

**Panel of experts for constituting Independent Expert Committee to examine the SAE-Death occurring during clinical trials:-**

1. Dr. Arun Agarwal, Chairman, Professor of ENT & Dean, Maulana Azad Medical College, Bahadur Shah Zafar Marg, New Delhi.
2. Dr. Y.K Gupta, Head, Department of Pharmacology, AIIMS, Ansari Nagar, New Delhi – 110029.
3. Dr RK Grover, Director, DSCI, Delhi State Cancer Institute, Dilshad Garden, Delhi.
4. Dr. RajababuPanwar, Vice Chancellor, The Rajasthan University of Health Sciences, Sector-18, KumbhaMarg, Pratap Nagar, Tonk Road, Jaipur.
5. Dr. S.D Banavali, Head, Dept. of Medical Oncology, Tata Memorial Hospital, Parel, Mumbai-12.
6. Dr. VinodRaina, Prof. & Head, Dept. of Oncology, AIIMS, New Delhi.
7. Dr. T.G Sagar, Chairman & Prof. Dept. of Medical Oncology, Cancer Institute, Adyar Chennai.
8. Dr. Anil Bansali, Addl. Prof. & Head, Dept. of Endocrinology, PGIMER, Chandigarh.
9. Dr. V.K Bahl, Prof. & Head, Dept. of Cardiology, AIIMS, New Delhi.
10. Dr. A. C. Ammini, Prof. & Head Dept. of Endocrinology, AIIMS, New Delhi.
11. Dr. SandeepGarg, Associate Prof., Dept. of Medicine, Maulana Azad Medical College, New Delhi.
12. Dr. MadhuriBehari, Prof & Head, Dept. of Neurology, AIIMS, New Delhi.
13. Dr.K.Narayanasamy, Professor and Head, Dept. of Hepatology, Madras Medical College and Rajiv Gandhi Government General Hospital, Chennai.
14. Dr. Rajendra Prasad, U.P Rural Institute of Medical Sciences & Research, Saifai, Itawah.
15. Dr. Shobhna Bhatia, Prof. & Head, Dept. of Gastroenterology, SGS & KEM Hospital, Mumbai.
16. Dr. Anil Agarwal, Prof. & Head of Dept. of Gastro-Intestinal Surgery, G.B. Pant Hospital, New Delhi.
17. Dr. Rakesh Yadav, Additional Professor, Cardiology, All India Institute of Medical Sciences (AIIMS), Ansari Nagar, New Delhi-110029.
18. Dr. Girish MP, Associate Prof., Dept. of Cardiology, G.B. Pant Hospital, New Delhi.

19. Dr. C. Nath, Chief Scientist, Scientist-G & Scientist –in-charge, Division of Toxicology, Central Drugs Research Institute (CDRI), Lucknow.
20. Dr. Raju Titus Chacko, Medical Oncology, Christian Medical College, Vellore – 632004.
21. Dr. Geetha Narayanan, Prof. & Head, Dept. of Medical Oncology, Regional Cancer Centre, Trivandrum.
22. Dr. Anup Kumar Kundu, Prof & Head, Dept. of Urology, IPGMER & SSKM, Kolkata.
23. Dr. Tushar Agarwal, Associate Professor, Dept. of Ophthalmology (R.P.C.), AIIMS, Ansari Nagar, New Delhi-110029.
24. Dr. Asit Mittal, Professor, Dept. of Dermatology , Venerology & Leprosy, R N T Medical College, Udaipur, Rajasthan – 313001.
25. Dr. Santanu Tripathi, Professor & Head, Department of Clinical & Experimental Pharmacology. School of Tropical Medicine, 108, Chittaranjan Avenue, Kolkata.
26. Dr. Sandeep Seth, Addl. Prof., Dept. of Cardiology, AIIMS, New Delhi.
27. Dr. Hemant Malhotra, Prof. & Head of the Dept. of Oncology, SMS Medical College & Attached Hospitals, J.L.N. Marg, Jaipur - 302004 Rajasthan.
28. Dr. H.K. Kar, Medical Superintendent, Dr. Ram Manohar Lohia Hospital, Baba Kharak Singh Marg, Connaught Place, New Delhi.
29. Dr. Debasis Basu, Prof. & Head, Dept. of Neurology, N R S Medical College, Department Of Neurology, 138 A J C Bose Road, Kolkata.
30. Dr. Bikash Medhi, Additional Professor, Dept. of Pharmacology, PGIMER, Chandigarh.
31. Dr. Sheffali Gulati, Associate Professor, Child Neurology Division, Department of Pediatrics, All India Institute of Medical Sciences, Ansari Nagar, New Delhi-110029.
32. Dr. Renuka Kulkarni-Munshi, Associate Professor & In-charge, Clinical Pharmacology, TN Medical College and BLY Nair Charitable Hospital, Mumbai.
33. Dr. Nadukuru N Raju, Prof. of Psychiatry & Vice Principal, Andhra Medical College, Visakhapatnam.
34. Dr. Neeraj Kumar Agrawal, Associate Professor, Dept. of Endocrinology and Metabolism, Institute of Medical Sciences (I.M.S.), BHU, Varanasi.
35. Dr. Urmila Thatte, Prof & Head Dept of Clinical Pharmacology, SGS Medical College & KEM Hospital, Mumbai.

