

**Minutes of IND Committee meeting held on  
03.12.2018 at ICMR (HQ), V. Ramalingaswami  
Bhawan, Ansari Nagar,  
New Delhi.**

**List of Participants:**

1. Prof. Balram Bhargava, Secretary, Department of Health Research & Director General, Chairperman, IND Committee.
2. Dr. Nilima Kshirsagar, Chair in Clinical Pharmacology, National Institute for Research in Reproductive Health, Mumbai.
3. Dr. Y.K. Gupta, Ex. Dean, AIIMS, New Delhi.
4. Dr. S.K. Sharma, Ex-Prof. & Head, Department of Medicine, AIIMS, New Delhi.
5. Dr. C. D. Tripathi, Prof. & Head, Department of Pharmacology, VMMC, New Delhi.
6. Dr. Bikash Medhi, Prof., Department of Pharmacology, PGIMER, Chandigarh.

**ICMR Representative:**

1. Dr. Vijay Kumar, Scientist G, Division of BMS-Co-ordinator, ICMR, New Delhi.
2. Dr. Rajni Kaul, Scientist G, Division of BMS, ICMR, New Delhi.

**CDSCO Representatives:**

1. Mr. A. K. Pradhan, Deputy Drugs Controller (India), CDSCO (HQ).

**Following members could not attend the meeting:**

1. Dr. Chandishwar Nath, Ex. Scientist-G & Scientist-in-charge, Division of Toxicology, Central Drug Research Institute, Lucknow.
2. Dr. A. K. Saxena, Ex. Scientist-G, Central Drug Research Institute, Lucknow.
3. Dr. Deepak Kaul, Prof. & Head, Department of Experimental Medicine & Biotechnology, PGIMER, Chandigarh.
4. Prof. Dinesh Puri, Head, Department of Medical Bio-Chemistry, GTB Hospital, Shahdara, New Delhi.

Prof. Balram Bhargava, Secretary, DHR and DG ICMR, Chairman of the Committee welcomed the members. The Chairman also informed the committee that since he has to attend another important meeting after some time, in his absence Dr. Y. K. Gupta and Dr. Nilima Kshirsagar would Chair the meeting. Thereafter, the agenda items were discussed one by one:

**Agenda No. 1**

**Phase II clinical trial with NRC-2694 of M/s Natco Pharma**

The firm presented their proposal for grant of permission to conduct a Phase II clinical trial with NRC-2694-A entitled, "A Phase II Clinical Study to evaluate the efficacy and

