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ASIA EDITION

Bloopers made by Indian Drug Standards Control organization

17 August 2012 | Analysis | By BioSpectrum Bureau

Bloopers made by the CDSCO

The report of the Indian parliamentary standing committee that focuses on the functioning of the Central Drugs Standards Control Organization, is finally out. Read the excerpts and the arguments of the CDSCO below and judge for yourself if the Central Drugs Standards Control Organization is functioning to the best of its abilities.

The report highlighted that the health and lives of patients in India cannot be put to risk in the hope of detecting adverse drug reactions (ADRs) within the country. The CDSCO acknowledged that not a single new adverse drug reaction was reported from anywhere in the country. The evaluation was carried out under a World Bank funded programme (from November 23, 2004-to- June 30, 2008) to detect side effect of drugs.

Many approvals were given to foreign drugs without testing them on Indians. Some of the reasons given for irregular approvals are as follows.

1.The presence of "Serious diseases". We ask - Is the presence of these serious diseases not reason enough to conduct

clinical trials in order to ensure that patients in India really benefit from such imported, exorbitantly expensive drugs;

2. The presence of "Rare disease status according to the US FDA". We ask - How can the US FDA decide what the rare diseases are in India?;

3."Orphan drug status in Europe and US". We ask - How can this be possible as there is no provision in Indian laws to give special treatment to foreign drugs.

Moreover, the committee also made many observations on the reasons provided by the CDSCO for its functioning. In response to the DCGI granting approvals without phase III trials, the committee said that on an average, DCGI is approving one drug every month without trials. This cannot be in public interest by any stretch of imagination.

In response to the identical letters of recommendation for approval of drugs being submitted as expert opinions, the committee observed that, there is sufficient evidence on record to conclude that there is collusive nexus between drug manufacturers, some functionaries of CDSCO and some medical experts.

The maximum expert opinions that were being sought by CDSCO or DTAB were located in Delhi. In response to this the committee wondered why expertise on drugs was confined to Delhi.

The committee was of the firm opinion that most of the ills besetting the system of drugs regulation in India are mainly due to the skewed priorities and perceptions of the CDSCO. For several decades it has been according primacy to the propagation and facilitation of the drugs industry, due to which, unfortunately, the interest of the biggest stakeholder (the consumer) has never been ensured, observed the parliamentary standing committee.