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ASSOCHAM petitions health ministry, seeks predictable regulatory structure for clinical trials

04 September 2015 | News | By BioSpectrum Bureau

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In a note submitted to the health ministry, the key industry body, ASSOCHAM has pointed towards the fact that despite having 16 percent of the world's population and 20 percent of the disease burden, currently only 1.5 percent (approx) of global clinical trials are being conducted in India.

The chamber mentioned that while industry is committed to complying with the new regulations notified in 2013 to ensure the interest of patients like: Rule 122 DAB of the Drugs & Cosmetics Amendment Rules, 1945 (DCR) on Compensation in case of injury or death of a clinical trial subject during clinical trials. However, certain outstanding concerns remain particularly in respect of criteria entitling a patient to compensation, broad definition of 'trial related injury' and the strict and unreasonable reporting timelines required to be followed in case of serious adverse events.

"The issues pertaining to Issues pertaining to definition of clinical trial related injury, compensation to be paid in case of clinical trials related injuries or deaths, establishment of the appellate authority in case of disputes on causality and compensation issues, bio-equivalence and bio-availability studies, timelines for approval process etc. need to be streamlined at the earliest along the lines of international best practices in order to establish a regulatory mechanism which is predictable, stable and transparent," said the note.

ASSOCHAM also suggested that Central Drug Standard Control Organisation (CDSCO) should be strengthened and up-gradated with skilled and experienced personnel so that clinical research applications are reviewed expeditiously.

Other suggestions included the ones on right communication about importance of clinical trials. The note mentioned: "There is an urgent need to allay the myths around clinical trials - clinical trials are not unsafe and are not conducted in India only because of cost effectiveness, patient vulnerability and lack of regulatory safeguards. Patients/subjects across the globe take an informed decision to participate in clinical research after made fully aware of the potential benefits and risks involved and

clinical research is carried out in a highly regulated environment. Such myths can be allayed by creating awareness at all levels - judiciary, law making authorities, Members of Parliament and the media."

The note by ASSOCHAM concluded by mentioning that health ministry needs to create awareness about the importance of clinical research to be conducted in India along the lines of recommendations of the Department Related Parliamentary Standing Committee on Health and Family Welfare in its 59th Report, i.e., testing drugs in the Indian ethnic groups is of paramount importance before approving any drug of foreign origin.