

File No. 12-01/14-DC Pt.47
Central Drugs Standard Control Organization
Directorate General of Health Services
Ministry of Health & Family Welfare
FDA Bhawan, Kotla Road, New Delhi-110002

Dated: 03.07.2014

ORDER

SUBJECT: Procedure for review of applications of clinical trials and new drugs- renaming of New Drugs Advisory Committees (NDACs) - regarding

The Ministry of Health & Family Welfare had constituted an Expert Committee under the Chairmanship of Prof. Ranjit Roy Chaudhury to formulate policy and guidelines for approval of new drugs, clinical trials and banning of drugs. The Expert Committee submitted its report to the Ministry of Health & Family Welfare. The actions proposed to be taken on the recommendations of the Expert Committee were finalised by the Ministry of Health & Family Welfare.


As per the action, New Drug Advisory Committees (NDACs) will be renamed as Subject Expert Committees. The members for their meetings will be drawn randomly from a large pool of experts. Applications of clinical trials and new drugs will initially be evaluated by the Subject Expert Committees and their recommendations will be reviewed by the Technical Review Committee (TRC). The TRC is proposed to be constituted under DGHS consisting of experts from each areas i.e. clinical pharmacology, regulatory clinical toxicology / pathology, medicinal / pharmaceutical chemistry, pharmacy and immunology including clinicians, basic scientists involved in drug development and subjects specialists (drug indication wise). CDSCO will grant approval of Clinical Trial and New Drugs based on the recommendations of TRC.

In pursuance to above, the twelve NDAC committees constituted vide order number X.19029/5/2011- DFQC dated 31.03.2011 are renamed as Subject Expert Committees (SEC) as under:

1. SEC- Oncology & hematology
2. SEC- Cardiovascular and renal
3. SEC- Metabolism & endocrinology
4. SEC- Antimicrobial, Antiparasitic & Antifungal, Antiviral
5. SEC- Reproductive & Urology
6. SEC- Gastroenterology & Hepatology
7. SEC- Dermatology & Allergy, immunology
8. SEC- Pulmonary
9. SEC- Neurology & Psychiatry
10. SEC- Analgesic, Anesthetics & Rheumatology
11. SEC- Ophthalmology
12. SEC- Vaccines

The terms of reference and other conditions will remain same.

Henceforth, in all correspondence related to evaluation of application of clinical trials, new drugs etc., the term Subject Expert Committee (SEC) as above should be used in place of NDAC.


(Dr. G. N. Singh)
Drugs Controller General (India)

- To
1. NDAC members
 2. IDMA / IPA / OPPI / ISCR / ACRO / FOPE / CIPI
 3. All officers of CDSCO

Copy to : US (D), MOH&FW, New Delhi.