MINUTES OF THE SIXTH MEETING OF THE APEX COMMITTEE HELD ON 30-07-2013 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, DHR & DG ICMR
   New Delhi

3. Dr. Jagdish Prasad,
   Director General of Health Services,
   New Delhi

4. Shri R.K. Jain,
   Addl. Secretary & DG (CGHS)
   Ministry of Health and Family Welfare

5. Dr. Arun K.Panda
   Joint Secretary,
   Ministry of Health & Family Welfare

6. Dr. G.N. Singh,
   Drugs Controller General (India)

The Apex Committee was apprised that the sixth meeting of the Technical Committee was held on 25.07.2013 under the Chairmanship of DGHS and that Committee deliberated on different issues related to different categories of Clinical Trials including Investigational New Drugs (IND), Global Clinical Trials etc. It also considered the issue of expansion of panel of experts in various therapeutic areas for NDACs.

The minutes of the sixth meeting of Technical Committee were circulated to the members.

The Committee noted that the Technical Committee in its sixth meeting had examined the details of 40 proposals of clinical trials of new drugs (including fixed dose combinations, subsequent new drugs, biological), medical devices and global clinical trials. Out of these 40 proposals, there were 4 cases of clinical trials of New drugs, 23 cases of Global Clinical trials. The remaining cases were clinical trial proposals related to fixed dose combinations, subsequent new drugs, biological products, medical devices and institutional trial. Details of these 40 cases are **annexed.**

The Committee noted that the Technical Committee while examining these proposals observed that in one of the proposals of Dr. Saibal Mukhopadhyay, G.B Pant Hospital, New Delhi for conducting clinical trial with Ambrisentan + Tadalafil (case no. 5), only two NDAC experts were present during the meeting and have recommended for the proposal. The Technical Committee did not recommend for giving permission for these cases as these were recommended by only two members of NDAC and desired that these should be further deliberated by the concerned NDACs with a proper representation of members.

The Committee noted the following observations/ recommendations of the Technical Committee.

1. In one case of Tenecteplase (TNK-TPA) of M/s Gennova Biopharmaceuticals Limited (case no. 36), two Psychiatric members along with one Pharmacologist of the NDAC had recommended for the proposed study. However, the study should be assessed and reviewed by Neurologists.
2. In case of the proposal of Japanese Encephalitis Purified inactivated Vaccine [JE-PIV] of M/s Biological E. Limited (case no. 35), one of the recommended clinical sites by NDAC is Sant Dyaneshwar Medical Education Research Centre, Pune. One member mentioned that there are no cases of Japanese Encephalitis in Pune area. It was proposed that the clinical trial sites should be in Gorakhpur and Varanasi, Uttar Pradesh. It was also stated that in Exclusion Criteria the history of any clinical manifestation of either Japanese Encephalitis or Dengue or Yellow Fever is included which has no relevance in Indian scenario.

3. In view of the above reasons, the Technical Committee recommended that the proposal of Tenecteplase (TNK-TPA) of M/s Gennova Biopharmaceuticals Limited (case no. 36) shall be further deliberated by concerned NDAC for review by Neurologists. 50% of the clinical trial sites should be Govt. Hospitals / Medical Colleges.

4. In case of proposal of Japanese Encephalitis Purified Inactivated Vaccine [JE- PIV] of M/s Biological E. Limited (case no. 35), the Technical Committee recommended that clinical trial sites from Gorakhpur and Varanasi, Uttar Pradesh should also be included in addition to Kolkata and Pune.

5. Further, the Committee recommended that 50% of clinical trial sites should be at Government Hospitals / Medical Colleges. The clinical trial sites should also have Institutional Ethics Committee and should also be geographically distributed across the country.

6. In the following four proposals for Global Clinical Trials, Dr. Mathew Thomas is an Investigator at Health Research Centre, TC 1/1668, Yamuna, Navarangam Lane-North-2, Medical College P.O., Trivandrum, Kerala.

S. No.	Name of Drug	Name of the applicant	Proposal no
1	Fluticasone propionate/ salmeterol combination and fluticasone propionate	PAREXEL International Clinical Research Pvt. Ltd.	CT/79/12-DCG (I)
2	Baricitinib (LY3009104)	M/s Eli lilly	CT/212/12-DCG (I)
3	Baricitinib (LY3009104)	M/s Eli lilly	CT/205/12-DCG (I)
4	Blisibimod	Pharm-Olam International (India) Pvt. Ltd	CT/02/13-DCG (I)

The Technical Committee recommended that this site should be re-examined by the NDAC and these trials should not be allowed at this centre till NDAC re-examines the facilities etc available at this site.

After deliberation, the Apex Committee agreed to the recommendations of Technical Committee for approval of 38 cases except for the proposals mentioned at case no. 5 & 36 which shall be re-examined by the respective NDACs.

Further, the Apex Committee also deliberated on the following recommendations made by the Technical Committee as under:

1. The list of approx. 2000 experts identified for NDAC expansion may be forwarded to Dr. Ashok Kumar Das, Professor of Medicine & Medical Superintendent, JIPMER, Puduchery who will finalize the list of experts in consultation with other members. The experts selected may be of the level of Associate Professors to Professors, Professors & HODs of the Govt Medical Colleges / Hospitals having 5 years to 8 years experience in the relevant field.

   The Apex Committee recommended that experts at the level of Assistant Professor may also be considered.

2. The fees submitted by the applicants for seeking approval of new drugs and clinical trials shall be increased to Rs. 2.5 lakh in case of marketing authorizations and Rs. 1.5 lakh in case of global clinical trials.

   The Committee opined that this requires amendment in Drugs & Cosmetics Rules. Proposal to amend the relevant provisions of D&C Rules in this regard may be forwarded to DTAB for its consideration.

3. The members of the Technical Committee should be provided @ Rs.5000.00 per meeting as sitting fees.

   The Committee opined that the concurrence of Integrated Finance Division (IFD), MOHFW should be obtained in this regard.

Meeting ended with a vote of thanks to the Chair.