Strengthening National Regulatory Authorities WHO-CDSCO Workshop on "Reviewing Good Regulatory Practices (GRP)" for National Regulatory Authorities

8th -10th July 2014

India Habitat Centre, New Delhi

Group Photograph of GRP workshop-2014

BACKGROUND

- Subsequent to the WHO recent assessment of the National Regulatory System (CDSCO), that covers vaccines and WHO recommendation to strengthen the National Regulatory Authority to enhance the Quality Safety and Efficacy of Health Products through reviewing existing Good Regulatory best practices and framing a GRP development plan, WHO organized the first workshop on Good Regulatory Practices at New Delhi, India from 8th to 10th July 2014 in collaboration with CDSCO.
- International experts from the WHO HQ, Geneva, WHO SEARO, New Delhi, Thailand, Indonesia, Mexico, France and USA were speakers for various technical sessions on Good Regulatory Practices alongwith India.
- The participants of the workshop were the Heads/ Controlling officers of CDSCO and State Drugs Control Organization, Central Drugs Testing Laboratories, Regional Drugs Testing Laboratories, NIB Noida and IPC Ghaziabad. There were heads or senior level officers from 16 states viz. Gujarat, Madhya Pradesh, Chhattisgarh, Jammu & Kashmir, Andhra Pradesh, Telengana, Tamil Nadu, Himachal Pradesh, Kerala, West Bengal, Assam, Orissa, Jharkhand, Sikkim, Punjab and Goa.

OBJECTIVES OF THE WORKSHOP

To achieve regulatory balance of transparency, accountability, flexibility, equity it is required to have trained man power to meet the objectives of Good Regulatory Practices to provide optimal service to the public besides meeting the current national and international standards in regulation.

- To foster an environment of international regulatory convergence where all regulators work with common goal of ensuring public health through availability of quality, safety and effective medicines.
- Review the best know practices of GRP in the area of health products and technologies as documented in several countries regulatory systems : Australia, China, India, Indonesia, France and Mexico.
- To develop an outline of the WHO guideline.
- Discuss and propose a road map for the development of the WHO GRP strategy aimed to strengthen NRAs.
- Discuss the draft GRP guidelines outline and make recommendations for its finalization and endorsement to WHO experts committees.

AGENDA FOR THE WORKSHOP

Tuesday, 8 July 2014		
Time	**Inaugural Session**	
9.00 - 9.45	Welcome Address Dr. G N Singh, Drugs Controller General (India)	
	Background and Importance of the workshop Mr. Lahouari Belgharbi, Group Leader: NRA Assessment, WHO HQ, Geneva	
	Special Address Dr. Nata Menabde, WHO Representative to India	
	Inaugural Address Dr. Arun Panda, Joint Secretary, Ministry of Health & Family Welfare	
	Vote of Thanks Dr. Madhur Gupta, Technical Officer- Pharmaceuticals, WHO India	
9:45-10:00	Coffee break : Group Photo	
Time	**Session Topic**	**Speakers**
10:00– 11:00	• Introduction of facilitators and participants • Objectives, expected outcome and deliverables of the workshop • WHO SEARO: update on regional situation: listing challenges and issues.	• Lahouari Belgharbi, WHO HQ • Stephane Guichard WHO -SEARO

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11:00 - 12:30	GRP overview, principles, current experiences including quality management and risk approach: • WHO global overview about good regulatory practices (GRP): Principles, Definition and current experiences. • Quality Management Principles , Risk management approach including challenges documented within NRAs,	Lahouari Belgharbi, Team leader, WHO Alireza Khadem, WHO
12:30 – 14:00	Lunch break	
14:00 –15:30	• Risk management experience in Mexico : COFEPRIS\ • Discussion and recommendations	• Julio Sanchez, Mexico-COFEPRIS
15:30 – 16:00	Coffee break	
16:00 – 17:30	• Emerging Global and Regional issues that may affect R&D, Access, Equity and QSE of health products and health technologies	• Madhur Gupta, WHO India
17.30 - 18.00	Facilitators meeting	

