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**MINUTES OF THE THIRD MEETING OF THE APEX COMMITTEE HELD ON 29-04-2013 UNDER THE CHAIRMANSHIP OF SECRETARY, HEALTH AND FAMILY WELFARE FOR SUPERVISING CLINICAL TRIALS ON NEW CHEMICAL ENTITIES IN THE LIGHT OF DIRECTIONS OF THE HON'BLE SUPREME COURT OF INDIA DATED 03.01.2013**

**Present :**

1. Shri Keshav Desiraju,  
Secretary,  
Department of Health and Family Welfare.
2. Dr. V M. Katoch,  
Secretary ,  
Department of Health Research,  
and Director General, ICMR.
3. Dr. Jagdish Prasad,  
Director General of Health Services,  
New Delhi
4. Dr. Arun K.Panda  
Joint Secretary,  
Ministry of Health & Family Welfare

**Special Invitees:**

1. Shri R.K. Jain,  
Addl. Secretary & DG (CGHS)  
Ministry of Health and Family Welfare.
2. Dr. G.N. Singh,  
Drugs Controller General (India)

The Apex Committee was apprised that the third meeting of the Technical Committee was held on 29.04.2013 under the Chairmanship of DGHS and the committee deliberated on various issues related to registration of Independent Ethics Committees, recommendations of NDACs on 33 Global Clinical Trial applications,

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status of evaluation of applications by NDACs, examination of Serious Adverse Events (SAEs) in clinical trials etc.

The minutes of the third meeting of Technical Committee was circulated to the members.

The committee was also apprised that in compliance to its recommendations in the first meeting held on 27.02.2013, the details of clinical trials including study titles, sites and investigational products of 145 global clinical trials which were permitted by CDSCO in 2012 and the details of 243 Institutional Ethics Committee registered so far with CDSCO have been uploaded on CDSCO website.

As regards to the Ethics Committee registration, the committee was informed that CDSCO is presently registering only Institutional Ethics Committees as recommended by the Apex Committee in its second meeting. The Technical Committee however, noted in its meeting that Schedule Y of the Drugs & Cosmetics Rules permits acceptance of approval granted to a clinical trial protocol by an Independent Ethics Committee (constituted as per Appendix VIII of the schedule Y). Further, Bioavailability / Bioequivalence studies of approved drugs are not same as clinical trials of new drugs. Therefore, the Technical Committee agreed that applications for registration of Independent Ethics Committees can also be considered for approval subject to the condition that these Independent Ethics Committees should be allowed to review and approve only protocols for Bioavailability/ Bioequivalence (BA/BE) studies of approved drug molecules, and not the protocols of clinical trials. These Independent Ethics Committees will be further subject to intense monitoring by the zonal offices of CDSCO through inspection within 6 to 9 months of the grant of registration to check for the compliance of these committees. In case of any non-compliance by these committees, actions like suspension or cancellation of registration will be undertaken.

The Apex Committee after deliberation agreed to the recommendations made by the Technical Committee as above regarding registration of Independent Ethics Committee with the aforementioned conditions.

The Apex Committee deliberated on the recommendations of NDACs on 33 applications for approval of Global clinical trials and recommended that details of Investigators and study sites, no. of subjects involved alongwith details of exemption of requirements as per Drugs & Cosmetics Rules, if any, considered for these 33 cases, should be placed before the Apex Committee for further consideration in the matter.

The committee was apprised of the deliberations of Independent Expert Committees for examination of Serious Adverse Events (SAEs) of deaths occurring during clinical trials. These committees have opined that examination of SAEs of deaths to recommend the cause of deaths and the quantum of compensation in case of related deaths, essentially involves several steps. Hence, it is difficult to complete the examination within the prescribed timelines of one month. Therefore, the timelines for the Expert Committee should be extended from the existing one month to three months and the timelines for taking final decision on such cases by DCG(I) should also be extended from the existing three months to six months.

The Committee recommended that the issues related to overall process of reporting and prescribed timelines for examination of Serious Adverse Events including deaths occurring during clinical trial, to be followed by the Investigators, Sponsors, Ethics Committees, Independent Expert Committees & the DCG(I) should be placed before the Drug Technical Advisory Board for consideration and recommendation in the matter.

The committee noted the status reports with respect to various other activities like evaluation of applications by NDACs, registration of Ethics Committees, monitoring of clinical trials by zonal offices of CDSCO etc. as mentioned in the minutes of the third meeting of Technical Committee. Details are as under:

- The zonal offices of CDSCO have already been directed to maintain the records of the details of names, qualification etc. of Investigators, and clinical trial sites falling under their jurisdiction and also to constitute Expert Committees for visiting the clinical trial sites at least once in a year to verify the compliance of the Investigators, clinical trial sites as per Schedule-Y of Drugs & Cosmetics Rules,

GCP Guidelines and other applicable regulatory requirements. The Technical Committee recommended that the zonal offices should submit their reports every 3 months to DCG(I). The zonal office should also be provided with a checklist to be followed by them during such inspections.

- As regards the status of evaluation of applications by NDAC, the Committee noted that the NDACs have since held 64 meetings and have evaluated 749 out of 1021 applications of various categories of new drugs including biological, Fixed Dose Combinations and clinical trials. Out of these, 274 applications were related to Global Clinical Trials and the NDACs have recommended 236 cases for approval. Since 03.01.2013, CDSCO has received a total of 91 applications of clinical trials and new drugs including biological and fixed dose combinations. Since then the New Drugs Advisory Committees have met a total of 17 times and have evaluated 259 applications. Out of which, 43 applications were global clinical trials.
- Since 03.01.2013, clearance of 199 proposals for protocol amendments, grant of Test License, NOC for export of biological samples and addition of study sites related to global clinical trials permitted before the said date, have been considered and granted by CDSCO.
- As regards to the status of registration of ethics committees, the Committee was informed that the office of DCG(I) received 755 applications. Out of this about 550 applications are from Institutional Ethics Committees and about 200 applications are from Independent Ethics Committees. CDSCO has processed 295 applications from Institutional Ethics Committees, out of which registration has been granted to 260 Committees and remaining 35 committees have been asked to submit further information.

The meeting ended with the vote of thanks to the chair.