**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**

**Date: 03.07.2014**

**ORDER**

**SUBJECT: Requirement for filing of application to market New Chemical Entities - 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 finalized by the Ministry of Health & Family Welfare.

Pursuant to above, it has been decided that if Indian participates in global clinical trials of NCE(s) to be used for diseases that are prevalent in our population, after approval for marketing in the innovator country or in well-regulated developed country markets, approval should be sought from CDSCO for marketing these NCEs in India. After approval from CDSCO, these NCEs should be marketed in India speedily, preferably by production within the country.

All the sponsors / clinical trial applicants are hereby directed to provide an undertaking to CDSCO alongwith the application for approval of clinical trials of such New Chemical / Biological Entity that after approval for marketing of such entity in the innovator country or in well-regulated developed country, they will file application to CDSCO seeking approval for marketing such drugs in the country.

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

**To**
1. **NDAC Members**
2. **IDMA / IPA / OPPI / ISCR / ACRO**

**CC to:**

**US (D), Ministry of Health and Family Welfare**