AGENDA FOR THE WORKSHOP

Wednesday, 9 July 2014		
09:00 - 09:30	Wrap up of the previous day findings and recommendations and introduction of the agenda of the day	Participant selected from the audience
09:30 - 10.30	Transparency and independency of a regulatory authority. openness of regulatory systems to all participation by citizens and stakeholders; • GRP on AEFI surveillance: lesson learned through WHO NRA assessment	Syed Fazal Shah, WHO STC, USA
10:00 – 10:30	Building consumer confidence, and establishing of providing effective communication between consumers and suppliers (including stakeholders) • Indonesia: Halal issue • France: Diane 35's experience	Lucky Slamet, Indonesia Pierre Henry Bertoye, Former AFFSAPS Deputy Director of Inspections.
10:30 – 11:00	Coffee break	None

AGENDA FOR THE WORKSHOP

11:00 – 12:30	Parameters that can influence the health technologies market resulting in access to affordable and quality health products • Mexico: experience and lessons learned Added value of a flexible regulatory frame work. • India: lessons learned , constraints and challenges • ASEAN: harmonization and streamlining regulation • Quality Control testing: Considerations for NCL	Julio Sanchez, Mexico-COFEPRIS Dr. V.G. Somani /Rubina Bose, CDSCO T. Jivapaisarnpong, Thailand and Lucky Slamet, Indonesia. T. Jivapaisarnpon, Thailand
12:30 – 14:00	Lunch break	None
14:00 – 15:30	Codes of practice: Effectiveness, members (customers and stakeholders) involved in the development and monitoring of the code of conduct • France: AFFSAPS experience, lessons learned and EMA system. Measuring the performance and maintaining the state of service • Mexico: experience within COFEPRIS	Pierre Henry Bertoye, Former AFSSAPS Deputy Director of Inspections. Julio Sanchez, Mexico-COFEPRIS

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15:30 – 16:00	Coffee break	None
16:00 – 17:30	Building confidence with stakeholders and consumers. India: Federal and State level experience, issues and constraints or challenges. • Federal level regulatory organization and constraints • State level regulatory operations and constraints • NCL organizations and constraints: Medicines & Vaccines (CDL Kasauli, Chandigarh) China: National and Provincial level experience and constraints or challenges.	• Dr. V.G. Somani, CDSCO • Representative from State • CFDA, DIC through teleconference.
17:30 – 18:00	Facilitators meeting	None
Thursday, 10 July 2014		
09:00 – 09.30	Wrap up of the previous day findings and recommendations and introduction agenda of the day	DCG(I) staff
09.30 – 10:30	Developing a flexible regulatory framework	Plenary and Working group session

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10:30 – 11:00	Coffee break	None
11:00 – 12:30	Points to consider for developing the outline of the WHO Good Regulatory Practices	Plenary
12:30 – 14:00	Lunch break	
14:00 – 15:30	• Concluding remarks from Health Secretary and WHO Representative to India • Points to consider for developing the outline of the WHO Good Regulatory Practices	Mr Lov Verma, Secretary, Health Lucky Slamet, Indonesia and T.Jivapaisarnpon, Thailand
15:30 – 16:00	Coffee break	
16:00 – 17:00	Wrap up of recommendations and closing	Lahouari Belgharbi, WHO Team Leader
17:00 – 17.30	Facilitators meeting	All facilitators to wrap up next steps.

SPEAKERS/ RESOURCE PERSON

Following are the details of Experts for the workshop:

1. Dr. Lahouari Belgharbi, WHO HQ, Geneva
2. Dr. Alireza Khadem Broojerdi, WHO HQ, Geneva
3. Mr. Stephane Guichard, WHO SEARO
4. Ms. Teeranart Jivapaisarnpong, Thailand
5. Dr. Lucky Slamet, Indonesia
6. Dr. Julio Sanchez Y. Tepoz, Mexico
7. Dr. Pierre-Henri Bertoye, France
8. Dr. Syed Fazal Shah, USA
9. Dr. Madhur Gupta, WHO India Country Office

