

MINUTES OF THE MEETING OF TECHNICAL COMMITTEE HELD ON 25-03-2013 UNDER CHAIRMANSHIP OF DGHS FOR SUPERVISING CLINICAL TRIALS ON NEW CHEMICAL ENTITIES IN THE LIGHT OF DIRECTIONS OF THE HON'BLE SUPREME COURT OF INDIA ON 03.01.2013

Present:

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| 1. | Dr. Jagdish Prasad,
Director General of Health Services. | Chairman |
| 2. | Dr. Ranjit Roy Chaudhury,
National Professor of Pharmacology,
Former Member, BOG – MCI,
Y-85, Hauz Khas, New Delhi-110016 | Member |
| 3. | Dr. Yashpal Sharma,
Prof. & Head, Dept. of Cardiology,
PGIMER, Chandigarh. | Member |
| 4. | Dr. Nikhil Tandon,
Professor, Dept. of Endocrinology & Metabolism,
AIIMS, New Delhi. | Member |
| 5. | Dr. Kamlakar Tripathi,
Prof., Dept. of Medicine,
Institute of Medical Sciences, Banaras Hindu
University,
Varanasi – 221005. | Member |
| 6. | Dr. P.K. Dalal,
HOD, Dept. of Psychiatry,
CSMU Medical College, Lucknow. | Member |
| 7. | Dr. Raju Titus Chacko,
Prof. & Head,
Dept. of Medical oncology,
CMC, Vellore. | Member |
| 8. | Dr. B.L. Sherwal,
Director-Professor, Dept. of Microbiology, LHMC &
Associated Hospitals, New Delhi | Member |
| 9. | Dr. Nandini Kumar,
Former Deputy Director General Sr. Grade,
Co-Investigator, NIH Bioethics Project, National
Institute of Epidemiology, ICMR, Chennai | Member |

From CDSCO:

1. Dr. G.N. Singh,
Drugs Controller General (India)
2. Sh. A.K. Pradhan,
Deputy Drugs Controller (India)
3. Dr. Ravi Kant Sharma,
Assistant Drugs Controller (India)

DCG(I) welcomed the members and briefed them about the outcome of the first meeting of the Technical Committee which was held on 27.02.13. The minutes of the first meeting approved by the Chairman were already circulated to the members.

The Chairman stated that this Technical Committee plays an important role for ensuring the scientific and ethical conduct of clinical trials in the country. The Technical Committee will give recommendations to the Apex Committee constituted under Chairmanship of Secretary (HFW) for supervision of clinical trials in the country.

The Chairman also mentioned that the Ministry of Health & Family Welfare has constituted an expert committee under the Chairmanship of Prof. Ranjit Roy Chaudhury for formulating policy, guidelines and SOPs for approval of clinical trials and new drugs. The committee is already engaged in deliberation for framing such policy, guidelines and SOPs which are very important for approval of clinical trials and new drugs in the country.

As regards to the concerns on certain clauses of the recent amendment in the Drugs &Cosmetics Rules related to examination of Serious Adverse Events occurring during clinical trials, Chairman informed that the Apex Committee, in the last meeting held on 27.2.2013, has decided that the representations of stakeholders in this regard along with the recommendations of this Technical Committee shall be placed before the Drug Technical Advisory Board (DTAB) for its consideration and recommendations. Experts and other stakeholders may send further representation in this regard, if any, for consideration of DTAB.

During the first meeting, the Technical Committee deliberated on various issues like approval of clinical trials of new drugs & INDs including Global Clinical Trial applications through New Drug Advisory Committees (NDACs) and IND Committee, requirement of an IT enabled database of clinical trials alongwith the recent amendments in Drugs and Cosmetics Rules to strengthen the regulation of clinical trial in the country especially the amendment related to the examination of reports of SAEs including death occurring in clinical trial.

As advised by the committee in its last meeting, the details of clinical trials proposals evaluated by NDACs and IND committee alongwith their

recommendations were forwarded to the members of committee through e-mail for review. Committee members mentioned that the various details related to large number of global clinical trials including clinical trials of NCEs received by them are under review. The members stated that they will take some more time to review these details. Some of the members also requested that details of such clinical trials including the details of clinical trial proposals evaluated recently by the NDACs shall be forwarded to the members through e-mail.

