NO. MCI-211(2)/2012-Ethics/

MEDICAL COUNCIL OF INDIA SECTOR-VIII, POCKET- 14, DWARKA, NEW DELHI.

Minutes of the meeting of the Ethics Committee held on 20th November, 2012 at 09:00 A.M. in the Council Office, Sector - 8, Pocket- 14, Dwarka, N.Delhi - 77.

Present in the meeting:

1.	Prof. Sneh Bhargava	Chairperson
	e	-
2.	Dr. Sanjay Gupte	Member
3.	Dr. (Prof.) Chander Shekhar Shetty Member	
4.	Dr. Atul Sood	Member
5.	Dr. B.G. Tilak	Member
6.	Dr. G.K. Sharma	Member
7.	Dr. Kumudini Sharma	Member
8.	Dr. Rama V. Baru	Member
	Dr. P.Prasannaraj	Addl. Secretary, MCI
	Dr.M.Rajalakshmi	Consultant

Leave of absence were received from Dr. Y.K. Gupta, Dr. Raja Babu Panwar, Dr. V. Sakhuja, Dr. Sangeeta B. Desai.

1. <u>Minutes of the last meeting of the Ethics Committee- Confirmation of.</u>

The minutes of the meeting of the Ethics Committee held on 27.10.2012 were read and confirmed.

2. <u>Action taken on the previous minutes presented before the Ethics Committee on 22.9.2012.</u>

The Ethics Committee noted that the minutes dated 22.09.2012 were yet to be approved by the Board of Governors and directed the Council to complete action on receipt of the same.

3. Appeal made by Dr. Arvind Poswal against Dr. Charu Sharma (F.No. 37/2012).

The Ethics Committee considered the Appeal dated 24.5.2012 filed by Dr.Arvind Poswal against the order dt.2.2.2012 passed by Delhi Medical Council and after deliberation on the matter in detail, the Committee decided that both the parties i.e. complainant Dr.Arvind Poswal, as well as respondent Dr. Charu Sharma (Delhi Medical Council Regn. No.22466) be called for personal hearing in subsequent meeting alongwith all the relevant records pertaining to the case.

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Member Member Member

(Dr. B.G. Tilak) (Dr. G.K. Sharma) (Dr. Kumudini Sharma)
Member Member Member

(Dr. Rama V. Baru)
Member

4. R.C. 24(A)/2010 of CBI ACB, Chennai - initiation of Regular Departmental Action for Major Penalty against 8 doctors nominated by MCI for inspection and such action as deemed fit against 70 teaching faculties as detailed in the self contained note - reg. [Shri Laxmi Narayana Institute of Medical Sciences, Pondicherry.

The Ethics Committee considered the registered complaint vide RC 24(A)/2010 of CBI ACB, Chennai, dated 5.10.2012 received by the Council on 12.10.2012 which reads as under:-

"....... A case in RC 24(A)/2010 was initially registered against Dr.Ketan Desai, the then President, Medical Council of India, New Delhi, M/s. Sri Lakshmi Narayana Institute of Medical Sciences, Pondicherry represented by its Managing Trustee and unknown others on 21.05.2010 for commission of certain irregularities. in the matter of recommending renewal of permission for admission of 150 students of MBBS for academic session 2010-2011 of M/s Sri Lakshmi Narayana institute of Medical Sciences, Pondicherry.

On completion of investigation, it was revealed by CBI that the following 8 Doctors nominated by MCI for inspection failed to conduct proper inspection to point out major deficiencies in the Medical College, including actual shortage in the strength of the teaching faculties/doctors, etc., during their inspection (conducted on various dates at Sri Lakshmi Narayana institute of Medical Sciences, Pondicherry for the purpose of renewal of permission for admission of students for the academic years 2006-2007 to 2010-2011:-

(I) Dr. P. Dlleepan (ii) Dr.M.S.Dhananjaya, (iii) Dr.K.Ravi (iv) Dr.Yamini Nilesh Trivedi, (v) Dr.Kirti Dubey, (vi) Dr.Shipa Rao (vii) Dr.Srikumari Damodaran and (viii) Dr. K.V. Niranjana Murthy.