List of Participants

S.No.	Name	Designation	Organization / Division
Participants from WHO and other International Regulatory Authorities			
1.	Mr. Lahouari Belgharbi	Team Lead, NRA Assessment	WHO (HQ)
2.	Dr. Alireza Khadem Broojerdi	Scientist	WHO (HQ)
3.	Mr. Stephane Guichard	Regional Adviser	WHO SEARO
4.	Ms. Teeranart Jivapaisarnpong	Director	Thailand
5.	Ms. Lucky S. Slamet	Advisor for the Head of Agency	Indonesia
6.	Mr. Julio Sanchez Y Tepoz	--	Mexico
7.	Dr. Pierre-Henri Bertoye	--	France
8.	Dr. Syed Fazal Shah	Consultant Epidemiologist	USA
9.	Dr. Madhur Gupta	Technical Officer	WHO (CO)
10.	Dr. Sujeet Kumar Jain	AEFI Focal Point	WHO (CO), NPSP
11.	Dr. Hamsadvani Anand	National Consultant	WHO (CO)
12	Shri Sahil Aggarwal	Interm WHO	WHO (CO)

List of Participants

Participants from CDSCO			
13.	Dr. V.G. Somani,	Joint Drugs Controller (India)	CDSCO (HQ)
14.	Shri S. Dey	Deputy Drugs Controller (India)	CDSCO (HQ)
15.	Dr. K. Bangarurajan	Deputy Drugs Controller (India)	CDSCO (WZ)
16.	Smt. Shanthy Gunasekaran	Deputy Drugs Controller (India)	CDSCO (SZ)
17.	Shri Satyapal Shani	Deputy Drugs Controller (India)	CDSCO (EZ)
18.	Shri A.K. Pradhan	Deputy Drugs Controller (India)	CDSCO (NZ)
19.	Dr. S. Manivannan	Deputy Drugs Controller (India)	CDSCO (SZ)
20.	Shri P.B.N. Prasad	Deputy Drugs Controller (India)	CDSCO (Hyderabad)
21.	Dr. Eswara Reddy	Deputy Drugs Controller (India)	CDSCO (Ahmedabad)
22.	Smt. Annam Visala	Deputy Drugs Controller (India)	CDSCO (HQ)
23.	Shri Ranga Chandrashekhar	Deputy Drugs Controller (India)	CDSCO (HQ)
24.	Shri Aseem Sahu	Deputy Drugs Controller (India)	CDSCO (HQ)
25.	Dr. A. Ramkishan	Deputy Drugs Controller (India)	CDSCO (HQ)
26.	Shri Arvind Kukrety	Assistant Drugs Controller (India)	CDSCO (HQ)
27.	Smt. Rubina Bose	Assistant Drugs Controller (India)	CDSCO (HQ)
28.	Smt. Swati Srivastava	Assistant Drugs Controller (India)	CDSCO (HQ)
29	Shri Somnath Basu	Assistant Drugs Controller (India)	CDSCO (HQ)
30.	Dr. Inderjeet Singh Hura	Assistant Drugs Controller (India)	CDSCO (HQ)
31.	Dr. Ravi Kant Sharma	Assistant Drugs Controller (India)	CDSCO (HQ)

List of Participants

Participants from State Drugs Control Department			
32.	Shri M. Amruth Rao	Deputy Director	Telangana
33.	Shri M.B.R. Prasad	Joint Director	DCD, Andhra Pradesh
34.	Shri Biswajit Talukdar	Inspector of Drugs	Assam
35.	Shri Hemant Srivastava	Assistant Drugs Controller	Chhattisgarh
36.	Shri Salim A. Veljee	Drugs Controller	Goa
37.	Shri V.R. Shah	Assistant Commissioner	Gujarat
38.	Dr. G.L. Singal	Drugs Controller	Haryana
39.	Shri Navneet Marwah	Drugs Controller	Himachal Pradesh
40.	Shri Surinder Mohan	Assistant Drugs Controller	Jammu & Kashmir
41.	Shri Ravi S Menon	Deputy Drugs Controller	Kerala
42.	Shri Shobhit Koshta	Deputy Drugs Controller	Madhya Pradesh
43.	Shri H. Mahapatra	Drugs Controller	Orissa
44.	Shri Pardeep Kumar	Assistant Drugs Controller	Punjab
45.	Shri C.N. Sharma	Drugs Controller	Sikkim
46.	Shri K. Sivabalan	Deputy Director	Tamilnadu
47.	Dr. Chintamoni Ghosh	Director of Drugs Control	West Bengal

