

MINUTES OF THE 6th MEETING OF TECHNICAL COMMITTEE HELD ON 25-07-2013 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. Yashpaul Sharma,
Prof. & Head, Dept. of Cardiology,
PGIMER, Chandigarh | Member |
| 3. | Dr. Rajutitus Chacko,
Prof. & Head, Dept. of Medical Oncology, CMC,
Vellore. | Member |
| 4. | Dr. Nandini Kumar,
Former Deputy Director General Sr. Grade,
ICMR. | Member |
| 5. | Dr. Ashok Kumar Das,
Director – Professor of Medicine & Medical
Superintendent,
JIPMER, Puduchery-605006. | Member |
| 6. | Dr. Kamlakar Tripathi,
Prof., Dept. of Medicine,
Institute of Medical Sciences,
Banaras Hindu University, Varanasi – 221005. | Member |
| | | Member |

From CDSCO:

1. Dr. G.N. Singh,
Drugs Controller General (India)
2. Sh.R. C.Chandrashekar
Deputy Drugs Controller (India)

DCG(I) welcomed the members and briefed them about the outcome of the fifth meeting of the Technical Committee which was held on 01.07.13. The minutes of the fifth meeting approved by the Chairman were already circulated to the members.

DCGI informed the Chairman that in the earlier committee meeting held on 01.07.13, the committee had recommended that a panel of experts of various therapeutic

areas from Govt. medical college / institutes from across the country should be prepared by CDSCO and forwarded to the Chairman for his consideration.

In view of above, DCGI placed list of approx. 2000 experts identified from Govt. medical colleges / institutes as well as from Private Institutions across the country in respect of Oncology & hematology, Cardiovascular, renal, Metabolism & endocrinology, Antimicrobial, Antiparasitic& Antifungal, Antiviral, Reproductive & Urology, Gastroenterology &Hepatology, Dermatology & Allergy, immunology, Pulmonary, Neurology &Psychiatry, Anesthetics & Rheumatology, Ophthalmology and Vaccines in order to expand the NDACs.

The Chairman recommended that the list of proposed experts may be forwarded to Dr. Ashok Kumar Das, Professor of Medicine & Medical Superintendent, JIPMER, Puduchery. Then he requested Dr. Das to finalize the list of experts in consultation of other members. He also suggested that 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. He also requested Dr. Das to prepare list of various therapeutic areas such as Oncology, Hematology, Cardiovascular, Renal, Metabolism & Endocrinology, Antimicrobial, Antiparasitic & Antifungal, Antiviral, Reproductive, Urology, Gastroenterology & Hepatology, Dermatology, Allergy, Immunology, Pulmonary, Neurology, Psychiatry, Anesthetics, Rheumatology, Ophthalmology, Vaccines etc. It was also decided in the meeting that the other members may also prepare and forward list of experts to Dr. Das for compilation.

The Chairman had also suggested that the experts may also be selected from Delhi based hospitals / medical colleges such as Maulana Azad Medical Colege, GTB Hospital, Safdarjang Hospital, AIIMS etc.

Thereafter, 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 as per the format approved by the committee in its fourth meeting were already circulated to the members through e-mail. Out of these 40 proposals there were 4 cases of clinical trials of New drugs, 23 cases of Global Clinical trials and remaining were clinical trial proposals related to fixed dose combinations, subsequent new drugs, biological, medical devices and institutional trial. List of these proposals is as under:

S.No.	Drug	Applicant	Category
1.	Ibutilide Fumarate	Zuventus Helathcare	New Drugs
2.	Trimethobenzamide	Lupin	New Drugs
3.	Vilazodone	MSN Labs	New Drugs
4.	Bimatoprost	Allergan	New Drugs
5.	Ambrisentan + Tadalafil	Dr. Saibal Mukhopadhyay, G.B Pant Hospital, Delhi	Institutional Clinical Trial

