



**“WORKSHOP ON REVIEW OF PERIODIC SAFETY  
UPDATE REPORT (PSUR)” (VACCINES)  
FOR**

**OFFICERS OF CENTRAL DRUGS  
STANDARD CONTROL ORGANIZATION**

**ON**

**18<sup>th</sup> DECEMBER, 2013**

“Workshop on Review of Periodic Safety Update Report (PSUR)” for Vaccines was organized by Quality Assurance Division of Central Drugs Standard Control Organization (CDSCO) on 18<sup>th</sup> 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 on Review of Periodic Safety Update Report (PSUR) for Vaccines were the representatives from vaccines 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 and AEFI division of Immunization Programme of India.

The objective of this workshop was to improve the understanding and reviewing capacity of PMS/PSUR data submitted by the vaccine manufacturers by CDSCO reviewers and also to discuss the “Guidance for industry: Pharmacovigilance Requirement for Biological products” drafted by CDSCO with all the stakeholders namely vaccine manufacturers including the Public Sector Units (PSUs), pharmacovigilance division (PvPI) IPC and AEFI division of Immunization Programme of India.

# Agenda for 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10:50 HR – 11:50 HR	Presentation on Draft Guidance Document for Industry: Pharmacovigilance Requirement for Biological Products.	CDSCO
11:50 HR – 12:45 HR	Presentation from Vaccine Manufacturers	Representatives from Vaccine Manufacturer.
12:45 HR – 13:30 HR	Lunch Break	
13:30 HR – 15:30 HR	Presentation from Vaccine Manufacturers	Representatives from Vaccine Manufacturer.
15:30 HR – 15:45 HR	Tea Break	
15:45 HR – 16:15 HR	Presentation from Vaccine Manufacturers	Representatives from Vaccine Manufacturer.
16:15 HR – 17:00 HR	Open House Discussion	Plenary

## List of Participants in the workshop on “Review of Periodic Safety Update Report of Vaccines”.

<b>Sr. No.</b>	<b>Name of the Participant</b>	<b>Designation</b>	<b>Office Address</b>
1.	Dr. K. Bangarurajan	Deputy Drugs Controller (India)	CDSCO, HQ
2.	Mr. S.P. Shani	Deputy Drugs Controller (India)	CDSCO, HQ
3.	Dr. A. Ramkishan	Deputy Drugs Controller (India)	CDSCO, HQ
4.	Ms. Annam Visala	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.	Dr. Inderjeet Singh Hura	Assistant Drugs Controller (India)	CDSCO, HQ
10.	Mr. Shashi Paul	Drugs Inspector	CDSCO, HQ

<b>Sr. No.</b>	<b>Name of the Participant</b>	<b>Designation</b>	<b>Office Address</b>
11.	Ms. Shraddha Srivastava	Drugs Inspector	CDSCO, HQ
12.	Mr. Yogesh Shelar	Drugs Inspector	CDSCO, HQ
13.	Mr. Rajesh Kumar Verma	Drugs Inspector	CDSCO, HQ
14.	Mr. Ankur Bansal	Drugs Inspector	CDSCO, HQ
15.	Mr. Rahul Panwar	Drugs Inspector	CDSCO, HQ
16.	Mr. Fahim Khan	Drugs Inspector	CDSCO, HQ
17.	Mr. Saurabh Garg	Drugs Inspector	CDSCO, HQ
18.	Mr. Sourabh Mittal	Drugs Inspector	CDSCO, HQ
19.	Mr. Devendra Nath	Drugs Inspector	CDSCO, HQ
20.	Mr. Rakesh Negi	Drugs Inspector	CDSCO, HQ
21.	Mr. Amol Eknath Kandekar	Drugs Inspector	CDSCO, HQ
22.	Dr. Simirita Singh	Deputy Director	CRI, Kasauli


<b>Sr. No.</b>	<b>Name of the Participant</b>	<b>Designation</b>	<b>Office Address</b>
23.	Dr. V. Kalaiselvan	SSO	IPC, Ghaziabad
24.	Dr. T.F. Hassan	-	BCG Guindy
25.	Mr. B. Sundaram	Assistant Director	Pasteur Institute Coonoor
26.	Dr. Deepak	Programme Manager	AEFI
27.	Dr. Bhagwat K. Gunale	Sr. manager	Serum Institute of India
28.	Dr. Manoj Sharma	Manager	Panacea Biotech
29.	Mr. Adhir Chaubal	-	Human Biological Institute
30.	Dr. Arani Chatterjee	Senior VP	Biological E. Ltd
31.	Dr. Jamal Baig	-	Merck
32.	Dr. Anit Singh	-	Bharat Biotech
33.	Dr. M. V. Jayanth	Manager	Shantha Biotech

<b>Sr. No.</b>	<b>Name of the Participant</b>	<b>Designation</b>	<b>Office Address</b>
34.	Dr. Sangeet Mohan	Manager	Shantha Biotech
35.	Mr. D. Srinivasa Raju	Technical Director	Dano Vaccines and Biologicals Pvt. Ltd
36.	Mr. S.G. Pal	Manager Marketing	Haffkine Biopharmaceuticals corporation limited
37.	Mr. Hemant Jain	RA Manger	Chiron Behiring Vaccine pvt ltd
38.	Dr. Sanjay Gandhi	General Manager, CRDMA	Glaxo Smith Kline Pharmaceuticals Ltd.
39.	Dr, Ved Singh	Sr. Advisor	Glaxo Smith Kline Pharmaceuticals Ltd.
40.	Dr. Rohit Arora	Medical Director	Sanofi Pasteur
41.	Mr. Sandeep Kumar	Manager Regulatory Affairs	Sanofi Pasteur
42.	Mr. Srinivas kosaram	V.P. QA / RA	Biological E., Hyderabad
43.	Divyanshu Siroli	QA	Bio-Med Pvt. Ltd



**“Workshop on Review of Periodic Safety Update  
Report ( PSUR )”  
for Officers of  
Central Drugs Standard Control Organization  
18<sup>th</sup>-19<sup>th</sup> December 2013**

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

  
Workshop on Review of Periodic Safety Update  
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Drugs Standard Control Organization  
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Metropolitan ... Road, New Delhi - 110001



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

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

Drugs Controller General (India) also explained the purpose for drafting the guidance for industry on Pharmacovigilance Requirements for Biological products. 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.

It was also 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.



The official Opening of the workshop was made by Mr. A. K. Pradhan, Deputy Drugs Controller (India), CDSCO.



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



The procedure of the workshop was explained by Mrs. Rubina Bose, Assistant Drugs Controller (India) Quality Assurance Division.



During workshop, salient features of the drafted guidance for industry: Pharmacovigilance Requirement for Biological products was explained by Mr. S.P. Shani, Deputy Drugs Controller (India) to the participants.



Presentations on Pharmacovigilance were made by different vaccine manufacturers during the workshop.



All the participants actively participated in the various discussions on the guidance documents.



The workshop was concluded with vote of thanks from CDSCO, HQ.



Organizer of the workshop