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: Consideration of ethnicity for approval of new drugs- 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.

In pursuance to above, in regard to the consideration of ethnicity for approval of new drugs, it has been decided that the following properties of a compound which make it more likely to be sensitive to ethnic factors shall be taken into consideration during evaluation of new drug applications:

1) Non-linear pharmacokinetics
2) A steep pharmacodynamic curve (a small change in dose results in a large change in effect) for both efficacy and safety in the range of the recommended dosage and dose regimen
3) A narrow therapeutic dose range
4) Highly metabolized, especially through a single pathway, thereby increasing the potential for drug-drug interaction
5) Metabolism by enzymes known to show genetic polymorphism
6) Administration as a prodrug, with the potential for ethnically variable enzymatic conversion
7) High inter-subject variation in bioavailability
8) Low bioavailability, thus more susceptible to dietary absorption effects
9) High likelihood of use in a setting of multiple-co-medications
10) High likelihood of inappropriate use, e.g. analgesics and tranquil1izers.

It has also been decided that the following factors may be taken into consideration in deciding whether the available data could be ethnically sensitive or insensitive:

1) Definition of the disease and diagnosis of the patient
2) Choice of control group
3) Method of assessment of safety- Similarity of medical practice to the country of origin
4) Duration of trial
5) Regional medical practice of concomitant medication use
6) Severity distribution of eligible subjects
7) Similarity of dose and dosage regimen
8) Clinical end-point has to be acceptable to the region in assessing efficacy.

NDAC experts are therefore requested that applications for approval of new drugs should be evaluated keeping in view the above factors that may result in ethnic variations.

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

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

CC to:

US (D), Ministry of Health and Family Welfare