

REPORT

SYMPOSIUM CUM WORKSHOP ON NATIONAL PHARMACOVIGILANCE PROGRAMME

20th December 2006

AT

S.M.S. MEDICAL COLLEGE

JAIPUR

Organized by

Department of Pharmacology

All India Institute of Medical Sciences

Ansari Nagar, New Delhi.

Sponsored by

World Health Organization, New Delhi.

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EXECUTIVE SUMMARY

A symposium cum workshop on National Pharmacovigilance Programme was organized by Zonal Pharmacovigilance Center at Department of Pharmacology, All India Institute of Medical Sciences, New Delhi at S.M.S Medical College, Jaipur on 20th December 2006. This workshop was held in conjugation with the annual conference of Indian Pharmacological Society as pre-conference workshop. This is a sequel of an earlier meeting conducted in 2006.

The workshop was inaugurated by Dr. Ashok Pangariya, Principal, S.M.S. Medical College, Jaipur. The keynote address was delivered by Dr. M.Venkateshwarlu, Drugs Controller General (India) followed by the vote of thanks by Dr. Mukul Mathur. The members of the National Pharmacovigilance Programme participated in the workshop. The members of CDSCO also attended the workshop. The coordinators of the Pharmacovigilance centers i.e. from the zonal, regional, peripheral centers actively took part in the workshop. The workshop was attended by more than 110 participants across the country.

The workshop was organized with the objective to take stock of the present functioning of zonal, regional, and peripheral centers. To identify bottlenecks and suggest solutions in ADR reporting. To impart training of causality assessment to the coordinators from the zonal and regional centers.

The workshop comprised of session on Pharmacovigilance terminologies, adverse events reporting in clinical trials, Pharmacovigilance of herbal drugs, causality assessment in Pharmacovigilance. In the afternoon session, the zonal,

regional and peripheral centers coordinators presented the activities of their centers, the status of collection of ADR reports, the problems faced and the success stories of each centre. This was followed by a panel discussion with the coordinators, CDSCO members, national advisory committee members, and the DCG(I). Suggestions were made to improve the functioning of the programme.

The meeting ended with the conclusion that necessary actions shall be taken to tackle the problems faced by the coordinators with regard to logistics, administrative and financial issues. It was also decided that a database will be developed to enter the data of all the centers by the respective zonal centers.

Symposium cum Workshop on National Pharmacovigilance Programme

20th December 2006 at S.M.S. Medical College, Jaipur

08.30 – 9.00 am Registration

9.00 – 10.00 am Inaugural session

Welcome : Dr. Z.Y.Khan

Need for Workshop on
Pharmacovigilance : Dr. Y.K.Gupta

Keynote address : Dr. M.Venkateshwarlu

Inauguration of workshop by Principal
SMSMC : Dr. Ashok Pangariya

Vote of Thanks : Dr. Mukul Mathur

10.30 – 11.30 Session I	Madhur Gupta Pooja Gupta	Terminologies in Pharmacovigilance
	Urmila Thatte	Methods in Pharmacovigilance
	Shantanu Tripathi	Causality Assessment in Pharmacovigilance
11.30-12.30 Session II	Kamala Rai	Reporting of AE in Clinical trials
	Avijit Hazra	How to get involved in Pharmacovigilance Activities
	P.K.Debnath	Pharmacovigilance of Herbal Drugs
12.30-01.15 Session III	Panel Discussion	DCG(I), Urmila Thatte, Y.K.G., Shantanu, Kamala Rai.
1.15-2.15	Refreshment	
2.15 – 4.30	Presentations	By the coordinators of Pharmacovigilance centers
4.30-5.30	Discussion	

INTRODUCTION

Pharmacovigilance, a useful tool in post marketing surveillance, is the process of identifying evaluating and responding to ADRs and safety issues about medicinal products. Pharmacovigilance is a new emerging area in India and there is a need to develop capacity as well as competence. Hence it is imperative to conduct training workshops for CDSCO staff as well as for coordinators of regional and zonal centers in performing causality assessment of received ADRs.

