

Stem cell sector sees need for regulations to be simplified and approval process to be seamless

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Stem cell industry experts are now pressing for the need to get the faster clearances for their products from the committees coming under the ambit of the Drug Controller General of India. These are the Institutional Ethics Committee (IEC) or Institutional Committee for Stem Cell Research (IC-SCR) and National Apex Committee for Stem Cell Research and Therapy (NAC-SCRT) and the final consent from the DCGI.

The multiple levels of approval for the stem cell product are cumbersome and time consuming. We need the government to look at fast track clearances, said BN Manohar, managing director, Stempeutics Research.

The three level approval process now needs to be revised and we are looking for a single window clearance. When stem cell therapy is gaining ground, we see tissue engineering, induced pluripotent stem cells (IPSC) to take off in some time along with advances in stem cell therapies that are proving to indicate unique regenerative abilities, and offering new potentials for treating Burgers disease, ischemic heart disease to osteoarthritis.

The hope is that stem cell treatment will repair, regenerate and restore organs which are diseased or from traumatic injuries, he added. Globally there have several advancements as three products are launched in Korea, Japan has approved the first therapy for graft versus host condition, European Union too had cleared stem cell therapy for cornea replacement and enzyme deficiency and India too has a slew of products under clearance, he said.

At a session on 'Regenerative Medicine- from hope to reality', Manohar who moderated the session pointed out that in recent years, the area of stem cell research has undergone rapid developments promising new leads in the treatment of several incurable diseases.

Dr. Satyen Sanghavi, chief scientific officer and executive director, Regenerative Medical Services, Mumbai said that there is an urgent need to strengthen the regulatory framework for faster approvals. It is challenging to educate patients in the country that stem cells therapy is curative and not a disease management product like a drug.

According to Dr. C Randall Mills, president and CEO, California Institute for Regenerative Medicine (CIRM) pointed out that it was important to accelerate stem cell treatment to patients with unmet needs. The key factors for stem cell research and therapy are infrastructure, education and training besides regulatory paradigm enabling a level playing field.

Dr. Himanshu Matalia, medial superintendent and head, stem cell research group Narayana Nethralaya and Narayana Health City provided a peek into the success of cornea regeneration.

Stating that with no drugs to treat Burger's disease, stem cell treatment has been the answer and achieving over 70 per cent success, Prof. SR Subramaniam averred that this specialty should now become a major branch of medical treatment and could be a standard practice of care in the years to come.