36. Dr. R.K. Arya, Prof. & Head, Dept. of Orthopedics, RML Hospital, New Delhi.
37. Dr. SmitaDeshpande, Prof. & Head, Dept. of Psychiatry, RML Hospital, New Delhi.
38. Dr. Kishore Singh, Department of Radiotherapy & Medical Oncology, Maulana Azad Medical College, New Delhi.
39. Dr. KamalakarTripathi, Dept. of Medicine, institute of Medical Science, BHU, Varanasi.
40. Dr. B.T. Kaul, Prof. of Law, Delhi University, Law Centre-II, DholaKuan, New Delhi.
41. Dr. NiranjanMohanty, Prof. & Head, Dept. of Pediatrics, SCB Medical College, Cuttack.
42. Dr. UshaAcharya, Prof. & Head, Dept. of Pediatrics, SMS Medical College, Jaipur.
43. Dr. KakbirDhaliwal, Prof. & Head of Obstetrics&Gynaecology, PGIMER, Chandigarh.
44. Dr. S.V. Parulekar, Prof. & Head, Prof. & Head, Dept. of Obstetrics&Gynaecology, SGS Medical College & KEM Hospital, Mumbai.
45. Dr. R.K. Saran, Head of Dept. of Cardiology, KGMC, Lucknow.
46. Dr. S.R. Chandra, Prof. & Head, Dept. of Neurology, NIMHANS, Hosur Road, Bangalore.
47. Dr. T.K. Dutta, Prof. & Head, Dept. of Medicine, JIPMER, Puducherry.
48. Dr. DM Thappa, Prof. & Head, Dept. of Dermatology, JIPMER, Puducherry.
49. Dr. SangitaYadav, Director Professor, Dept. of Pediatrics, Maulana Azad Medical College, New Delhi.
50. Dr. Sanjeev Jain, Prof. & Head. Dept of Psychiatry, National Institute of Mental Health and Neuro Sciences, (NIMHANS) Hosur Road, Bangalore.
51. Dr. Nikhil Tandon, Dept. Of Endocrinology & Metabolism, Room No. 311, III Floor, AIIMS, New Delhi.
52. Dr. Lalit Kumar, Prof. of Oncology, AIIMS, New Delhi.
53. Dr. S.K. Agarwal, Prof. & Head, Dept. Of Nephrology, AIIMS New Delhi.
54. Dr. Sudhir Gupta, Dept. of Gastroenterology, Govt. Medical College & Super Specialty Hospital, Nagpur.
55. Dr. S.P. Kataria, Consultant & Head, Medical Oncology, V.M.M.C. &Safdarjung Hospital, New Delhi.

56. Dr Atul Sharma, Additional Professor, Dept of Medical Oncology, AIIMS, New Delhi.
57. Dr S. Deshpande, Prof., Dept of Psychiatry, RML Hospital, New Delhi.
58. Dr. Bangali Majhi, Senior Specialists, Dept. of Obstetrics &Gynaecology, RML Hospital, New Delhi.
59. Dr. Rajesh Khadgawat, Additional Professor, Dept. of Endocrinology & Metabolism, AIIMS, New Delhi-110029.

The panel of Experts may be expended regularly based on feedback from the subject Experts.