Hence a symposium cum workshop on National Pharmacovigilance Programme was organized by Zonal Pharmacovigilance Center at Department of Pharmacology, All India Institute of Medical Sciences, New Delhi at S.M.S Medical College, Jaipur on 20th December 2006.

The main objective of the workshop was to take stock of the functioning of the participating centers, to identify the bottlenecks and finding solutions in ADR reporting, to address the administrative and financial matters of the centers, to impart training in causality assessment to the coordinators from the zonal and peripheral centers.

The purpose of the workshop was also to help health professionals to participate in the very important process of continuous surveillance of safety and efficacy of the pharmaceutical products which are used in clinical practice. Continuous evaluation of their benefit and harm will help to achieve the ultimate goal to make safer and more effective treatment available to patients.

The workshop was inaugurated by Dr. Ashok Pangariya, Principal, S.M.S. Medical College, Jaipur. The keynote address was delivered by Dr.

M.Venkateshwarlu, Drugs Controller General (India) mentioning about the need of the Pharmacovigilance and its importance in drug regulation. Prof. Y.K.Gupta highlighted the need of Pharmacovigilance in India. The vote of thanks was delivered by Dr. Mukul Mathur. The workshop was attended by more than 120 participants across India. The members of the National Pharmacovigilance Programme participated in the workshop. The members of CDSCO were also attended the workshop. The coordinators of the Pharmacovigilance centers i.e. from the zonal, regional, peripheral centers actively took part in the workshop. The nominees of the Indian Pharmacological Society were also attended the workshop on Pharmacovigilance.

SESSION ON PHARMACOVIGILANCE:

The presentations covered most of the aspects of Pharmacovigilance, including terminologies in Pharmacovigilance, methods in Pharmacovigilance, causality assessment in Pharmacovigilance, reporting of AE in clinical trials and pharmacovigilance of herbal drugs.

The workshop was attended by a lot of budding pharmacologists and other post graduate students. To sensitize them, there was a presentation on terminologies in Pharmacovigilance where in the audience was briefed about the National Pharmacovigilance Programme and the common terms used in ADR reporting like Adverse Event, Adverse Drug Reaction, Serious Adverse Event

Various methods of reporting adverse drug reactions were discussed by Dr Urmilla Thatte including spontaneous reporting, Case control studies, cohort studies, intensive hospital monitoring and record linkage. Reporting varies with severity of the reaction, time for market introduction, promotional claims.

Dr Shantanu Tripathi discussed Causality assessment with a mention of the WHO-UMC Criteria and Naranjo scale of causality assessment.

Reporting of Adverse Events in Clinical Trials was also elaborated upon with special reference to timelines for reporting an AE to various authorities like Sponsor, Ethics Committee, Regulatory Authorities and reporting of serious adverse events.

There was also a talk on how to get involved in Pharmacovigilance activities by Dr Avijit Hazra where in how to become a part of the national Pharmacovigilance

programme, the basic knowledge required, how to collect ADR reports, special reporting requirements were discussed.

Motivation of the team involved in collection of ADR reports from the OPD/ward, convincing the physician for spontaneous reporting, reporting of focused ADRs, urgent reporting of serious adverse events and online reporting were also elaborated upon. It was emphasized that education and training of health professionals in drug safety, exchange of information between the national centers, co-ordination of such exchange, linking clinical experience of drug safety with health policy and research all serve to enhance better and effective patient care.

Dr Debnath spoke about the pharmacovigilance of herbal drugs which is increasingly important in the era of herbal medicines. He discussed the current status of Pharmacovigilance with respect to herbal drug with a focus on the need, problems faced, present status and limitations of the existing system.

This was followed by a panel discussion and causality assessment exercise wherein the participants were divided into groups and were given ADRs for causality assessment. Each group then discussed their ADR and its causality.

