

Govt seeks to define stem cells as drug, regulate use in therapy

An amendment proposed by the Centre may finally bring stem cells and cell-based products under the ambit of the law. The health ministry said that stem cells and their derivatives will have to follow protocols mandated for any new drug development.

MUMBAI: The Union health ministry has proposed an amendment to the **Drugs and Cosmetics Act** that may finally bring stem cells and cell-based products under the ambit of the law. Interestingly, the **Indian Council of Medical Research (ICMR)** — an arm of the health ministry that has been at the forefront of demanding stringent rules for stem cell use and even formulated guidelines last year — was apparently not consulted.

In a notification issued on **April 4**, the ministry defined the category of stem cells and their derivatives that would be termed a drug, and would thereby have to follow the protocols mandated for any drug development. It said stem cells and products which are substantially altered, amounting to a change in biological characteristics or those subjected to gene editing or modification, will be treated as a drug and will have to seek the regulator's approval before coming to the market. Currently, no such nod is necessary.

The notification though has practically left the use of autologous stem cells — where the individual's own stem cells are collected and minimally treated before infusing it back into the patient — unchecked. Such “therapies” meant to repair or regenerate damaged cells, tissues and organs are more rampantly used in centres across the country. The proposed amendment to the **Drugs and**

Cosmetics Act states that these would be considered “minimal manipulation”. Hence, doctors could continue to offer them without requiring a nod from the drug regulatory body.

Stem cells harvested from the umbilical cord and bone marrow have been scientifically proven to treat cancers, immunological diseases, etc. But, over the years, many doctors have started offering stem cell treatment for diseases where efficacy and safety are yet to be established.

“It’s a draft and definitely requires more clarity. We are discussing the contents and will submit our suggestions to the health ministry,” said **Dr Geeta Jotwani** from the **ICMR**, who was at the helm of framing the 2017 stem cell guidelines.

“In a country where stem cell therapy is already exploited, there has to be absolute clarity in defining it. Stem cells are currently being used for genetic disorders, dementia, autism, etc, without explaining to patients or relatives that autologous mononuclear cells transplant is not going to benefit them in any way,” she said. “The health ministry has to define immune therapy, gene therapy and stem cells individually in the Drugs and Cosmetics Act, else the risk of exploiting the science will remain.

Stem cell practitioners though have termed it as the first big step by the government to legitimise the use of such therapies in the country. “There is a huge outcry about the legality of using stem cells to treat patients when they are being used world over. Doctors fear losing their registration. The autologous therapies need an operation theatre setting as cells are removed from bone marrow but most reputed hospitals refuse permission,” said orthopedic surgeon **Dr Bhagat Singh Rajput**, who routinely uses stem cell therapy to treat muscular dystrophy, and spinal cord injuries. He claimed that there are 500-odd doctors in India using stem cells and products and the health ministry has paved the way

for them to do the job in a respectable manner.

“It will change the market because of the clarity that comes with the law. Now there will be an enforcing agency that will regulate and leave the unethical players out of the market,” said Dr Rohit Kulkarni, vice-president, Stem Cell Society of India. Asked why the industry was not producing enough data to substantiate their claim, Dr Rajput said there are enough case studies to show its success.

“Internationally, only hematologists can call themselves stem cell therapists, but here physicians and surgeons have given up their specialisations and started using stem cells on patients,” said a senior doctor.