Three Independent Expert Committees have been reconstituted for examination of reports of Serious Adverse Events (SAEs) of death occurred during clinical trials, details of which are as under:-

**F. NO. CT/SAE-D-Misc-Committee-13/2014**  
**Office of Drugs Controller General (India)**  
**SAE-Division**

FDA Bhawan, Kotla Road  
New Delhi-110002

Dated: 1 JUL 2014

**OFFICE MEMORANDUM**

**Subject:** Constitution of Independent Expert Committee- Cardiology for examination of reports of Serious Adverse Events (SAEs) of deaths occurred during clinical trials-regarding.

In pursuance of sub-clause (b) (i) (A) of Clause (6) of Appendix XII of the Schedule Y of the Drugs & Cosmetics Rules, 1945, the Independent Expert Committee comprising of following members is hereby reconstituted:-

- |  |            |
|--|------------|
| 1. Dr. Arun Agarwal, Chairman, Professor of ENT, Maulana Azad Medical College, Bahadur Shah Zafar Marg, New Delhi. | - Chairman |
| 2. Dr. Urmila Thatte, Prof. & Head Dept of Clinical Pharmacology, SGS Medical College & KEM Hospital, Mumbai.      | - Member   |
| 3. Dr. V.K Bahl, Prof. & Head, Dept. of Cardiology, AIIMS, New Delhi.  | - Member   |
| 4. Dr. Girish MP, Associate Prof., Dept. of Cardiology, G.B. Pant Hospital, New Delhi.                             | - Member   |
| 5. Dr. Bikash Medhi, Additional Professor, Dept. of Pharmacology, PGIMER, Chandigarh.                              | - Member   |
| 6. Dr. R.K. Saran, Head of Dept. of Cardiology, KGMC, Lucknow.   | - Member   |
| 7. Dr. Anil Agarwal, Prof. & Head of Dept. of Gastro-Intestinal Surgery, G.B. Pant Hospital, New Delhi.            | - Member   |
| 8. Dr. Rajesh Khadgawat, Additional Prof., Dept. of Endocrinology & Metabolism, AIIMS, New Delhi.                  | - Member   |

The **Terms of Reference** of the Independent Expert Committee shall be as under:


1. The quorum of the committee for examination of any Serious Adverse Event (SAE) of death shall be as under:
  - a. Chairman or his nominee from members of the committee.
  - b. One subject expert\*.
  - c. Any one other expert member.

2. The Independent Expert Committee shall function under the provisions as specified in Appendix XII of Schedule Y of Drugs & Cosmetics Rules.
3. The Chairman of the expert committee shall receive reports of Serious Adverse Events of death from Investigator, Sponsor or his representatives whosoever had obtained permission from the DCG(I) for conducting the clinical trial and the Ethics Committee.
4. The Committee shall examine the reports of Serious Adverse Events of death, to determine the cause of death & if the cause of death is due to following reasons which are considered as clinical trial related death & gives its recommendation to DCG(I).
  - a. adverse effect of investigational product(s);
  - b. violation of the approved protocol, scientific misconduct or negligence by the Sponsor or his representative or the investigator;
  - c. failure of investigational product to provide intended therapeutic effect;
  - d. use of placebo in a placebo-controlled trial;
  - e. adverse effects due to concomitant medication excluding standard care, necessitated as part of approved protocol;
  - f. for injury to a child *in-utero* because of the participation of parent in clinical trial;
  - g. any clinical trial procedures involved in the study.
5. In case of clinical trial related death, the committee shall also recommend the quantum of compensation to be paid by the sponsor or his representative, to DCG(I).
6. The committee shall examine each reports of death within a time period of 30 days of receiving the reports from the respective Ethics Committee.
7. The Chairman of the expert committee can invite subject and other outside experts, if considered necessary.
8. Each member of the committee shall be paid Rs. 500/- (Rupees Five hundred only) for examination of each SAE of death subject to a maximum of Rs. 5000/- (Rupees Five Thousand only) in a single sitting.
9. TA/DA for attending the meeting as well as honorarium will be paid from Indian Pharmacopoeia Commission budget.
10. The experts nominated as a member for the committee should not have any conflict of interest. The members shall sign declaration on conflict of interest.
11. The members of the committee shall hold office up to 31.03.2016.
12. The members of the committee should follow the Principle of Confidentiality with respect to the documents submitted to them for examination.
13. The reports of SAEs of death shall be evaluated by the committee through meetings.
14. In the event of the inability of the Chairman to chair a meeting, he can nominate one of the member of the committee to chair the meeting.