It was also revealed during investigation that 70 Teaching Faculty Members as mentioned in pages 15 to 20 of the Self Contained Note have been arranged fraudulently by the College Management to appear before the MCI Inspectors on the dates of MCI Inspection to mark their presence who have appeared and falsely signed in the Declaration Forms as Full Time Doctors, knowing fully well that they are not actually in the strength of the College."

In view of the above, Ethics Committee requested the concerned section dealing with the inspections as mentioned above, to apprise whether show cause notice had been issued to concerned parties and the current status of reply to said show cause notice.

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5. <u>Appeal against order dated 06.09.2011 passed by Karnataka Medical Council made by Ch. Shankaraiah against Dr. Kiran J. (F.No. 535/2011).</u>

The Ethics Committee considered the appeal dt.30.12.2011 and its decision taken on 17.7.2012 alongwith the comments provided by the Board of Governors which reads as under:-

Ethics Committee decision dt. 17.07.2012 is as under:

"The Ethics Committee considered the appeal against order dated 06.09.2011 passed by Karnataka Medical Council made by Ch. Shankaraiah against Dr. Kiran J. whereby the Karnataka Medical Council had exonerated the respondent Dr. Kiran. Both the parties appeared before the Ethics Committee alongwith their lawyers and made detailed submissions before the Ethics Committee on 17.4.2012 and also filed various documents in support of their case. The Ethics Committee perused the available records/documents as well as the oral submissions made by both the parties and the Committee was of the view that (Dr. Kiran had tampered the medical records of the patient at the hospital and exaggerated the disability of the patient, Mrs. Sheel Rodrigues to benefit the patient in the Motor Accident claims case filed by her against the insurance company). This amounts to misconduct in terms of Chapter 7.7 of the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 and clearly establishes guilty of professional misconduct of Dr. Kiran.

In view of above, the Committee recommended for removal of the name of Dr. Kiran from the Indian Medical Register for a period of two years. This should be sent to KMC for enforcement/implementation."

Board of Governors comments in their meeting of 31.8.2012 is as under.

"Too harsh a punishment for adding one line. Needs review as Dr. Kiran is not a treating physician, Dr. Nalini is a Junior Resident and Dr. Chodhary was treating physician and has notes tallying the description of the injury."

The Ethics Committee reviewed in detail the entire records including the comments provided by the Board of Governors and decided as under:-

Dr. Kiran J. has deliberately tempered with the records. A minimum punishment of removal of his name from Karnataka Medical Register for a period of one year.

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6. <u>Violation of "Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002" - complaint against Indore Clinical Trials conducted by doctors violating minimum ethical standards received from Swasthya Adhikar Manch, Indore (M.P) and Smt. Brinda Karat, Member, Polit Bureau, CPI(M), Former Member, Rajya Sabha) (F.No. 615/2011)</u>

The Ethics Committee considered the matter with regard to Violation of "Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002" complaint against Indore Clinical Trials conducted by doctors violating minimum ethical standards received from Swasthya Adhikar Manch, Indore (M.P) and Smt. Brinda Karat, Member, Polit Bureau, CPI(M), Former Member, Rajya Sabha and noted that the Ethics Committee at its meeting held on 14.2.2012 directed the Council to enquire from Drug Controller of India (DCG(I), Indian Council of Medical Research (ICMR), & Madhya Pradesh Medical Council to know the action taken on the outcome of their enquiries.

