

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

LIST OF PARTICIPANTS/ EXPERTS:

| 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 |
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| 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 |