

MINUTES OF THE 13th MEETING OF TECHNICAL COMMITTEE HELD ON 27.03.2014 UNDER THE 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, Chairman
Director General of Health Services
2. Dr. Nandini Kumar, Member
Former Dy. Director (Sr. Grade)
National Institute of Epidemiology, ICMR, Delhi
3. Dr. Rajutitus Chacko, Member
Prof. & Head, Dept. of Medical oncology,
CMC, Vellore.
4. Dr. Ashok Kumar Das Member
Director-Professor of Medicine & Medical
Superintendent, JIPMER, Puducherry
5. Dr. P.K Dalal, Member
HOD, Dept of Psychiatry, KGMU Medical College,
Lucknow

From CDSCO:

1. Dr. G.N. Singh,
Drugs Controller General (India)
2. Dr. V.G.Somani
Joint Drugs Controller (India)
3. Sh. R.Chandrashekar
Deputy Drugs Controller (India)
4. Mrs. A Vishala
Deputy Drugs Controller (India)

Dr.Jagdish Prasad, DGHS welcomed the members and briefed them about the outcome of the 12th meeting of the Technical Committee which was held on 28.02.14. The minutes of the 12th meeting approved by the Chairman were already circulated to the members.

1. DCGI informed the Chairman about the following order of Hon'ble Supreme Court of India in the matter, which came for hearing on 10.03.2014, in respect of W.P. (C) No. 33/2012 of Swasthya Adhikar Manch, Indore & Anr Vs. Ministry of Health and Family Welfare & Ors. with WP(C) No. 779/2012.

“Mr. Sanjay Parekh, learned counsel for the petitioners in Writ Petition (Civil) No. 33 of 2012 has raised the grievance that three parameters, namely, (i) assessment of risk versus benefit to the patients, (ii) innovation vis-a-vis existing therapeutic option and (iii) unmet medical need in the country, indicated by this Court in the order dated 21.10.2013, have not been followed in letter and spirit in granting approval to 157 NCEs.

Mr. Siddharth Luthra, learned Additional Solicitor General, submits that in the affidavit which is to be filed by the Union of India, this aspect too shall be responded.”

It was discussed in detail by the Committee.

The Committee opined that these 157 proposals of clinical trials were earlier evaluated and deliberated by NDACs based on which clinical trial permissions were granted by DCGI. As per the order of the Hon'ble Supreme Court of India, dated 21.10.2013 in the matter of W.P. (C) No. 33/2012 of Swasthya Adhikar Manch, Indore & Anr Vs. Ministry of Health and Family Welfare & Ors. with WP(C) No. 779/2012 regarding clinical trials, these proposals were forwarded to the Technical Committee as per the prescribed format decided by the committee. The format contains name of Drug including Chemical Name, Name of the Applicant, Therapeutic Category, Brief of Pre-Clinical Information, Brief of Clinical Information, Adverse effect if any known to be associated with the drug, Study Title, Study Design, Sample size, Investigators and Study sites details, Study Duration, Key Inclusion / Exclusion Criteria, Major Efficacy & Safety parameters to be evaluated, Name of participating countries in case of Global clinical trial, NDAC

Recommendations, NDAC Members. The members of the Technical Committee are qualified and are highly experienced in the field of medicine, oncology, respiratory, Endocrinology & Metabolism, Cardiology etc. The members after having appropriate preliminary review of the proposals forwarded to them were called for further discussion in the Technical Committee meetings. The meetings were held on 28.11.13 and 15.01.14. The committee evaluated these proposals keeping in view all relevant aspects of safety and efficacy particularly in terms of assessment of risk versus benefit to the patients, innovation vis-a-vis existing therapeutic option and unmet medical need in the country. Further, the recommendations of the Technical Committee were placed before the Apex Committee. The Apex Committee after deliberations on these 157 proposals of clinical trial also agreed to the recommendations of the Technical Committee.

The present Technical Committee reiterates its earlier recommendations on these 157 proposals of Global clinical trial which were deliberated in its meetings held on 28.11.13 and 15.01.14.

The Committee has also gone through the order of the Hon'ble Supreme Court of India, dated 03.01.2013 in the matter of W.P. (C) No. 33/2012 of Swasthya Adhikar Manch, Indore & Anr Vs. Ministry of Health and Family Welfare & Ors. with WP(C) No. 779/2012 wherein the order states that :

“In the meanwhile, we record and accept the statement of Mr. Siddharth Luthra, learned Additional Solicitor General that until further order by this Court, clinical trials of new chemical entity shall be conducted strictly in accord with the procedure prescribed in Schedule 'Y' of Drugs & Cosmetics Act, 1940 under the direct supervision of the Secretary, Ministry of Health & Family Welfare, Government of India.”

Therefore, the Committee observed that the order is restricted only to conduct of trials of new chemical entities. Hence, the Committee has recommended that proposals of clinical trials of new chemical entity shall only be placed before the Committee.

