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Government of India
Ministry of Health & Family Welfare

FTS 29644/2011
12

Nirman Bhavan, New Delhi
Dated the 10 May, 2011

ORDER

Subject: - Formulation/creation of 'General Expert Pool' for Medical Device Advisory Committee (MDAC) to advice Drugs Controller General (India) {DCG (I)} in matters for Review of Applications of new Medical Device & Clinical Trials- regarding.

It has been decided to Formulate/create a 'General Expert Pool' for **Medical Device Advisory Committees (MDAC)** to advise DCG(I) in matters related to review and regulatory approval of New Medical Devices & Clinical Trials (except for Investigational New Medical Devices) of Medical Devices. The committee is hereby Formulated/created with the following experts with immediate effect:

Sr. No.	Name of Expert	Designation	Institute
1	Prof. M.V.S. Valiathan	Ex Vice Chancellor	Manipal University
2	Dr. K. Satyanarayan	Sr. Deputy Director-General	ICMR, New Delhi
3	Dr. G.S. Bhvaneshwar	Head of Bio medical Technology	SCTIMSI, Trivandrum
4	Dr. Alok Roy	Head of Bio medical Engineering	IIT, New Delhi
5	Dr. V.K. Suri	Head, Precision Engineering	Bhabha Atomic Research Centre, Mumbai
6.	Dr. Jyotana Sokhe	Director	NIB, Noida
7.	Dr. Sathe	Head, Microbiology	NIV, Pune
8.	Dr. R.S. Paranjape	Director	NARI Pune
9.	Dr. Priya Abhraham	Department of Virology	CMC, Vellore
10.	Dr. M.M. Parida	Scientist, Division of Virology	Defense Research and Development Establishment, Gwalior
11.	Dr. Shoha Broor	HOD Microbiology	AIIMS, New Delhi
12.	Prof. Awades Surolia	Director	National Institute of Immunology, Delhi

1. Terms of Reference:

The experts from General Pool will be called for Medical Device Advisory Committee(MDAC) meetings as a member, when required, to advise Drugs Controller General (India) in the following matters:

(i) To undertake in-depth evaluation of non-clinical data, clinical trial data, etc, furnished by the applicant for approval of following:

- New Medical Device to be introduced for the first time in the country.
- Global clinical trials

(vi) Indentify devices that are needed to be regulated/Notified by the Govt. of India.

(vii) Preparing Guidelines for clinical research industry in evolving acceptance criteria for marketing approval of new Medical Device.

(viii) Defining roadmap for research industry for appropriate development of new Medical Device relevant to Indian population.

(ix) While considering for approval of new Medical Device the committees will examine the essentiality and desirability of new Medical Device in terms of:

- Assessment of Risk versus Benefit to the patient
- Innovation vis- a-vis existing device option
- Unmet medical need in India

2. Applications for new Medical Device and Global clinical trials can be evaluated by the committee either through meeting or by circulation of the applications.

3. For review of each proposal experts will be paid an honorarium of Rs. 1000/-

4. TA/DA for attending the meeting as well as honorarium will be paid from CDSCO budget.

5. The experts nominated as a member for the committee should not have any conflict of interest as per the declaration given at **Annexure-A.**

6. The members of the committee shall hold office for a period of three years but shall be eligible for re-nomination provided that the persons nominated continue to hold their offices in their respective organization by virtue of which they are nominated.

7. In case a member retires during the term of validity, an alternative member from the same Institute or from some other Institute will be nominated as member for the Pool.

8. Office of Drugs Controller General (India) {DCG(I)} will initially examine such applications, if any particular data is lacking same will be informed to the applicant within 45 working days or else the data will be forwarded to the members of the committee.

9. The members of the committee should be in a position to give their expert opinion within a period of 6 weeks from the receipt of such proposal.

10. The members of the committee should follow the Principle of Confidentiality with respect to the documents submitted by the applicants.

11.The members of the Committee should submit their Bio-data as per the format annexed at **Annexure-B**.

12. This issues with the approval of IFD vide their Dy. No. 5460 dated 17.02.2011.

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

Copy to :

1. Office of Drugs Controller General (India) – to inform all members of MDAC- General Pool Experts.
2. Secretary(H&FW)/DG, Dte.GHS/AS&DG(CGHS)/SS&FA/JS(R)/Director (Drugs)
3. Cash(Health) Section/IFD