DISCUSSION:

The coordinators of the pharmacovigilance centers presented their report on the center activities. Starting from the peripheral centres going on to regional and then zonal centres, each centre coordinator presented a compilation of their data with special reference to the drug of interest. They also talked about the problems in collection of ADR, spontaneous reporting, and other administrative issues. They also mentioned their problems in causality assessment and the requirement for text books that are needed for causal analysis. The books for causal analysis will be provided by CDSCO. An ADR database will be made available to enter the ADR reports by an indigenous database or it will be decided after the discussion with Uppsala monitoring center to use their database. There was a suggestion that the participating physicians should be updated with summary of the ADR reports. Suggestions were also made as to how to improve the efficiency and smooth functioning of the programme. It was also decided that a quarterly news bulletin will be brought out to provide an update on the programme.

LIST OF PARTICIPANTS/ EXPERTS

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S.No	Name of Participants/Experts	City/State
1.	Mr.Kesavan	Pondicherry
2.	Dr. T.K. Ponnuswamy	Coimbatore
3.	Dr. Padma.G.M. Rao	Manipal
4.	Dr. Shobha Rani R.H.	Bangalore
5.	Dr. B. Prabha Rao	Cochin
6.	Dr. G.P. Mohanta	Chidambaram, Tamilnadu
7.	Dr. Sarala N	Kolar, Bangalore
8.	Dr. G.Parthasarathi	Mysore
9.	Dr. Urmila Thatte	Mumbai
10.	Dr. Bharat Gajjar	Anand, Gujarat
11.	Dr. R.K. Dikshit	Ahmedabad
12.	Mr. Gajanan Joshi	Nagpur
13.	Dr. R.N. Kadam	Satara, Maharastra

S.No	Name of Participants/Experts	City/State
14.	Dr. Rajesh Kumar Jha	Wardha, Maharastra
15.	Dr.YK Gupta	New Delhi
16.	Dr. Harmeet Singh Rehan	New Delhi
17.	Prof. A. Ray	New Delhi
18.	Dr.Surabhi Gupta	Meerut, New Delhi
19.	Dr. Avijit Hazra	Kolkatta
20.	Dr. Z.M. Wafai	Srinagar
21.	Dr. Bikas Medi	Chandigarh
22.	Dr. Sanjay Singh	New Delhi
23.	Dr. Partha gogoi	Guwahati
24.	Dr. M. Venkateswarlu	New Delhi
25.	Mr. A.B. Ramteke	New Delhi
26.	Mr. J.B. Mathur	New Delhi
27.	Ms. Swati Srivastava	New Delhi

S.No	Name of Participants/Experts	City/State
28.	Ms. Narmata	New Delhi
29.	Ms. Preeti	New Delhi
30.	Mr. Rishi	New Delhi
31.	Mr. Asheem Sahoo	New Delhi
32.	Mr. Gaurav	New Delhi
33.	S. Perumal	New Delhi
34.	Dr. Seema Briyal	New Delhi
35.	Mr. Gajinder Kumar	New Delhi
36.	Mr. Jogendar Mehla	New Delhi
37.	Mr. Mahaveer Jain	New Delhi
38.	Dr. Sudhir Sarangi	New Delhi
39.	Dr. Viswanath	New Delhi
40.	Mr. Vikas Sarangal	New Delhi
41.	Ms. Anjali	New Delhi

S.No	Name of Participants/Experts	City/State
42.	Dr. Jitendra Sharma	Bangalore
43.	Dr. Laxman Das	Manipur
44.	Dr. Sammod Vardhan K	Manipal
45.	Dr. Shilpa Sharma	Manipal
46.	Dr. Amit Saxena	Allahabad, U.P
47.	Dr. Anand R Kanaki	Gulbargh, Karnataka
48.	Dr. Santhosh Kugali	Gulbargh, Karnataka
49.	Dr. Jagdish Chandra S.Ratnakar	Gulbargh, Karnataka
50.	Ms. Anurag Maheshwari	Pune, Maharastra
51.	Dr. Ashish Yadav	Meerut, U.P
52.	Dr. Satwika Sinha	Meerut, U.P.
53.	Dr. Sukanta Sen	Meerut, U.P.
54.	Dr. Vinod K Bhardwaj	Meerut, U.P.
55.	Mr. N.Anil Babu	Manipal, Karmataka