2. The Technical Committee deliberated twenty two cases of fresh proposals of clinical trials. These cases have already been recommended by the NDACs. The Committee has assessed these proposals based on NDAC's assessment and their own assessment of various scientific and ethical parameters of the proposal specially with respect to risk versus benefit to the patients, innovation *vis-a-vis* existing therapeutic option and unmet medical need in the country. Out of these 22 proposals there were 4 cases of clinical trials of new drugs, 11 cases of Global Clinical trials and remaining were clinical trial proposals related to fixed dose combinations, biological and institutional trial. Detailed information on these proposals as per the prescribed format was forwarded to the members through e-mail. List of these proposals with recommendations of the Technical Committee including the above parameters is as under:

Sr. No.	Drug	Names of the Applicant	Parameters	Recommendations
1.	NT 201	Siro Clinpharm	risk versus benefit to the patients	Committee evaluated and recommended for the study
			innovation <i>vis-a-vis</i> existing therapeutic option	
			unmet medical need in the country	
2.	Fluocinolone Acetonide Intravitreal Insert	Excel Life Sciences	risk versus benefit to the patients	Committee evaluated and recommended for the study
			innovation <i>vis-a-vis</i> existing therapeutic option	
			unmet medical need in the country	
3.	Ranibizumab	Novartis	risk versus benefit to the patients	Committee evaluated and recommended for the study
			innovation <i>vis-a-vis</i> existing therapeutic option	
			unmet medical need in the country	
4.	Cyclosporine	Aurobindo Pharma	risk versus benefit to the patients	Committee evaluated and

				recommended for the study
			innovation <i>vis-a-vis</i> existing therapeutic option	
			unmet medical need in the country	
5.	Algeron	Biocad	risk versus benefit to the patients	Committee evaluated and recommended for the study
			innovation <i>vis-a-vis</i> existing therapeutic option	
			unmet medical need in the country	
6.	Ifetroban	Max Neeman	risk versus benefit to the patients	Committee recommended to resubmit the proposal along with the opinion of Pharmacologist.
			innovation <i>vis-a-vis</i> existing therapeutic option	
			unmet medical need in the country	
7.	Masitinib Mesylate	Maya Clinicals	risk versus benefit to the patients	Committee evaluated and recommended for the study
			innovation <i>vis-a-vis</i> existing therapeutic option	
			unmet medical need in the country	
8.	Asenapine	Parexel	risk versus benefit to the patients	Committee evaluated and recommended for the study
			innovation <i>vis-a-vis</i> existing therapeutic option	
			unmet medical need in the country	
9.	Perampanel	PPD	risk versus benefit to the patients	Committee evaluated and recommended for the study
			innovation <i>vis-a-vis</i> existing therapeutic option	
			unmet medical need in the country	
10	E2007 (perampanel)	PPD	risk versus benefit to the patients	Committee evaluated and recommended for the study
			innovation <i>vis-a-vis</i> existing therapeutic	

			option	
			unmet medical need in the country	
11	Biosimilar adalimumab (GP2017)	Novartis	risk versus benefit to the patients	Committee evaluated and recommended for the study
			innovation <i>vis-a-vis</i> existing therapeutic option	
			unmet medical need in the country	
12	Recombinant Human Chorionic Gonadotrophin (r-hCG)	Bharat Serums And Vaccines Limited,	risk versus benefit to the patients	Committee evaluated and recommended for the study
			innovation <i>vis-a-vis</i> existing therapeutic option	
			unmet medical need in the country	
13	Rituximab	Dr. Reddy's Laboratories	risk versus benefit to the patients	Committee evaluated and recommended for the study
			innovation <i>vis-a-vis</i> existing therapeutic option	
			unmet medical need in the country	
14	Trastuzumab	Reliance Life Sciences	risk versus benefit to the patients	Committee evaluated and recommended for the study
			innovation <i>vis-a-vis</i> existing therapeutic option	
			unmet medical need in the country	
15	SmofKabiven Peripheral	Fresenius Kabi	risk versus benefit to the patients	Committee evaluated and recommended for the study
			innovation <i>vis-a-vis</i> existing therapeutic option	
			unmet medical need in the country	
16	SmofKabiven	Fresenius Kabi	risk versus benefit to the patients	Committee evaluated and recommended for the study
			innovation <i>vis-a-vis</i> existing therapeutic option	
			unmet medical need in the country	

17	Nadifloxacin 1% w/w Adapalene 0.1 % w/w Gel	Wockhardt Limited	risk versus benefit to the patients	Committee evaluated and recommended for the study
			innovation <i>vis-a-vis</i> existing therapeutic option	
			unmet medical need in the country	
18	Tizanidine	Dr. Pratibha.D.Singhi,	risk versus benefit to the patients	Committee evaluated and recommended for the study
			innovation <i>vis-a-vis</i> existing therapeutic option	
			unmet medical need in the country	
19	Plerixafor (Mozobil) solution	Sanofi- Synthelabo (India) limited	risk versus benefit to the patients	Committee evaluated and recommended for the study
			innovation <i>vis-a-vis</i> existing therapeutic option	
			unmet medical need in the country	
20	Retigabine	Hetero Labs Limited,	risk versus benefit to the patients	Committee evaluated and recommended for the study
			innovation <i>vis-a-vis</i> existing therapeutic option	
			unmet medical need in the country	
21	Fenspiride Hydrochloride	Zuventus Healthcare Ltd	risk versus benefit to the patients	Committee evaluated and recommended for the study
			innovation <i>vis-a-vis</i> existing therapeutic option	
			unmet medical need in the country	
22	Crofelemer	Glenmark Pharma	risk versus benefit to the patients	Committee evaluated and recommended for the study
			innovation <i>vis-a-vis</i> existing therapeutic option	
			unmet medical need in the country	

Further, the Committee recommended that in cases where NDAC has recommended for issue of clinical trial permission without the presence of pharmacologists, the cases may be referred to pharmacologists of other NDAC panels and written opinion is to be obtained.

3. The Committee was apprised about the constitution of new 38 NDAC finalized from the pool of experts who have consented verbally or through-mails. It was also informed that as and when consent from other members is received, additional committees will be finalized.

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