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CDSCO kick-starts much required regulatory overhaul

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Facing criticism over the last few years for not being in tune with industry requirements leading to lack of confidence, the CDSCO has finally come out with orders catering to various aspects of trials. Interestingly, the orders that came in a single day on July 3, 2014, would hopefully bring much required clarity. However, the real impact on the ground would be visible in next six months.

Let us have a look at each one of them and try to understand the significance in the present context.

The first order on generics or biosimilars, in countries like USA, that have been marketed there for more than 4 years, and have a satisfactory report, would be approved for marketing in India after abbreviated trials. The number of clinical trials an investigator can undertake should be commensurated with the nature trial facilities available. However, under no circumstancesshould it be more than 3 at a time. This one is remarkable considering the lack of clarity on the issue.

For a new drug, which has properties that make it sensitive to ethnic factors, these factors shall be considered during evaluation of NDA. This order addresses a point that many had raised in the past.

Special concessions will not be for every imported drug. According to one of the orders, the waiver fo clinical trails of new drugs approved outside India can be considered only in cases of national emergency, extreme urgency, epidemic, orphan drugs for rare disease or drugs indicated for diseases which have no therapy.

Bringing clarity, the order on academic clinical trials, the DCGI order says that these may be approved by ethics commitee. However, if a new drug is being evaluated or new use of an existing drug is evaluated, DCGI approval is needed.

An issue that has been debated by civil society and more often used by activists as a tool to halt trials is that of compensation to be paid to victims. One of the orders says that compensation is to be provided if any drug related anomaly is discerned at a later stage and is accepted to be drug related injury or death. The order says that ancillary care should be provided to the subject suffering from any other brief illness during the trial in the same hospital or trial site, wherever required.

The streamlining of trial approvals has also started with the order which states that 12 NDACs have been renamed as Subject Expert Committees (SEC). Their recommendations will be reviewed by the Technical Review Committee (TRC). The CDSCO will grant approvals for CT and NDA based on recommendations of TRC. For medical devices, procedures for CT NOC, accreditation of PI, sites, ECs and such other conditions would be similar to clinical trials of new drugs and vaccines.

CDSCO officials have constituted a cell which will coordinate with agencies such as Indian Council for Medical Research (ICMR) for the conduct of specific studies like post marketing surveillance of drugs, rational use of medicines, drug utilization studies, adverse reaction monitoring etc. that would enable CDSCO for continued evaluation of market in India and to take regulatory actions on continued use of such drugs in the country.

The order on unsafe drugs is of utmost importance as India would no longer be a dumping ground. If two or more countries, remove a drug from their market on grounds of efficacy and safety, then continued marketing of the drug in India will considered for examination and appropriate actions.

The CDSCO also directed sponsors, CROs, Clinical Trial Applicants and Ethics Committees to ensure that the design used in placebo controlled clinical trial is appropriate, efficient and ethical. NDAC members have also been requested to approve placebo controlled trials with such design.

The sponsors or Clinical Trial Applicants will now have to provide an undertaking to CDSCO along with clinical trial no objection certificate (NOC) application for NCE/ NBE that after approval of marketing application in innovator country, they will file an application with the agency for domestic marketing.

The CDSCO order on drugs for mandatory inclusion of Indian subjects in phase III trials will make it necessary for companies to do trials in India. The order says that the number of Indian subjects in Phase III global clinical trials should be adequate for considering the drug for approval in India.

Although there are many other issues that might require attention from CDSCO, the quick decisions taken by the agency certainly point towards a shift from unresponsive to a much more active mode of governance.