In this regard, as per the report dt.7.3.2012 received from Dr.V.M. Katoch, Director General, ICMR, New Delhi, he stated that the Role of ICMR is in capacity building, setting up various guidelines and standards for conducting Clinical Trials properly. The DCG(I) and Medical Council of India may initiate action for proper enquiry. Accordingly, a letter was sent to DCG(I) with a request to inform the status of the enquiry, if any, initiated. The DCG(I) in its letter dt.15.5.2012 informed that CDSCO team constituted has carried out inquiry of various trials and the report is as under:-

- "I) 11 trials from January,2008 to October,2010 sponsored by a) M/s Cadila Healthcare Ltd., Ahmedabad; b) M/s Emcure Pharmaceuticals, Pune & d) M/s Intas Pharmaceuticals, Ahmedabad conducted by Psychiatrist of MGM Medical College at their private clinics with necessary permission DCG(I), involved 241 patients participation under the Principal investigators a) Dr.Raghulam Razdan; b) Dr.Abhey Paliwal; c) Dr.V.S.Pali; d) Dr.Pali Rastogi & e) Dr.Ujjwal Sardesai. Allegations are as under:-
- a) The said department did not inform the concerned college authorities and did not submit ethical clearance from competent authorities attached to the college.
- b) Dr.Raghulam Razdan & Dr.Pali Rastogi did not maintain any source data for trials conducted for Intas Pharmaceuticals and Cadila Healthcare which is contrary to Drugs & Cosmetics Acts & Rules under Appendix VII of Schedule Y.
- c) Emcure Pharmaceutical did not monitor trial properly (for instance the Lab. finding value for the test on screening day & the last visit were exactly

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identical for 4 subjects of DAPOXITINE trial conducted by Dr.Abey Paliwal & transcription error of data from source by Dr.Ujjwal Sardesai.

- d) The investigator site of Dr.Raghulam Razdan sponsored by Cadila Healthcare (subject code 011 male 39 years) shows 1st site visit on 7.3.2009 whereas the consent form of the subject patient is dt.9.3.2009. <u>In another subject code No.34 female 42 years shows 1st site visit on 7.4.2009 and the informed consent is on 30.6.2009.</u>
- e) Dr.Raghulam Razdan in his study of efficacy/safety of fixed dose of PARAXETINE Hcl and CLONAZEPAM in comparison PARAXETINE reported adverse event as Erectile disfunction in subject No.27 female 45 which is not practical.
- f) The report examined by CDSCO (HQ) observed that there were many discrepancies in respect of the clinical trials conducted by Dr.Raghulam Razdan for Cadila & Dr.Abhey Paliwal and Dr.Ujjwal Sardesai for Emcure. Show cause notice were issued to the above said doctors by CDSCO and received their reply. CDSCO observed that there had been certain irregularities in conduct of clinical trials which were not in accordance with the Good Clinical Practices (GCP) guidelines for clinical research in India.

In view of the above, the said pharmaceutical firms and the investigating doctors have been issued warning by CDSCO vide letter dt. 2.5.2012 to be careful while conducting trials so as to ensure strict compliance of GCP guidelines and applicable regulations.

- II. News report quoting use of drug TADALAFIL in Pulmonary Arterial Hypertension (PAH) trial conducted by Dr.Anil Bharani & Dr.Ashish Patel was investigated by the M.P.State Drug Controller Authority & CDSCO (WZ) on 10.8.2011 and found that the said trial was conducted without permission from DCG(I) and also the drug was not approved by DCG (I) for the said indication at the time of initiation of the trial (18.9.2005). The said Regulatory Authorities directed the investigators to stop the trial and also restrict them to conduct any clinical trial for a period of six months.
- III. Report on Clinical Trial conducted by Dr.Hemant Jain at Chacha Nehru Hospital, Indore by the investigating team comprising DDC(I), West Zone, Drug Inspector & Experts constituted by CDSCO on 16-20 April revealed that Dr.Hemant Jain of the 26 clinical trials conducted after due permission of DCG(I), between 2006-2010, there were some irregularities in 23 trials. The main findings in all the said 23 trials were that the quorum of the Ethics Committee of MGM Medical College and M Y Hospital that reviewed & accorded approvals of the trials protocols were

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not as per requirement of schedule Y to Drugs & Cosmetic Rule as no lay person/legal expert were present in the meetings of the Ethics Committee.

