MINUTES OF THE 8th MEETING OF TECHNICAL COMMITTEE HELD ON 30-09-2013 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:

1.	Dr. Jagdish Prasad, Director General of Health Services.	Chairman
2.	Dr.Rajutitus Chacko, Prof. & Head, Dept. of Medical Oncology, CMC, Vellore.	Member
3.	Dr. Kamlakar Tripathi, Prof., Dept. of Medicine, Institute of Medical Sciences, Banaras Hindu University, Varanasi	Member
4.	Dr. Ashok Kumar Das Director-Professor of Medicine & Medical Superitendent, JIPMER, Puducherry.	Member
5.	Dr. Nikhil Tandon, Professor, Dept of endocrinology & Metabolism, AIIMS, New Delhi.	Member
6.	Dr. S.N. Gaur, Prof. & Head, Dept. of Respiratory Medicine, V.P. Chest Institute, New Delhi	Member

From CDSCO:

1. Dr. G. N. Singh
   Drugs Controller General (India)
2. Sh. A.K. Pradhan
   Deputy Drugs Controller (India)
3. Sh. S.P. Shani
   Deputy Drugs Controller (India)
4. Dr. S.E. Reddy,
   Deputy Drugs Controller (India)

Dr. Jagdish Prasad, DGHS welcomed the members and briefed them about the outcome of the seventh meeting of the Technical Committee which was held on

23.08.13. The minutes of the seventh meeting approved by the Chairman were already circulated to the members.

The committee appreciated the efforts made by CDSCO in preparing the list of about 2000 experts for expansion of NDAC expert panel. Dr. A.K. Das informed that he is segregating these lists of experts therapeutic areawise and will discuss the list with Chairman shortly for finalization of the panel.

The committee then deliberated the details of 43 proposals of clinical trials one by one, which were circulated to the members as per the prescribed format through e-mail. Out of these 43 proposals there were 13 cases of clinical trials of New Drugs & IND, 19 cases of Global Clinical trials and remaining were clinical trial proposals related to fixed dose combinations, subsequent new drugs, biologicals. List of these proposals is as under:

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.)	Biomed 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	Troikkaa 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.	Bioplatin	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 chrondrocytes)	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

The committee observed that the proposal at S.No. 3 is not a clinical trial as per Rule 122DAA of Drugs & Cosmetics Rules and the same has also been noted and recommended by NDAC. Committee recommended that such proposals are not required to be placed before the committee.

As regards to the proposals mentioned at S.No. 16, 17, 18, the committee observed that 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. The Committee, therefore recommended that these proposals shall be again deliberated by the NDAC in its meeting with a proper representation of Neurologist.

Similarly, in proposal no. 20, i.e, of Varicella Vaccine of M/s. Biomed Pvt. Ltd. four experts attended the NDAC meeting, out which two subject 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 pediatrician or microbiologist present in the NDAC meeting when this was recommended. The committee therefore recommended that this proposal shall also be again deliberated by the NDAC in its meeting with a proper representation of Microbiologist and Paediatrician.

The committee further noted that for 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 committee recommended that the revised clinical trial protocol as recommended by the NDAC shall be reviewed by them and recommended for further action.

The committee noted that proposal at S.No. 27 of Vilazodone of M/s. Torrent Pharma is a similar proposal of clinical trial of same drug in same indication which has already been approved by the Technical Committee and Apex Committee in its earlier meetings for other firms. While recommending for giving permission for the proposed study the committee opined that such proposals of clinical trials of same drug in same indications is not required to be placed before the committee.

As regards to proposal mentioned at S.No. 29, committee observed that as per the protocol, patients in one arm will not receive the standard treatment. The 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 meeting.

As regards to the proposals mentioned at S.No. 40, 41 & 42 which are related to clinical trials of stem cells, the committee recommended that these proposals shall be deliberated in the next meeting of the committee.

Thus out of a total of 43 proposals, the 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. As for the one case at proposal no. 3, is not covered under the definition of clinical trial, hence does not come under purview of DCG(I).

Committee further recommended that expansion of NDAC panel will be made shortly. However, till such time DCG(I) with the approval of DGHS may include additional experts in the NDAC committees on-need basis depending on the nature of the proposals.

Committee also recommended that list of members of the technical committee, who have not attended for the last three consecutive meetings, should be forwarded to the Chairman for replacing these members by other experts.

Committee opined that the number of proposals to be deliberated by the NDAC in one meeting should not be more than five.

The meeting ended with the vote thanks to the chair.