DCG(I)/Misc/2010/2010(Pt. Stem Cells)/DT-ac

Government of India
Ministry of Health & Family Welfare

Nirman Bhavan, New Delhi
Dated the 1st September, 2010

ORDER

Government of India, New Delhi, Ministry of Health & Family Welfare) has decided to constitute a Core IND panel of Experts namely "Cellular Biology Based Therapeutic Drug Evaluation Committee (CBTDEC)" under the Chairmanship of Dr. V.M. Katoch, Secretary, Department of Health Research & Director General, ICMR, New Delhi to advice Drugs Controller General (India) in matters pertaining to regulatory pathways leading to the approval of clinical trials and Market Authorization for the "Therapeutic products derived from Stem Cell, Human Gene manipulations and Xenotransplant technology", with the following composition :

1. Prof. (Dr.) P.N. Tandon, President NBRC, Gurgaon, Ex-Professor & Head, Neurosurgery, AIIMS. Presently Chairman National Ethics Committee at ICMR.
2. Prof. (Dr.) S.S. Agarwal, Ex-Director, SGPGI, Lucknow/Ex-Director ARTREC.
3. Prof. (Dr.) Alok Srivastava, CMC, Vellore, Tamil Nadu.
4. Prof. N. K. Mehra, Head, Department of Transplant Immunology and Histocompatibility, AIIMS, New Delhi.
5. Dr. D. Balasubramaniam, Director, LVPIE, Hyderabad, Ex-Director CCMB, Tarnaka, Hyderabad.
6. Emeritus Prof.(Dr.) M.S. Valiathan, Ex-Director SCTIMS/EX-VC, Manipal Academy of Higher Education.
7. Prof. R.M. Pichhapan, Ex-Madurai Kamraj University.
8. Dr. Vineeta Bal, NII, Aruna Asaf Ali Marg, New Delhi.
9. Dr. Rita Mulherkar, ACTREC, Mumbai.
10. Drugs Controller General(India)/his representative.

2. Terms of Reference(TOR)

(i) To undertake in-depth evaluation of the technical documents furnished by the applicant (an individual and /or a registered company) for approval of clinical trial (Phase-I, II & III) and Market Authorization of the "Therapeutic products derived from Stem Cell, Human Gene Manipulations and Xenotransplant technology".

(ii) To advise the DCG(I) in matters relating to regulatory pathways as per the provisions made under the Drugs and Cosmetics Act and Rules thereof and also during the post licensure life period.

3. Time Schedule for processing of application

(i) Within 15 days of submission of IND application along with relevant data received by the office of DCG(I), the data will be referred to concerned experts mentioned in the Core Panel List.

The experts will be requested to give their opinion/comments within 30 days with effect from the date when the complete dossier have been dispatched by the Office of DCG(I). If it is felt that in case the data is lacking in any particular detail, the expert may bring the same to the notice of DCG(I) within 10 working days by e-mail or by post which would be subsequently intimated to the applicant within next 7 working days.

(ii) Within next 30 days of complete data submission, a meeting will be convened to discuss the matter amongst all the members of the said Committee and approval or any recommendation would be conveyed to the applicant.

(iii) Thus within 90 days, the complete dossier including the trial proposals (Protocol) will be reviewed, evaluated and approved on the recommendation of the Core Expert Panel .

(iv) After receiving the report of study as approved above by the CBTDEC, members will be consulted and the next phase of action will be decided within 45 calendar days.

(v) Similarly, after receiving Phase-II study reports and consultation with members, Phase-III clinical trial protocol will be cleared within 60 days. Wherever felt necessary, the panel may co-opt outside subject experts from specific field.

(vi) After submission of Phase-III study reports, the Panel would examine the data and would advise DCG(I) for approval of drug or otherwise.

4. The Core Panel shall hold office for two(2). years but shall be eligible for re-nomination provided that the persons nominated continue to hold their offices in their respective organizations by virtue of which they were nominated.

5. Honorarium of Rs. 1000/- per examination will be paid to the Expets and TA/DA to the Experts would be paid as per the Central Government Rules from the DTAB Budget(PP&SS Account).

6. In order to avoid any conflict of interest, a member who may be directly or indirectly associated with Research & Development activities related to a product under examination, would inform the office of DCG(I) and would volunteer to abstain from evaluation of such applicant.

7. PMS data will be generated as per the recommendations of the Experts Panel after clearance of Phase-III trials and formal approval of a New "Therapeutic products derived from Stem Cell, Human Gene Manipulations and Xenotransplant technology".

8. This issues with the approval of IFD vide their Diary No. 2513, dated 18.08.2010

(Sudhir Kumar)
Under Secretary to the Government of India
Telefax: 23062292

To :

1. Chairperson and all members of the Expert Panel.
2. PPS to Secretary(H&FW)/DG, Dte.GHS/AS(VV)/AS&FA
3. JS(R)
4. DCG(I)
5. Cash(Health) Section