S.No	Name of Participants/Experts	City/State
56.	Ms. K.Meena Kumari	Manipal, Karmataka
57.	Dr. V.Madhusudan Rao	Manipal, Karmataka
58.	Dr.Mohan Amberkar	Manipal, Karmataka
59.	Dr. Smita Shenoy	Manipal, Karmataka
60.	Dr. Pawandeep Kaur	Patiala, Punjab
61.	Dr. Inderpal Singh Grover	Amritsar, Punjab
62.	Dr. Raj Kumar	Amritsar, Punjab
63.	Dr. Prachi Arora	Ghaziabad, U.P.
64.	Dr. Anudeep sandhu	Amritsar, Punjab
65.	Dr. Nishant V. Sangole	Mumbai
66.	Dr. Samir M.Adsule	Aurangabad
67.	Dr. Vashita Shukla	Manipal, Karnataka
68.	Dr. K. Sreedhara R Pai	Manipal, Karnataka
69.	Dr. Anil Kumar	Ootacamund, Tamil Nadu

S.No	Name of Participants/Experts	City/State
70.	Dr. R.M.Syed	Ahmednagar, Maharashtra
71.	Dr. Sunil N	Chennai, Tamilnadu
72.	Dr. N.V.S.Kumar	Mumbai, Maharashtra
73.	Dr. Manoj Karwa	Mumbai, Maharashtra
74.	Mr. Venu Pamidiboina	Mumbai, Maharashtra
75.	Dr. Lalit Joshi	Mumbai, Maharashtra
76.	Dr. Jigar Ravindrabhai katwala	Ahmedabad, Gujarat
77.	Dr. Amrita A.Desai	Mumbai, Maharashtra
78.	Dr.S.Basalingappa	Chittoor, A.P
79.	Dr.K.M.Latha	R.C.Puram, Hyderabad
80.	Dr.K.Swarnalatha	Hyderabad, A.P.
81.	Dr. G.H. Bindu	Punjagalta, Hyderabad
82.	Dr.Manohar M.Bende	Nagpur, Maharashtra
83.	Dr.Ashok Dubey	Jabalpur
84.	Dr. Debasish Sahu	Kolkatta
85.	Prashant Mathur	Jaipur

S.No	Name of Participants/Experts	City/State
86.	Dr.Sheilesh Sharma	Jaipur
87.	Dr.Harsahay Meena	Jaipur
88.	Dr.Ajay Kushwaha	Jaipur
89.	Dr.Vandana Chaturvedi	Jaipur
90.	Dr.Meena Yadav	Jaipur
91.	Dr. Shruti Upadhyay	Jaipur
92.	Dr.Vivek Gupta	Jaipur
93.	Dr. Sameer Rastogi	Jaipur
94.	Dr.Saurabh Srivastava	Jaipur
95.	Dr. Mukul Mathur	Jaipur
96.	Dr.Deepali Jaybhaye	Jaipur
97.	Dr. Sonalee Chaturvedi	Jaipur
98.	Dr. S Soniya Satish	Jaipur
99.	Dr. Rupali Bajrang Jadhav	Jaipur
100.	Dr. Rajendra Pawade Bajabhau	Jaipur
101.	Dr. Prakash Chandak	Jaipur

S.No	Name of Participants/Experts	City/State
102.	Dr. Ankesh Digamber Barnwal	Jaipur
103.	Dr. Vasudha	Jaipur
104.	Dr. Pradeep R Jadhav	Jaipur
105.	Dr. Biswa Mohan	New Delhi
106.	Dr. Rakesh Gupta	New Delhi
107.	Dr. L.Sharma	New Delhi
108.	Dr. R.K. Rathore	New Delhi
109.	Dr. P.K. Debnath	Kolkatta
110.	Dr. Kamala rai	New Delhi
111.	Dr. S.K.Tripathi	Kolkatta
112.	Dr. Madhur Gupta	New Delhi
113.	Dr. Pooja Gupta	New Delhi
114.	Dr. K.H. Reeta	New Delhi
115.	Dr. R.Kapadia	Jaipur
116.	Dr. M. Jain	Jaipur