Based on the findings of the investigating report, the concerned sponsors/companies investigator, Dr.Hemant Jain, Chairman of the Ethics Committee, Director of MGM Medical College & M Y Hospital have been issued show cause notice on 7.8.2012 and their replies received are under examination. As per the letter received from Deputy Drug Controller of India on 18.10.2012.

The Ethics Committee required the investigation report with supportive documents from the Drug Controller of India and action taken report from the Madhya Pradesh State Medical Council and State Health Authorities in the said matter.

The Ethics Committee observed that ethical irregularities have been observed in the conduct of the clinical trials done by the concerned doctors on the basis of the documents discussed in the meeting. Therefore, the following doctors 1) Dr.Raghulam Razdan; 2) Dr.Abhey Paliwal; 3) Dr.V.S.Pali; 4) Dr.Pali Rastogi; 5) Dr. Ujjwal Sardesai; 6) Dr.Anil Bharani; 7) Dr.Ashish Patel & 8) Dr. Hemant Jain are called for hearing with all supporting documents in the meeting scheduled subsequently.

The committee also decided that the concerned doctors be sent all relevant papers so that they can attend the meeting with a written reply.

7. Newspaper coverage regarding treatment provided by the sweeper & ward boys to injured patient at Bulandshahr's District Hospital, Uttar Pradesh (F.No. 80/2012)

The Ethics Committee considered the matter wherein the media (print as well as electronic) on 10.7.2012 had brought to the knowledge of the public and the concerned authorities that an injured patient brought to Bulandshahar District Hospital was provided treatment including application of stitches on the wounds by a sweeper and the ward boy under the supervision of the Chief Medical Superintendent. The Hon'ble Health Minister of U.P. State Shri Ahmed Hasan had ordered a probe to enquire into this matter by appointing Dr. Chiranji Lal, Director General of Health Services, U.P. as inquiring officer in the said matter. The above matter was brought to the notice of Dr.Sneh Bhargav, Chairperson, Ethics Committee and as suggested by the Chairperson, the Director General of Health Services, U.P. appointed to enquire into the matter was requested to provide the inquiry report as early as possible while appreciating the prompt action taken by the State Health Authorities. Accordingly, letter dt.11.7.2012 was sent to Director General of Health Services, U.P. and on completion of the inquiry, report has been received from DGHS, U.P. state on 7.8.2012. The

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Committee perused the inquiry report and found that the following doctors as alleged in the inquiry report were found to be lacking in their duties and the enquiry officer recommended action against them:-

- 1. All the 11 patients who received treatment and enquired by the said Committee confirmed that the doctors of District Hospital, Bulundshahar did not give proper treatment and referred them to District Hospital, Meerut. In one case, class iv employee, Shri Ayub (Bhisti), ward boy confirmed that he had applied stitches on the child as alleged by Shri Deepak, & Shri Vivek Kumar. The Chief Medical Superintendent, Dr.Shishir Kumar, confirmed the said incidence and the enquiry committee found him prime-facia guilty of not discharging his duties and of having no effective administrative control in the hospital.
- 2. Dr. R.Verma and Dr. Sachin Kumar who were on emergency duty on 3.7.2012 were found negligent in discharging their duties.

In view of the above mentioned findings of the Enquiry Report submitted by the DGHS,UP State, the Ethics Committee referred the matter to U.P. State Medical Council for immediate action against Dr. Shishir Kumar, Dr. R.Verma and Dr. Sachin Kumar under intimation to the Council.

