

**MINUTES OF THE 8th MEETING OF THE APEX COMMITTEE HELD ON
30-09-2013 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. 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 under the Chairmanship of Secretary (HFW) was apprised that the 8th meeting of the Technical Committee was held on 30.09.2013 under the Chairmanship of DGHS. The Technical Committee deliberated on various issues related to approval of various categories of Clinical Trials. The proposals were related to Investigational New Drugs (IND), Global Clinical Trials, FDCs, Biological and New Drugs.

2. The Minutes of the 8th meeting of the Technical Committee were circulated to the Members.

3. The Apex Committee was informed that the Writ Petition (Civil) 33 of 2012 filed by Swasthya Adhikar Manch, Indore against the UOI relating to clinical trial came up for hearing on 30.09.13 in Supreme Court. During the hearing, the issue of approval of 162 global clinical trials by DCG(I) till 30.08.2013 based on recommendation of NDACs, was discussed.

4.1. The Apex Committee noted that the Technical Committee in its 8th meeting deliberated the details of 43 proposals of clinical trials of new drugs (including fixed dose combinations, subsequent new drugs, biological) and global clinical trials. Out of these 43 proposals, there were 13 cases of clinical trials of New Drugs and IND, 19 cases of Global Clinical trials and remaining were clinical trial proposals related to fixed dose combinations, subsequent new drugs and biological. Details of these 43 cases are placed at Annexure I.

4.2 The recommendations of the Technical Committee for these proposals are as under:

- a) Proposal at S.No 3: It is not a clinical trial as per Rule 122DAA of Drugs & Cosmetics Rules and the same has also been noted and recommended by NDAC.
- b) Proposals at S.No. 16, 17, 18: These are clinical trial proposals of anti-epileptic drugs. However, there was no Neurologist present during NDAC meeting when these proposals were recommended for approval. Therefore, these proposals shall be again deliberated by the NDAC in its meeting with a proper representation of Neurologist.
- c) Proposal at S.No.20: Four experts attended the NDAC meeting, out of which two experts, i.e, one Microbiologist and one Paediatrician did not participate in the decision making process as they had conflict of interest. There was no paediatrician or microbiologist present in the NDAC meeting when this was recommended. Therefore, this proposal should again be deliberated by the NDAC in its meeting with a proper representation of Microbiologist and Paediatrician.

- d) Proposal at S.No. 24: The NDAC has recommended that the firm should submit the revised clinical trial protocol to DCG(I) for his approval. The Technical Committee recommended that the revised clinical trial protocol shall be reviewed by NDAC for further action.
- e) Proposal at S.No. 27: It is a similar proposal of clinical trial of the same drug in the same indication which has already been approved by the Technical Committee and Apex Committee in its earlier meetings for other firms. It was recommended by the Technical Committee that such proposals of clinical trials of the same drug in the same indication are not required to be placed before the Committee.
- f) Proposal at S .No. 29: As per the protocol, patients in one arm will not receive the standard treatment. The Technical Committee deliberated the matter and desired that the complete protocol of the study should be circulated to the Members. The proposal will be deliberated again in the next Technical Committee meeting.
- g) Proposals at S. No. 40, 41 & 42: These are related to clinical trials of stem cells. The Technical Committee recommended that these proposals shall be deliberated in the next meeting of the Committee.

4.3 Thus, out of a total of 43 proposals, the Technical Committee recommended for approval in 33 cases except for proposals mentioned at S.No. 16, 17, 18, 20, 24, 29, 40, 41 and 42 for which the Committee recommended for actions as mentioned above. The case at proposal no. 3, is not covered under the definition of clinical trial. Hence, it does not come under the purview of DCG(I).

4.4 The Apex Committee agreed to the above recommendations of the Technical Committee. However, implementation of these recommendations will be subject to the Order of the Hon'ble Supreme Court.

5.1 The Apex Committee also deliberated the recommendation of the Technical Committee that expansion of NDAC panel should be made quickly. However, till such time DCG(I) with the approval of DGHS may include additional experts in the NDAC Committees depending on the nature of the proposals.

5.2 The Apex Committee agreed for the expansion of NDAC expert panel and recommended that till such time the panel is expanded, DCGI may invite the experts from Delhi based Govt. hospitals like RML Hospital, Safdarjung Hospital, AIIMS, New Delhi, MAMC etc.

5.3 The Apex Committee also agreed to the recommendations of the Technical Committee that the number of proposals to be deliberated by the NDAC in one meeting should not be more than five.

6. The meeting ended with a vote of thanks to the Chair.

LIST OF 43 CASES OF CLINICAL TRIALS PROPOSALS

Annexure I

S.No.	Drug	Applicant	Division
1.	PEGylated recombinant factor VIII (rFVIII)	Baxter	GCT
2.	Quadrivalent seasonal influenza vaccine	Glaxo Smithkline	GCT
3.	ISCHEMIA Study	IProcess	GCT
4.	Everolimus	Novartis	GCT
5.	Sofosbuvir	KlinEra	GCT
6.	Tenofovir Alafenamide	KlinEra	GCT
7.	Tenofovir Alafenamide	KlinEra	GCT
8.	Everolimus	Novartis	GCT
9.	Everolimus	Novartis	GCT
10.	Secukinumab	Novartis	GCT
11.	Nimorazole	Dr. Ashwini Budrukar, Associate Prof. Dept. of Radiation Oncology, Tata Memorial Hospital, Parel, Mumbai	GCT
12.	Afatinib	Boehringer	GCT
13.	QVA149	Novartis	GCT
14.	Ceftazidime-Avibactam	Astra Zeneca	GCT
15.	Alirocumab	Sanofi Synthelabo	GCT
16.	YKP3089	Quintiles Research	GCT
17.	Perampanel	PPD-Pharma	GCT
18.	Perampanel	PPD Pharma	GCT
19.	Empagliflozin	Beohringer Ingelheim	GCT
20.	Varicella Vaccine, Live (I.P.)	Blomed Pvt.	Biological (Vaccine)
21.	Typhoid VI capsular polysaccharide -- Tetanus Toxoid protein conjugate vaccine (Typbar-TCV)	Bharat Biotech	Biological (Vaccine)
22.	Rituximab	Roche Scientific	Biological (Recombinant)
23.	Lidocaine	Troikka Pharma	SND
24.	Mometasone	Cadila Healthcare	SND
25.	Progesterone	Synokem Pharma	SND
26.	Choline Fenofibrate + Rosuvastatin	Intas Pharma	FDC
27.	Vilazodone	Torrent Pharma	NDA
28.	DS5565	Ranbaxy Labs	IND
29.	PA-284	CSIR	IND
30.	SMRX-11	Symmetrix Biotech	IND
31.	GRC 17536	Glenmark Pharma	IND
32.	Crofelmer	Glenmark Pharma	IND
33.	Saroglitazar	Cadila Healthcare	IND

34.	Bloplatin	Rasayani Biologics	IND
35.	Efonidipine	Zuventus	NDA
36.	Roflumilast	MSN Labs	NDA
37.	Roflumilast	Cadila Healthcare	NDA
38.	Arbekacin	Alkem Labs	NDA
39.	Teneligliptin	Glenmark Pharma	NDA
40.	Placental Derived Cells (PLX-PAD)	ClinRx Laboratories	Biological (Stem Cells)
41.	R-STE-001 (Autologous cultured chondrocytes)	Reliance Life Sciences, India.	Biological (Stem Cells)
42.	R-STE-009 (Autologous Myoblast)	Reliance Life Sciences, India.	Biological (Stem Cells)
43.	Estradiol	Famy Care	Therapeutic Equivalence Trial

