25.	Mr. Devendra Nath	Drugs Inspector	CDSCO, HQ
26.	Mr. Rakesh Negi	Drugs Inspector	CDSCO, HQ
27.	Mr. Amol Eknath Kandekar	Drugs Inspector	CDSCO, HQ
28.	Mr. S.R. Manikandan	Drugs Inspector	CDSCO, HQ
29.	Ms. Nisha Kaushik	Drugs Inspector	CDSCO, HQ
30.	Mr. V. Sooraj	Drugs Inspector	CDSCO, HQ
31.	Mr. Avinash Kumar Yadav	Drugs Inspector	CDSCO, HQ
32.	Mr. Baljeet Singh	Drugs Inspector	CDSCO, HQ
33.	Mr. Popat Dattatraya Thorat	Drugs Inspector	CDSCO, HQ

Sr. No.	Name of the Participant	Designation	Office Address
34.	Mr. Bikash Roy	Drugs Inspector	CDSCO, HQ
35.	Mr. J. Suresh Kumar	Drugs Inspector	CDSCO, HQ
36.	Mr. Abhinav Kapoor	Drugs Inspector	CDSCO, HQ
37.	Mr. Bikram Aditya Chowdhary	Drugs Inspector	CDSCO, HQ
38.	Mr. Rahul Singh	Drugs Inspector	CDSCO, HQ
39.	Dr. S.K. Gupta	Dean and Director General	Institute of Clinical Research in India
40.	Dr. V. Kalaiselvan	SSO	IPC, Ghaziabad
41.	Dr. Jamal Baig	-	Merck
42.	Dr. Kirti Chavan	Manager	Novartis
43.	Dr. Percy Sanjana	-	Glaxo Smith Kline Pharmaceuticals Ltd.

Sr. No.	Name of the Participant	Designation	Office Address
44.	Dr. Y. Kiran	-	Dr. Reddy's Laboratories
45.	Dr. Manish Paliwal	-	Pfizer Ltd.
46.	Mr. Abhay	Manager Regulatory Affairs	Cipla Ltd.
47.	Dr. Suman Yadav	-	Sun Pharma
48.	Dr. Manoj Sharma	Manager	Panacea Biotech Ltd.
49.	Nilesh Mhetre	SRS	Ranbaxy ltd.

"Workshop on Review of Periodic Safety Update Report (PSUR)"

for Officers of

Central Drugs Standard Control Organization

18th-19th December 2013

Venue: Hotel Metropolitan, Bangla Sahib Road, New Delhi - 110001

Official Inauguration and welcome address of the workshop was made by Dr. G.N. Singh , Drugs Controller General (India)

The significance, purpose and expected outcome of the workshop was explained by Dr. G.N. Singh, Drugs Controller General (India)

Drugs Controller General (India) mentioned the importance of Periodic Safety Update Reports (PSUR) of Medicines, the role of each participants in the review of PMS/ PSUR data.

Drugs Controller General (India) also 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.

It was explained by Drugs Controller General (India) that

1. It is mandatory to submit Pharmacovigilance plan by all the manufacturers at the time of issuance of Licence.

2. All manufacturers should appoint Nodal Safety Officer who will be in charge of Pharmacovigilance and safety related issues in their respective organization.

The introduction to the workshop was made by Mrs. Rubina Bose, Assistant Drugs Controller (India), Quality Assurance Division.

Background of the workshop was explained by Dr. K. Bangarurajan, Deputy Drugs Controller (India)

Importance of Periodic Safety Update Report was explained by Dr. Madhur Gupta, Technical Officer, WHO country Office.

Need for Adverse Drug Reaction (ADR) monitoring and Post Marketing Surveillance (PMS was discussed by Dr. S.K. Gupta, Advisor, Pharmacovigilance Programme of India to the participants.

During the workshop, the functions and role of Pharmacovigilance Programme of India (PvPI) was explained by Dr. V. Kalaiselvan, IPC to the participants.

Pharmacovigilance presentations were given by different Pharmaceuticals manufacturers during the workshop.

Case studies on PSUR was a part of the agenda and all participants were benefitted by the case study discussion

All the participants actively participated in the various discussions on PMS/PSUR submission

The expected outcome of the workshop was explained by Dr. G.N. Singh, Drugs Controller General, India

Following conclusion was drawn by Drugs Controller General (India) at the end of the workshop after summarization and it was decided to issue administrative order for:

i. Submitting data in PBRER format instead of PSUR for drugs approved in accordance with the current international practices as per ICH E2C (R2) for harmonization and effective review by CDSCO.

ii. Mandating to submit a pharmacovigilance plan at the time of Licensing by all the manufacturers.

iii. Appointing Safety Officer by each manufacturer as the in charge of pharmacovigilance and safety related issues.

Organizer of the workshop