8. <u>Complaint against Dr. Surender Pratap Singh working in Pushpanjali Medical</u>
<u>Centre under Dr. Vinay Kumar Aggarwal as alleged by Dr. Pankaj Singhal, Dr. M.C. Gupta & Dr. Babu K.V. (F.No. 463/2011)</u>

The Ethics Committee agreed with the decision of Delhi Medical Council which had issued warning to Dr.Vinay Agarwal of Pushpanjali Medical Centre for employing Mr. Surinder Pratap Singh, possessing only provisional registration, Dr. Vinay Aggarwal must ensure only those people with required qualification, experience and valid registration are employed.

9. Appeals by Sh. Ramesh Kumar Khatri Numbardar against(1) Order dated 30.12.2011 passed by Delhi Medical Council (DMC) (2) Order passed by Haryana State Medical and Dental Council (HSMDC) dated 12.10.2011 and against (3) DMC for referring the complaint to HSMDC and no action by both Councils.

The Ethics Committee considered the matter with regard to appeals by Sh. Ramesh Kumar Khatri Numbardar against (1) Order dated 30.12.2011 passed by Delhi Medical Council (DMC) (2) Order passed by Haryana State Medical and Dental Council (HSMDC) dated 12.10.2011 and against (3) DMC for referring the complaint to HSMDC and no action by both Councils and noted that all the three appeals relate to the patient care provided to Late Smt. Anita Khatri at Saxena Multi-speciality hospital, Sonipat and Ganga Ram Hospital. The Committee

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directed the Council to communicate following doctors to appear before the Committee with all relevant supportive documents at its ensuing meeting:-

Doctors of Saxena Multi Speciality Hospital, Sonipat

- 1.Dr.D.K.Srivastava
- 2.Dr.Garima Sharma
- 3.Dr.Divya Saxena

Doctors of Sethi Amar Hosapital

- 4.Dr.Anurag Arora
- 5.Dr.Anupama Sethi

Doctors of Ganga Ram Hospital

- 6. Medical Superintendent of the Hospital
- 7. Dr. Nitin

10. Appeal against order dated 27.07.2011 passed by Delhi Medical Council made by Dr. Bhupendra Nath Singh & Sh. U.K. Sinha. 10:30 AM

The Ethics Committee considered the Appeal against order dated 27.07.2011 passed by Delhi Medical Council made by Dr. Bhupendra Nath Singh & Sh. U.K. Sinha and noted that Dr. Khetrapal, Dr. Sinha, Dr. Vishal Sharma who were working at Indian Spinal Injury Centre, Vasant Kunj, New Delhi have given the written & oral submissions for the aforesaid matter. The Law Officer representing the said centre appeared before the Ethics Committee and informed that as he had not been provided with the appeal copy, his centre needed some The Committee observed that Law Officer and the hospital authorities had confirmed on 5.11.2012 with the Council that they would be attending the meeting of the Ethics Committee on 20.11.2012 and never requested for any documents pertaining to the appeal. This act was taken as primarily an action to unnecessarily delay the decision taking process. Ethics Committee taking into consideration the written and the oral submission of all the parties and observed that Delhi Medical Council's decision against Dr. Bhupendra Nath Singh who has submitted an application as 1st appeal is rejected. With reference to Dr. U.K. Sinha's appeal, the Committee upholds his request for enhancement of punishment to Dr. Bhupendra Nath Singh.

Based on records and the statement provided by Dr. Vishal, Dr. Khetrapal, Mr. Sinha & Dr. Bhupendra Nath Singh, the committee is of the view that Dr. Bhupendra Nath Singh has failed in discharging his duty to provide care to his patient as a primary consultant physician and his name may be removed from the Indian Medical Register for a period of one year in view of the violation of

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the Indian Medical Council (Professional Conduct, Etiquette & Ethics Regulations, 2002 under clause No.1.2.1 & 2.1.1.

The Ethics Committee observed that Dr. Vishal Sharma casualty medical officer who attended the patient both in the casualty and in the ward could not arrange, timely, appropriate medical care from the consultant physician. In view of the above, the Ethics Committee decided to issue a warning to Dr. Vishal Sharma to maintain good professional conduct in future.