\*In case subject expert of any specific therapeutic category is not available from the members, subject expert from the expert panel or from outside (in case subject expert is not available from the panel) may be invited by the Chairman.

To,

1. Dr. Arun Agarwal, Chairman, Professor of ENT, Maulana Azad Medical College, Bahadur Shah Zafar Marg, New Delhi.
2. Dr. Urmila Thatte, Prof. & Head Dept of Clinical Pharmacology, SGS Medical College & KEM Hospital, Mumbai.
3. Dr. V.K Bahl, Prof. & Head, Dept. of Cardiology, AIIMS, New Delhi.
4. Dr. Girish MP, Associate Prof., Dept. of Cardiology, G.B. Pant Hospital, New Delhi.
5. Dr. Bikash Medhi, Additional Professor, Dept. of Pharmacology, PGIMER, Chandigarh.
6. Dr. R.K. Saran, Head of Dept. of Cardiology, KGMC, Lucknow.
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8. Dr. Rajesh Khadgawat, Additional Prof., Dept. of Endocrinology & Metabolism, AIIMS, New Delhi.

  
(Dr. G.N. Singh)  
Drugs Controller General (India)

Copy to –

US (D), Ministry of Health & Family Welfare, New Delhi.

F. NO. CT/SAE-D-Misc-Committee-13/2014  
Office of Drugs Controller General (India)  
SAE-Division

FDA Bhawan, Kotla Road  
New Delhi-110002

Dated: - 1 JUL 2014

OFFICE MEMORANDUM

**Subject:** Constitution of Independent Expert Committee - Oncology for examination of reports of Serious Adverse Events (SAEs) of deaths occurred during clinical trials-regarding.

In pursuance of sub-clause (b) (i) (A) of Clause (6) of Appendix XII of the Schedule Y of the Drugs & Cosmetics Rules, 1945, the Independent Expert Committee comprising of following members is hereby reconstituted:-

1. Dr. Arun Agarwal, Chairman, Professor of ENT, Maulana Azad Medical College, Bahadur Shah Zafar Marg, New Delhi. - Chairman
2. Dr. Y.K Gupta, Head, Department of Pharmacology, AIIMS, Ansari Nagar, New Delhi. - Member
3. Dr. Renuka Kulkarni-Munshi, Associate Professor & In-charge, Clinical Pharmacology, TN Medical College and BLY Nair Charitable Hospital, Mumbai - Member
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5. Dr. S.D Banavali, Head, Dept. of Medical Oncology, Tata Memorial Hospital, Parel, Mumbai. - Member
6. Dr. T.G Sagar, Chairman & Prof. Dept. of Medical Oncology, Cancer Institute, Adyar Chennai. - Member
7. Dr. Kishore Singh, Department of Radiotherapy & Medical Oncology, Maulana Azad Medical College, New Delhi. - Member
8. Dr. S. Kataria, Consultant & Head, V.M.M.C. & Medical Oncology, Safdarjung Hospital, New Delhi. - Member

The **Terms of Reference** of the Independent Expert Committee shall be as under:

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- b. One subject expert\*.
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2. The Independent Expert Committee shall function under the provisions as specified in Appendix XII of Schedule Y of Drugs & Cosmetics Rules.
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(Dr. G.N. Singh)  
Drugs Controller General (India)

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Dated: - 1 JUL 2014

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| 6. Dr. Madhuri Behari, Prof & Head, Dept. of Neurology, AIIMS, New Delhi.  | - Member   |
| 7. Dr. Sangita Yadav, Director Professor, Dept. of Pediatrics, Maulana Azad Medical College, New Delhi.  | - Member   |
| 8. Dr. Sheffali Gulati, Associate Prof., Child Neurology Division, Dept. of Pediatrics, AIIMS, Ansari Nagar, New Delhi.  | - Member   |

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(Dr. G.N. Singh)  
Drugs Controller General (India)

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US (D), Ministry of Health & Family Welfare, New Delhi.