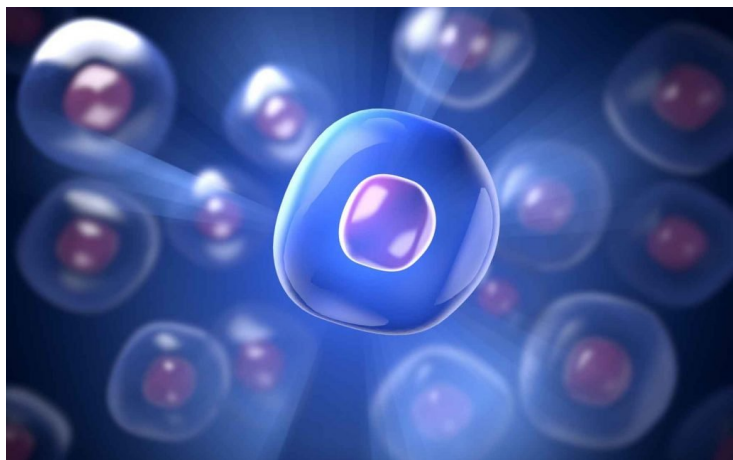


## Govt's new regulations to define 'stem cell therapy' from 'stem cell drug'

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**This amendment will facilitate growth of cell therapies in India and will also make these therapies available to lakhs of patients who are currently suffering with incurable diseases**



Stem Cell Society of India had organized its 4th international conference SCSICON 2018 in Delhi on April 28th and 29th in New Delhi. This year was the 4th annual international conference of the society.

“When the Prime Minister’s new and ambitious ‘Ayushman Bharat’, the National Health Protection Scheme, becomes operational, Stem cell therapy for providing relief to the disabilities in the ‘Rights of Persons with Disabilities Act, 2016 may be considered for inclusion under this scheme” Honorable Minister of Health & Family Welfare, Govt. of India, Shri Jagat Prakash Nadda mentions in a message for the SCSICON 2017-18 souvenir.

“The Drugs and Cosmetics Rules, 1945 are proposed to be amended to provide regulation of Stem Cell based drugs. At the same time, the stem cell based drugs are demarcated from stem cell therapy not to overstep the role of the treating physician”- Dr. S Eswara Reddy, Drug Controller General (India)

Dr Alok Sharma, President, StemCell Society of India said “The focus of the discussion in the conference was about the regulations for stem cell therapy in India. The scientists and doctors are hopeful about the future of stem cell therapy and welcome the new Indian Gazette. The progressive changes suggested in the Indian Drugs and Cosmetics Rule are highly appreciated.

As per the Gazette of India published on 4th April 2018; following additions are suggested as amendment of the Drugs and Cosmetics Rule, 1945. As per this Gazette it is proposed that, minimally manipulated stem cells will not be considered as ‘a Drug’ and therefore will be excluded from the Drugs and Cosmetics Rule; while the more than minimally manipulated and

substantially manipulated stem cells will be considered as 'a drug' and will therefore be under the purview of the Drugs and Cosmetics Rule."

Dr Alok Sharma explaining and elaborating further on the new regulations said, "Cells or tissues taken from the patients body, subjected to cleaning and separation for administering immediately without multiplying outside the body is termed as minimally manipulated cells. This is "stem cell therapy" which is under the surgeons or clinicians purview as opposed to "stem cell drugs" which would be a product or a drug. The cells or tissues which are taken from the body, multiplied in the laboratory or undergoes any genetic manipulation and stored in the laboratory to be used by the same patient or another patient are termed as more than minimally manipulated and these would be termed as "drugs" as per the amended Drugs and Cosmetics Act 1945 and will need to go through screening and trials as is expected from a new drug".

DrAlok Sharma further said "These changes are very progressive following the recent developments in countries like Japan, Korea and USA. This amendment will facilitate growth of cell therapies in India and will also make these therapies available to lakhs of patients who are currently suffering with incurable diseases."