The Ethics Committee observed that Dr. Sunil K. Khetrapal, Medical Superintendent, failed to put in place appropriate systems & processes to provide timely health care to the seriously ill patient. In view of the above, the Ethics Committee decided to issue a warning to Dr. Sunil K. Khetrapal to avoid such systems failure in future.

With reference to the poor quality of services provided by the hospital, the committee is of the opinion that the hospital authorities have failed to put in place appropriate systems & processes to address the seriously ill patient. However, the hospital did identify the failure of the doctor by terminating the services of Dr. Bhupinder Nath Singh. Since the said hospital is a Spinal Injuries Centre, it is possible that they may not be equipped to function as a multispeciality centre. The Principal Health Secretary, Govt. of NCT, Delhi may take necessary steps to review the functioning of the hospital to ensure quality health care delivery including care of seriously ill patients in Spinal Injury Centre, Vasant Kunj, New Delhi.

11. <u>Complaint against Dr. R. P. Singh, Eye Surgeon as alleged by Mr. P.C.Jain - Reg.</u>

The Ethics Committee considered the complaint against Dr. R. P. Singh, Eye Surgeon as alleged by Mr. P.C. Jain and noted that Dr. R.P.Singh was represented by his advocate Mr. Sandeep Kapoor who informed the Committee the inability of Dr. R.P. Singh to attend the Ethics Committee as his ailing father is in serious health condition under treatment on ventilator. The Ethics Committee considered the request of Dr. R.P. Singh and decided to give him an opportunity to appear before the Ethics Committee at its ensuing meeting. The Advocate representing Dr. Singh took the responsibility for the said doctor's presence on the prescribed date without fail.

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12. Complaint against various doctors of Melmaruvathur Adiparasakthi Institute of Medical Sciences, Melmaruvathur, Tamil Nadu giving false and misleading information regarding their working as full time faculty as alleged by CBI Case in RC.25(A)/2010 of ACB, Chennai.

The committee noted that the following doctors could not be contacted/ regretted to attend the hearing scheduled and decided to provide them one more opportunity to attend the Ethics Committee Meeting for hearing subsequently.

Sl. No.	Name of Doctors	Designation and Department
05	Dr.K.Jagadeesh	Sr. Resident, Department of Medicine
15	Dr. Chandan Jadhav. N	Sr. Resident, Department of General Surgery
17	Dr. C.V.P.K.B.H. Subrahmanyeswara Rao	Associate Professor Department of General Surgery
31	Dr.T.Manjunath	Professor, Deptt. Of Orthopedics

Dr. Manjunath was represented by his advocate, Mr. Gururaj, who submitted that Dr. Manjunath underwent cataract surgery on 7.11.2012 at Sushrutha Eye Hospital, Mysore and as advised by the treating doctor not to undertake long distance travel for a period of four weeks as mentioned in the medical record submitted by Mr. Gururaj, hence could not appear before the Ethics Committee. He further submitted the written explanation of Dr. Manjunath to the show cause notice issued and also ensured that Dr.Manjunath would attend before the Ethics Committee, if required, at its ensuing meeting.

Dr. K. Jagadeesh to be informed to appear before the Ethics Committee for submission of his statement, if desired so by him, failing which an ex-parte decision will be taken.

The Ethics Committee directed the Council to seek the assistance of local police authorities to trace the Dr. C.V.P.K.B.H. Subrahmanyeswara Rao & Dr. Chandan Jadhav, so that, the matter could be decided within the subsequent two meetings.

13. <u>Ineligibility for the post of Sr. Resident at Jawaharlal Nehru Institute of Medical Sciences, Imphal - Reg.</u>

The Ethics Committee observed that Dr. Khundongbam Bikramjeet Singh could not appear before the Committee and decided that one more chance may be given to Dr. K.B. Singh to appear before the Ethics Committee, failing which an ex-parte decision will be taken.

New Delhi, dated: 20/11/2012

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