No.12-01/12-DC (Pt-133)/DFQC
Government of India
Ministry of Health & Family Welfare
***

Nirman Bhavan,
New Delhi, dated the 6th February, 2013

ORDER

Subject: Constitution of two Expert Committees to formulate policy guidelines and SOPs for approval of new drugs, clinical trials, banning of drugs and FDCs - regarding

In pursuance of the observations / recommendations of the Department Related Parliamentary Standing Committee on Health & Family Welfare as contained in its 59th Report on the functioning of the Central Drugs Standard Control Organisation (CDSCO), the following two Expert Committees are hereby constituted by the Ministry:

(I) Expert Committee to formulate policy guidelines and SOPs for approval of New Drugs, clinical trials and banning of drugs

1. Professor Ranjit Roy Chaudhury. - **Chairman**
   National Professor of Pharmacology,
   Advisor- Department of Health and Family Welfare,
   Government of NCT of Delhi,
   Former Member, Board of Governor-MCI,
   Y-85 Hauz Khas New Delhi-110016.

2. Dr. V. P. Kamboj. - **Member**
   Former Director,
   Central Drugs Research Institute, Lucknow.
   C-1111, Opposite Church, Indira Nagar, Lucknow-226016.

3. Dr. B. T. Kaul, - **Member**
   Professor of Law,
   Delhi University, Delhi
   Law Centre-II, Dhaula Kuan, New Delhi- 110021.

4. Dr. Mira Shiva, - **Member**
   Coordinator, Initiative for Health, Equity and Society,
   A-60, Hauz Khas, New Delhi – 110016.

5. Dr. Vasantha Muthuswamy, - **Member**
   Former Senior Deputy Director General, ICMR,

A101,Manchester Regent,Avinashi Road,
P. N. Palayam, Coimbatore-641037

6. Dr. Uma Tekur
Professor of Pharmacology,
Maulana Azad Medical College, Delhi-110002. - **Member**

7. Dr. Sujith Chandy
Professor of Pharmacology
Christian Medical College, Vellore- 632002. - **Member**

Terms of Reference:

1. To formulate policy guidelines and SOPs for approval of New drugs including Biologicals 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 trial.

   e) Requirements of Post Marketing (Phase IV) trial to assess safety of new drugs in Post Marketing scenario.

2. To formulate policy guidelines and 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 matters.

6. To advise CDSCO in other matters referred to it for advice.

(II) **The Expert Committee to formulate policy guidelines and procedures for approval of Fixed Dose Combinations.**

1.	Prof C K Kokate, Vice Chancellor, KLE University, J N M C Campus, Belgaum -590010.		**Chairman**
2.	Dr. Urmila Thatte, Prof. & Head of Clinical Pharmacology, KEM Hospital & Seth GS Medical College, Mumbai- 400012.	-	**Member**
3.	Mr. Bikash Medhi, Addl. Prof of Pharmacology, Post Graduate Institute of Medical Education and Research, Chandigarh-160012.	-	**Member**
4.	Dr. R.K Khar, Former Dean, Jamia Hamdard University, Hamdard Nagar, New Delhi-110062.	-	**Member**
5.	Dr. H.G. Koshia Commissioner, Food & Drug Control Administration, Gujarat-382010.	-	**Member**

Terms of Reference:

1. To formulate policy guidelines and SOPs for approval of Fixed Dose Combinations with special emphasis on the following:-

   a) Requirements of clinical trial on Indian population.

b) Types of local clinical trial, its design, sample size, sites and their distribution etc. in the clinical trial.

c) Requirements of Post Marketing (Phase IV) trial to assess safety of Fixed Dose Combinations in Post Marketing scenario.

2. To formulate guidelines and SOPs on the functioning of New Drug Advisory Committees (NDACs) in respect of Fixed Dose Combinations.

Honorarium and TA/DA will be paid to the Experts as per the Central Government Rules from the budgetary allocation of CDSCO. The Committee in Clinical Trial may Co-opt the services of the following experts, if necessary:

(a) Dr. Lalit Kumar Professor Medical Oncology, AIIMS
(b) Dr. Sudha Prasad, Director & Professor Obstetrics & Gynaecology, MAMC
(c) Dr. Nikhil Tandon, Professor, Endocrinology, AIIMS

(Shailendra Kumar)
Director
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1. Drugs Controller General (India), FDA Bhavan, Kotla Road, New Delhi - for conveying this Order to the Chairpersons and all members of the Expert Committees.
2. Principal Accounts Office, Ministry of Health & Family Welfare, Nirman Bhavan, New Delhi
3. Pay & Accounts Office, DteGHS, Nirman Bhavan, New Delhi
4. IFD / Budget Section
5. PPS to Secretary (H&FW) / PPS to DG, Dte.GHS / PPS to AS&DG(CGHS) / PS to JS(AKP)