The committee was apprised about the updated status of evaluation of various applications of new drugs and clinical trials by the twelve New Drugs Advisory Committees (NDACs) as under:-

Out of total 996 applications received for approval of clinical trials and various categories of new drugs including biological and fixed dose combinations, the NDACs have, so far, evaluated 727 applications in 55 meetings. Out of these 727 applications, 248 were related to approval of Global Clinical Trials (GCTs) including clinical trials of new chemical entities. Of these 248 GCT applications, NDACs after deliberation have recommended for approval of 210 applications and have not recommended for approval in case of the remaining 38 applications.

Since 03.01.2013, CDSCO has received a total of 60 applications for approval of clinical trials and new drugs including biological and fixed dose combinations. Since then the New Drug Advisory Committees have met a total of 8 times and have evaluated 89 proposals of clinical trials and New Drugs. Out of which 14 applications pertain to global clinical trials. Out of these 14 applications of global clinical trials, NDAC has recommended for approval in 9 cases.

DCG(I) desired that in case of global clinical trial of any New Chemical or Biological Entity (NCE) discovered outside India, at the time of granting permission for such trial, a condition should be stipulated in the permission letter that as and when the chemical/biological entity is approved and launched in other country, the sponsor/applicant shall be required to file application seeking marketing of the same drug in Indian market. The members of the committee agreed to the above suggestion and expressed that the same should be implemented immediately to make such drug available in the country for which Indian patients have undergone clinical trials for development and approval of the drug.

The Committee was apprised about various actions being taken by CDSCO to monitor the conduct of clinical trials in the country including activities like examination of reports of SAEs and registration of Ethics Committees.

CDSCO through its six Zonal offices located in Mumbai, Chennai, Kolkata, Hyderabad, Ghaziabad and Ahmedabad is actively involved in regular inspections of sites of clinical trials. Since January, 2013 these offices have conducted more than 400 inspections at various clinical trial sites in various hospitals /medical colleges/institutions across the country. The office of DCG (I) has received the

reports of these inspections recently which are under examination. The committee desired that major findings/non-compliance, if any, of these inspections shall be placed before the committee for taking further necessary actions in the matter.

The Committee further desired that the zonal offices of CDSCO should keep the records of the details of names, qualification etc. of Investigators, and clinical trial sites falling under their Jurisdiction and also constitute Expert Committees to conduct clinical trial inspections. The Expert Committee along with drug inspectors shall visit the clinical trial sites at least once a year to verify the compliance with Schedule Y, GCP Guidelines and other applicable regulatory requirements.

As regards the examination of reports of Serious Adverse Events (SAEs) of deaths occurring in clinical trials, the Committee was apprised that a panel of 48 experts have so far been identified. In pursuance of the provisions of Appendix XII of Schedule Y of the Drugs & Cosmetics Rules three Independent Expert Committees each comprising seven experts from the expert panel have been constituted by DCG(I) to examine the reports of SAEs of deaths. On need basis more Expert Committee may be constituted. The expert panel may also be expanded, if needed to ensure examination of reports of SAEs of deaths within the prescribed timelines of three months of their occurrence.

As per newly introduced Rule 122DD, no Ethics Committee shall review and accord its approval to a clinical trial protocol without prior registration with DCG(I). The said rule also specifies guidelines and requirements for registration of Ethics Committee. Accordingly, DCG(I) office has started receiving applications for registration of Ethics Committees. Till date, CDSCO has received 307 applications for the registration of Ethics Committees which includes applications from Independent as well as Institutional Ethics Committees. The office of DCG(I) is examining these applications for their registration.

The committee is of the view that only Institutional Ethics Committee would review and accord approval to any clinical trial protocol for the respective Institute. As regards Bioequivalence/ bioavailability (BA/BE) studies conducted in Bioequivalence study centres in various parts of the country, the committee is of the view that such Bioequivalence/bioavailability study protocols may also be reviewed and approved by the Institutional Ethics Committees of the institutions located in the same area where the bioequivalence study centres are located depending on its scientific feasibility.

Meeting ended with the vote of thanks to the Chair.