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MINUTES OF THE FOURTH MEETING OF THE APEX COMMITTEE HELD ON 31-05-2013 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. Jagdish Prasad,
   Director General of Health Services,
   New Delhi

3. 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 briefed that the fourth meeting of the Technical Committee was held on 30.05.2013 under the Chairmanship of DGHS and the committee deliberated on various issues related to registration of Independent Ethics Committees, recommendations of NDACs on Global Clinical Trial applications, examination of Serious Adverse Events (SAEs) in clinical trials etc. The minutes of the fourth meeting of the Technical Committee were also circulated to the members.

The committee was apprised that the details of investigation sites, no. of subjects along with recommendation of NDAC in respect of 33 global clinical trials which was deliberated in the last meeting of the committee held on 29.04.13, was discussed by the technical committee. The Technical Committee also deliberated the recommendations of IND Committee in respect of 8 clinical trials of INDs. However, the Technical Committee recommended that the office of DCG(I) should prepare a format in consultation with the members of the committee for the purpose of the submission of the details of all clinical trial proposals including global clinical trials, clinical trials of new drugs, biologicals, medical devices, INDs along with recommendations of NDACs / IND Committee.

The Apex Committee agreed to the above recommendations of the Technical Committee.

The Committee was further apprised that Zonal offices of CDSCO have conducted inspections at various clinical trial sites in the country and submitted the inspection reports to CDSCO. A total of 530 inspection reports have been received by CDSCO which are under examination. So far show cause notices have been issued in 140 cases.

As regards the payment of compensation in cases of clinical trials related deaths, the committee was apprised that out of 89 cases of SAEs of related deaths occurred during clinical trials between January, 2005 to December, 2012 compensation has already been paid by the companies in 72 cases. In 10 cases, the amount has been decided and payments by the companies are under process. The matter is being further pursued with the companies in the remaining cases for payment of compensation. In one case, in spite of efforts by Investigator and his team including the advertisements in newspapers, the whereabouts of the subject could not be traced and the payments could not be made by the company. The committee opined in such cases the compensation amount should be kept with the institution involved in the clinical trial and not with the company.

As regards the registration of Independent Ethics Committee, the committee members were informed that as already decided, the Independent Ethics Committees

are being registered with CDSCO subject to the condition that they will review and accord approval to only the bioequivalence / bioavailability studies of approved new drug molecule. However, concerns have been raised with respect to the periodic review of ongoing clinical trials already approved by such Independent Ethics Committees.

The Technical Committee deliberated the issue and recommended that the Independent Ethics Committees should be allowed to make periodic review of the clinical trials already approved by them. However, no new clinical trials shall be reviewed and approved by such Independent Ethics Committees.

The Apex Committee agreed to the above recommendation of the Technical Committee.

As regards the status of applications for Ethics Committee registration, the committee was informed that so far a total of 808 applications for registration of Ethics Committees have been received which include applications from both Institutional as well as Independent Ethics Committees. Out of this, so far CDSCO has processed 578 applications and registration has been granted to 386 Committees, one case was rejected and remaining 191 committees have been asked to submit further information.

As regards the formula for deciding compensation in clinical trial related injury or death, the Apex Committee was informed that, the independent Expert Committees constituted for examination of SAEs of death, in their two meetings held on 23.04.2013 and 07.05.2013, deliberated in detail the criteria to be considered for deciding the quantum of compensation in trial related deaths and devised a general formula for the purpose. The committee was apprised about the details of the formula. It was also informed that the Technical Committee in its fourth meeting has deliberated the formula suggested by the independent Expert Committee and they have agreed to the formula in general with the opinion that the base amount should be 6 Lakh instead of 4 Lakh. In the case of high risk subjects the compensation amount should be 3 Lakh even if a subject dies because of the disease.

The Apex Committee opined that the issue under consideration is the payment of compensation in the case of death related to clinical trial of a subject while death due

to any disease is a separate issue. The criteria for deciding the compensation in case of trial related deaths should be defined with logical input. The committee however opined that the issue may be further deliberated after receiving the final decision from the independent Expert Committee in this regard. Committee also desired that guidelines / criteria, if any, followed by other countries for deciding the quantum of compensation in case of clinical trial related deaths may be looked into while preparing the guidelines in this regard.

The committee was also apprised of the status reports with respect to various other activities which were also placed before the Technical Committee as under:

- Out of total 1065 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 814 applications in 68 meetings. Out of these 814 applications, 288 relate to the approval of Global Clinical Trials (GCTs) including clinical trials of new chemical entities. Of these 288 applications, NDACs after deliberation have recommended for approval of 248 applications and have not recommended for approval in case of the remaining 40 applications.

  Since 03.01.2013, CDSCO has received a total of 119 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 21 times and have evaluated 311 proposals of clinical trials and New Drugs. Out of which 57 applications pertain to global clinical trials. Out of these 57 applications of global clinical trials, NDAC has recommended for approval in 50 cases.

- Clearance of a total of 203 proposals for protocol amendments, grant of test license, NOC for export of biological samples and addition of study sites related to global clinical trials approved before 03.01.2013, have been considered and NOCs/Test Licenses were granted by CDSCO.

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

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