F.No. X-11026/142/13-BD
Government of India
Ministry of Health and Family Welfare

Dated: 13th August, 2013.

ORDER

Subject: Constitution of an Expert Committee to guide Drugs Controller General (India) (DCGI) in matters related to regulation of Biotech products - reg.

The Government of India (Ministry of Health & Family Welfare) has decided to constitute an Expert Committee to guide DCG (I) in matters related to regulation of Biotech products. The committee will have the following experts:

1. Prof. Anurag Singh Rathore, Professor, Department of Chemical Eng., IIT, New Delhi **(Chairman).**
2. Prof. Y. K. Gupta, Prof and Head, Dept. of Pharmacology, AIIMS, New Delhi – Member.
3. Dr. Chandiswar Nath, Ex-Head, Department of Toxicology, CDRI, Lucknow, UP - Member
4. Dr. Girish Sahni, Director, Institute of Microbial Technology, Sector 39A, Chandigarh-160 036
5. Dr. Amulya Kumar Panda, Scientist, Product Development Cell, National Institute of Immunology, New Delhi- 110067
6. Prof. G.K. Suraishkumar, Department of Biotechnology, IIT, Madras, Chennai – 600 036

Terms of Reference for this expert committee would be as follows:

1) To formulate policy, guidelines, SOPs for approval of New and subsequent recombinant drugs with special emphasis on the following:-
   a) To plan a transparent, equitable system of clinical evaluation of new drugs.
   b) Requirements of local clinical trial on Indian population for drugs approved in other countries.
   c) Specific circumstances, if any, under which local clinical trial can be abbreviated, relaxed or omitted.
   d) Types of local clinical trial, its design, sample size, sites and their distribution, inclusion of ethnic population etc. in the local clinical trials of biotech products.
   e) Requirements of Post Marketing (Phase IV) trial to assess safety of new drugs in Post Marketing scenario.

2) To formulate policy, guidelines, SOPs for approval of clinical trials including global clinical trials of new drug substances discovered abroad and bioavailability and bioequivalence study for export with special emphasis on the following:-
   a) Monitoring the functions of Ethics Committees.
   b) Accreditation of Clinical trial sites and Investigators.
   c) Clinical trial inspections.
   d) Participation of State Authorities in monitoring of Clinical trials.

3) To formulate policy, guidelines and procedures for examination of issues related to continued marketing of drugs not only due to safety or other reasons but also due to launch/availability of safer and more efficacious alternative drugs in the country.

4) To formulate guidelines, SOPs on the functioning of New Drug Advisory Committees (NDACs).

5) To formulate policy, procedures for identification of experts for advising CDSCO in its various matter.

6) To advise CDSCO of to for changes in Drugs and Cosmetic Rules, 1945 pertaining to regulation of biotech products.

7) To constitute sub-groups (wider groups) for consultation and preparation of operating guidelines on safety, efficacy and quality for Industry as well as regulator.

8) To identify training needs of CDSCO in view of emerging challenges of regulation of biotech products. Train or facilitate training of CDSCO employees.

9) TA/DA and honorarium for all the members and Chairman for attending the meetings will be paid from the budgetary grants of Indian Pharmacopeia Commission (IPC) as per Govt. Of India Rules.

10) 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.

11) In case a member retires during the terms of validity, an alternative member from the same institute or from some other institute will be nominated as member for the committee.

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

1. Chairperson and all members of the Expert Committee.
2. PPS to Secretary (H&FW)/DG, Dte. GHS/AS&DG (CGHS)/JS(AKP)
3. DCG (I)
4. Cash (Health) Section/IFD