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Decline in new clinical trials in 2013

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Referring to the minutes of 63rd meeting of Drug Testing Advisory Board (DTAB) held on May 16, 2013, the Indian Society for Clinical Research (ISCR) has welcomed the move to address the concerns of all stakeholders. "Collaboration, transparency and open dialogue are important to ensure the progress of the industry, while securing the rights and safety of patients," said the recent statement from the association that represents clinical research professionals.

While ISCR agrres that much of the text in the gazette notification on compensation published by the ministry of health and family welfare on January 30, 2013, is along anticipated lines, except two of the listed criteria for determination of eligibility for compensation are contrary to the consensus reached in the stakeholder meetings, and some of the other listed criteria remain controversial.

"The current compensation rules make the continuing conduct of high quality, scientifically valid clinical trials in India virtually impossible, negatively impacting the availability of scientific data to assess the benefits and risks of medicine for the Indian population. We believe that all of these contentious rules need to be addressed with equal priority and emphasis," mentioned the Suneela Thatte, president, ISCR.

"Another critical area that we believe need to be addressed on priority is approvals for new clinical trials which have slowed down considerably in 2013. While we understand that this is due to procedural issues, we hope that these bottlenecks within the DCGI's Office will be sorted out at the soonest," she added.

India has a sixth of the world's population and a fifth of the global disease burden and, contrary to popular belief, less than 1.5% of global trials take place in India (now probably even less so). Therefore an ecosystem needs to be created that fosters drug discovery and development for diseases endemic to our region and growing lifestyle diseases that are affecting our population. Given the recent developments, this now looks a remote possibility unless key issues impacting the industry are addressed by the regulatory authorities.

"The potential that India offers in drug development arena cannot be ignored. We do hope that the current challenges prove to be part of a larger evolution process and that we will come through as a stronger player with a focus on ensuring the patients in India derive benefits from the value that clinical research has delivered world over," concluded Ms Thatte.