

**MINUTES OF THE SECOND MEETING OF THE APEX COMMITTEE
HELD ON 28-03-2013 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. Special Invitee
Shri R.K. Jain,
Addl. Secretary & DG(CGHS)
Ministry of Health and Family Welfare.
5. Dr. G.N.Singh.
Drugs Controller General of (India)
FDA Bhawan New Delhi

The Apex Committee was apprised that the Second meeting of the Technical Committee was held on 25.03.2013 under the Chairmanship of DGHS and it reviewed the status of evaluation of various applications for approval of new drugs and clinical trials by the 12 New Drug Advisory Committees (NDACs) along with other activities at CDSCO in respect of approval of new drugs and clinical trials. The minutes of the Technical Committee were circulated to the members for their perusal.

The committee agreed to the various recommendations of the Technical Committee which are as under.

1. In case of Global Clinical Trial of any New Chemical or Biological Entity (NCE) discovered outside India, at the time of granting permission for the trial, a condition should be stipulated that as and when the Chemical / Biological Entity is approved and launched in other country, the sponsor / applicant should file application for marketing the drug in India also.

The committee further recommended that in such cases, before granting permission for any global clinical trial, DCG(I) should obtain an undertaking from the sponsor / applicant in this regard.

2. CDSCO zonal office should keep the records of the names, qualifications of the investigators, clinical trials sites and an expert committee along with the Drug Inspector should visit the respective site falling under their jurisdiction at least once a year to verify the compliance to the applicable regulatory requirements.
3. The Institutional Ethics Committee should review and accord approval to any clinical trial protocol for the respective Institute. For the Bioequivalence/ bioavailability (BA/BE) studies conducted at Bioequivalence study centers in various parts of the country, the study protocols should be reviewed and approved by the Institutional Ethics Committees of Medical College / Hospitals / institutions located in the same area where the bioequivalence study centers are located. The present practice of review and approval of BA / BE study protocols by Independent Ethics Committees functioning outside any institutions should be discontinued within 60 days.

The committee noted that zonal offices of CDSCO have conducted more than 400 inspections at clinical trial sites in the country. The findings of these inspections will be placed before the Technical Committee after due processing for its consideration.

Committee also noted that the NDACs have since held 55 meetings and have evaluated 727 applications out of 996 applications received by the CDSCO. Out of

these 248 applications were related to Global Clinical Trials and the NDACs have recommended approval in 210 cases. 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 Drugs 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 of global clinical trials, NDAC has recommended for approval in 9 cases.

As regards the examination of Serious Adverse Events (SAEs) of deaths occurring in clinical trials, the committee was apprised that a panel of 48 experts has been constituted. Three independent Expert Committees, each comprising of seven experts from the panel, have been constituted by the DCG(I) to examine reports of SAE of the death.

The process of registration of Ethics Committees by CDSCO has since been initiated as per the requirements and guidelines specified in newly introduced rules 122 DD and Appendix VIII of Schedule Y of D&C Rules. The Apex committee was informed that CDSCO has received about 450 applications for registration of Institutional as well as Independent Ethics Committees which are under examination.

The committee was further apprised that in regard to the payment of compensation to subjects who have suffered SAE during clinical trial, the office of DCG(I) informed that out of 80 cases of SAEs of related deaths occurred during clinical trials between January, 2005 to June, 2012, payment of compensation has already been made by the companies in 45 cases. Matter is being further pursued with the remaining companies for making the payment of compensation.

The Committee was also informed about a case of death of a healthy volunteer in a bioequivalence of study conducted with an anti-hypertensive drug by M/s. Veeda Clinical Research, Ahamdabad. The matter was investigated by a committee constituted by DCG(I). Based on findings of the investigation, DCG(I) has suspended the permission granted to the firm to conduct BA / BE study. It was also informed that DGHS has constituted a three member expert committee to investigate the matter

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further to take final action in the matter. The committee desired that such cases of Serious Adverse Events in healthy volunteer should be brought to their notice.

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