List of Participants

Participants from Laboratories			
48.	Shri C. Hariharan	Director I/C	CDL, Kolkata
49 .	Dr. Arun Bhardawaj	Director	CDL, Kasauli
50.	Shri. Sunil Goel	Technical Officer	CDL, Kasauli
51.	Dr. N. Murugesan	Director	CDTL, Chennai
52.	Dr. R. A. Singh	Director	RDTL, Chandigarh
53.	Dr. Parthajoyti Gogoi	Director	RDTL, Guwahati
54.	Dr. Renu Jain	Scientist	NIB, Noida
55.	Dr. V Kalaiselvan	Principal Scientific Officer	IPC, Ghaziabad
Organizers from CDSCO			
56.	Shri Rahul Shakaphure	Drugs Inspector	CDSCO (HQ)
57.	Shri Saurabh Garg	Drugs Inspector	CDSCO (HQ)
58.	Shri Rakesh Negi	Drugs Inspector	CDSCO (HQ)
59.	Shri P. Mannavalan	Drugs Inspector	CDSCO (HQ)
60.	Shri V. Rajappan	Drugs Inspector	CDSCO (HQ)
61.	Shri Vinay Kumar Gupta	Drugs Inspector	CDSCO (HQ)

List of Participants

Organizers from CDSCO			
62.	Shri Sourabh Mittal	Drugs Inspector	CDSCO (HQ)
63.	Shri Devendra Nath	Drugs Inspector	CDSCO (HQ)
64.	Shri Amol Eknath Kandekar	Drugs Inspector	CDSCO (HQ)
65.	Shri Rahul Panwar	Drugs Inspector	CDSCO (HQ)
66.	Shri Ankur Bansal	Drugs Inspector	CDSCO (HQ)
67.	Shri Fahim Khan	Drugs Inspector	CDSCO (HQ)
68.	Shri Anku Sahu	Technical Data Associate	CDSCO (HQ)
69.	Ms. Vandana Mallah	Technical Data Associate	CDSCO (HQ)
70.	Ms. Shilpa Khandagale	Technical Data Associate	CDSCO (HQ)
71.	Shri Hirday Kumar	Data Entry Operator	CDSCO (HQ)

Welcome address by Dr. G.N. Singh, DCG(I) addressing participants

Background and importance of the workshop delivered by Mr. Lahouari Belgharbi, WHO (HQ)

Inaugural address delivered by Dr. Arun Kumar Panda, Joint Secretary, MoH&FW

Special address delivered by Dr. Nata Menabde, WHO (CO)

Vote of Thanks delivered by Dr. Madhur Gupta, WHO (CO)

Mrs. Rubina Bose, ADC(I), CDSCO, moderated the inaugural session

Mr. Lov Verma, Secretary, Ministry of Health & Family Welfare addressed the participants in the closing day of the three days workshop expressing the views and intension of the Government of India to implement the Good Regulatory Practices.

He also reiterated that the experience shared by experts from WHO & other International Regulatory Agencies like France, Mexico, Thailand, Indonesia & China has definitely helped the Indian Regulators to understand the best practices of Regulation.

He also emphasized the most important role played by India in the Global supply chain as a generic manufacturer & supply of medicines and hence the requirements of Good Regulatory Practices.

Presentation on “An analytical review and strategic framework and approach for SEARO supports to NRA strengthening 2016-2017” was delivered by Dr. Stephane Guichard

Presentation on “GRP Overview, Principles, Current Experiences including Quality Management and Risk Approach” was delivered by Mr. Lahouari Belgharbi

Presentation on “WHO global overview about good regulatory practices (GRP): principles, definition and current experiences NRAs” was delivered by Dr. Alireza Khadem

Presentation on “Risk management experience in Mexico COFEPRIS” delivered by Dr. Julio Sanchez

Presentation on “Emerging Global and Regional Issues impacting R&D, Equity, Access, QSE of medicinal products” was delivered by Dr. Madhur Gupta

Presentation on "GRP on AEFI Surveillance: Lessons Learned through WHO NRA assessment" was delivered by Dr. Syed Fazal Shah

Presentation on "Building consumer confidence & better communication between consumers and suppliers" was delivered by Ms. Lucky Slamet for Indonesia

Presentation on "Building consumer confidence & better communication between consumers and suppliers" was delivered by Dr. Pierre Henry Bertoye for France

Presentation on "Building confidence with Stakeholders and consumers" was delivered by Dr. V.G. Somani

Presentation on "Quality Control testing: Considerations for NCL" was delivered by Mrs. Teeranart Jivapaisarnpong

ORGANIZERS OF THE GRP WORKSHOP-2014