Recent Updates from CDSCO

CDSCO has released 14 orders on July 3, 2014 that may impact Clinical Trials in India. These orders are based on the recommendations made by the Prof. Ranjit Roy Choudhary committee report. Kindly visit the following link for full orders:
http://www.cdsco.nic.in/forms/list.aspx?lid=1843&Id=31

Following is brief detail of the orders for your reference:

1) **NDACs have been replaced as Subject Expert Committees (SECs)**. Members for the meetings shall be drawn randomly from a large pool of experts. Applications reviewed by SECs will then be reviewed by Technical Review Committees (TRC) TRC is proposed to be constituted under DGHS consisting of experts from each area. **Full notification:**
http://www.cdsco.nic.in/writereaddata/officer%20order%201.pdf

2) **Number of trial by an investigator:** Under no circumstances can an investigator be involved in more than 3 clinical trials at one time. **Full notification:**
http://www.cdsco.nic.in/writereaddata/officer%20order%202.pdf

3) **Clinical Trials of medical devices:** For clinical trials of medical devices, procedure for clinical trial approval, accreditation of investigators, sites, Ethics Committees and such other conditions shall be similar to clinical trials of new drugs / vaccines. **Full notification: http://www.cdsco.nic.in/writereaddata/oo3.pdf**

4) **With regard to compensation in case of injury or death discerned at a later stage**, compensation should be paid to trial participant / his / her nominee if any drug related anomaly is discerned at a later stage and accepted to be drug related. **Full notification: http://www.cdsco.nic.in/writereaddata/oo4.pdf**

5) **Providing ancillary care to clinical trial subjects:** There should be provision for providing ancillary care to patients suffering from any other illness during the trial.
Full notification: http://www.cdsco.nic.in/writereaddata/oo5.pdf

6) **Academic research** may be approved by institutional EC. However, if a new drug is being evaluated or new use for an existing drug is being evaluated, then approval of DCGI is also needed. **Full notification: http://www.cdsco.nic.in/writereaddata/oo6.pdf**

7) **Waiver of clinical trial in Indian population** for approval of new drugs which have already been approved outside India can presently be considered only in case of national emergency, extreme urgency, and epidemic and for orphan drugs for rare diseases and drugs indicated for conditions / diseases for which there is no therapy. **Full notification: http://www.cdsco.nic.in/writereaddata/oo7.pdf**

8) **With regard to ethnicity:** Various factors of a compound which should be considered in regard to ethnicity of a new drug are defined in the notification. NDAC experts shall be considering these factors while reviewing Clinical Trial applications. **Full notification:**
http://www.cdsco.nic.in/writereaddata/oo8.pdf

9) Drugs considered generics and similar biologicals in other countries like USA that have been marketed in these countries for more than 4 years and have a satisfactory report would be approved for marketing in India after abbreviated trials. **Full notification: http://www.cdsco.nic.in/writereaddata/oo9.pdf**

10) **Number of subjects in Phase III Clinical Trials:** If Indians have participated in Phase III global clinical trials, the number of participants would have to be adequate for consideration for approval in India. **Full notification: http://www.cdsco.nic.in/writereaddata/oo10.pdf**

11) **Placebo controlled trials:** All the sponsors / CROs / Clinical Trial Applicants / Ethics Committees are required to ensure that the design used in placebo controlled clinical trial is

appropriate, ethical and efficient. **Full notification:** **http://www.cdsco.nic.in/writereaddata/oo11.pdf**

12) **Requirement for filing of application for marketing of NCE:** All sponsors / Clinical Trial applicants are directed to provide an undertaking to CDSCO alongwith application for approval of clinical trials of NCEs to be used for diseases that are prevalent in our population, after approval for marketing in the innovator country or in well developed regulated markets. Approval should be sought for marketing these NCEs in India. **Full notification:** **http://www.cdsco.nic.in/writereaddata/oo12.pdf**

13) **Consideration of banning of a marketed drug:** If two or more countries remove a drug from their market on grounds of efficacy and safety, then the continued marketing of the drug in the country will be considered for examination and appropriate action. **Full notification:** **http://www.cdsco.nic.in/writereaddata/oo13.pdf**

14) **Creation of cell for coordination with institutes like ICMR for sponsoring various studies:** A cell has been constituted in CDSCO to coordinate with agencies such as ICMR for conduct of specific studies for post marketing surveillance of drugs, rational use of medicines, drug utilization studies, adverse drug reaction monitoring, etc. **Full notification:** **http://www.cdsco.nic.in/writereaddata/oo14.pdf**