F. No. DCGI/Misc./2014 (132)
Directorate General of Health Services
Central Drugs Standard Control Organization (CDSCO)
Office of Drugs Controller General (India)

FDA Bhawan, Kotla Road,
New Delhi-110 002

Date: 5 SEP 2014

ORDER

The clinical trials on new drugs are regulated under the provisions of Drugs & Cosmetics Rules 1945 as amended form time to time. The detailed requirements and guidelines for undertaking clinical trials are specified under Rule 122DAA, Rule 122DAB, Rule 122DAC, Rule 122DD, Rule 122E and Schedule Y of the said rules and other relevant provisions.

In the case of W.P. (C) No. 33/2012 of Swasthya Adhikar Manch, Indore & Anr. Vs. Ministry of Health & Family Welfare & Ors. with WP(C) No. 779/2012 regarding clinical trials, the Hon'ble Supreme Court. has passed an order dated 21/10/2013. As per the said order all the Global Clinical Trials (GCTs)/New Clinical Trials (NCEs) should be evaluated having regard to three parameters. namely, (i) **assessment of risk versus benefit to the patients**, (ii) **innovation vis-a-vis existing therapeutic option** and (iii) **unmet medical need in the country**.

In view of the above, it has been decided with the approval of the Ministry of Health & Family Welfare, all the applications for the conduct of clinical trials of new drugs in India should invariably provide the information on (i) assessment of risk versus benefit to the patients, (ii) innovation vis-à-vis existing therapeutic option and (iii) unmet medical need in the country.

All the Sponsors/CROs/Medical Institutions and other stakeholders involved in the conduct of clinical trials in the country are hereby directed to adhere to the above requirement of inclusion of the three parameters in their clinical trial applications with immediate effect.

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

To

1) **Concerned Sponsors/ CROs/Medical Institutions.**
2) **IDMA/IPA/OPPI/ISCR/ACRO.**

Copy to:

1) **PPS to Secretary, Ministry of Health & Family Welfare.**
2) **PS to Joint Secretary, Ministry of Health & Family Welfare.**
3) **PPS to Director General of Health Services.**
4) **PS to AS & DG.**
5) **NDAC (Subject Expert Committee)/MDAC members.**
6) **All State Drug Controllers (for the necessary information).**
7) **Zonal /Sub Zonal /Port Officers of CDSCO (for the necessary information).**