6.	GRC 17536	Glenmark Pharma	IND
7.	Conivaptan	PPD Pharma	GCT
8.	Tobramycin + Dexamethsone	Semler Research	GCT
9.	Diclofenac Sodium	Amneal Pharma	GCT
10.	Fluticasone + Salmeterol	Parexel	GCT
11.	Fosaprepitant	MSD Pharma	GCT
12.	Vancomycin	Dr. Reddy's Labs	GCT
13.	Baricitinib	Eli Lilly	GCT
14.	Baricitinib	Eli Lilly	GCT
15.	Baricitinib	Eli Lilly	GCT
16.	BEZ235	Novartis Healthcare	GCT
17.	Ciclosporin	Chiltern International	GCT
18.	Ciprofloxacin + Dexamethasone	Cliantha	GCT
19.	Brexpiprazole	Quintiles	GCT
20.	RO4917838	Quintiles	GCT
21.	RO4917838	Quintiles	GCT
22.	Fluvestrant	Quintiles	GCT
23.	LY2228820	Eli Lilly	GCT
24.	Blisibimod	Pharm-Olam	GCT
25.	Flocinolone Acetonide	Excel Life Sciences	GCT
26.	Brinzolamide	GVK Biosciences	GCT
27.	GSK 1437173A	Glaxo Smithkline	GCT
28.	Dulaglutide	Eli Lilly	GCT
29.	Dulaglutide	Eli Lilly	GCT
30.	Brinzolamide	Sun Pharma	Fixed Dose Combination
31.	Ondansetron	Inventia Healthcare	Subsequent New Drugs
32.	Hemophilus Influenzae Type B Conjugate Vaccine	Cadila Healthcare	Biological (Vaccine)
33.	10-valent Pneumococcal Conjugate Vaccine	Serum Institute	Biological (Vaccine)
34.	Diphtheria and Tetanus Vaccine	Biological E. Ltd.	Biological (Vaccine)
35.	Japanese Encephalitis Purified Inactivated Vaccine	Biological E. Ltd.	Biological (Vaccine)
36.	Tenectaplastase	Gennova	Biological (Recombinant)
37.	Teriparatide	Intas	Biological (Recombinant)
38.	Darbopoetin Alfa	Reliance	Biological (Recombinant)
39.	Ranibizumab	Intas	Biological (Recombinant)
40.	Cryoablation System for	India Medtronic	Medical

	Catheter Ablation of Cardiac Arrhythmias		Device
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The committee observed that in one of the above proposals of Dr. Saibal Mukhopadhyay, G.B Pant Hospital, N 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 Committee did not recommend for giving permission in this case mentioning that it has already decided in its last meeting held on 01.07.13 that the cases recommended by only two members of NDAC shall be further deliberated by concerned NDACs with a proper representation of members during the meeting.

It was pointed out by a member in the meeting that 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 have recommended for the proposed study. However, the study should be assessed and reviewed by Neurologists. Further, the proposed study has one of the clinical trial sites is at S.P Medical College and AG of Hospitals, Bikaner.

It was also pointed out that in case of proposal of Japanese Encephalitis Purified inactivated Vaccine [JE- PIV] of M/s Biological E. Limited (case no. 35) one of the recommended clinical site by NDAC is Sant Dnyaneshwar Medical Education Research Centre, Pune and the member mentioned that there are no cases of Japanese Encephalitis in the Pune area. What is the justification for Encephalitis in Pune. It was proposed that the clinical 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.

In view of above, the 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 and the clinical trial sites should be 50 % Govt. Hospitals / Medical Colleges.

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

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

It was also pointed out by the member that 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.

SNo.	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 Committee recommended that this site should be reexamined by the NDAC and these trials should not be allowed at this centre till NDAC reexamine the facilities etc available at this site

The Committee was informed that as per Drugs and Cosmetics Rules the applicants has to deposit T-Challan of Rs.50,000/- in the Govt. account for the grant of permission for marketing authorizations of new drug and in case of subsequent applications received after one year of approval of a new drug, T-Challan of Rs. 15000/- is to be deposited. In case of proposals of clinical trials, the applicants has to deposit T-Challan of Rs.50,000/- in the Govt. account for Phase I trial and Rs.25,000/- for Phase II and Phase III trials. The committee recommended that the fees shall be increased to 2.5 lakhs in case of marketing authorizations and 1.5 lakhs in case of global clinical trials.

The committee further recommended that the members of the Technical Committee should be provided @ Rs.5000.00 per meetings as sitting fees.

The Chairman also noted that some of the members of the committee are not coming to attend the meeting on regular basis. He, therefore, informed DCGI that a notice may be given to such members if they do not come consecutively in three meetings and they shall be excluded from the committee and be replaced by other members.

Meeting ended with the vote of thanks to the Chair.