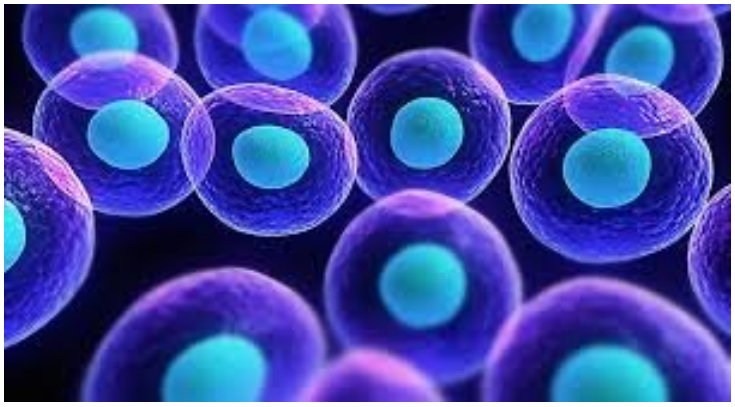
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# Govt to propose stem cells as drug, legitimize use in therapy

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**The ministry defined the category of stem cells and their derivatives that would be termed a drug**



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.

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 permission required.

Stem cells harvested from the umbilical cord and bone marrow has 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.

"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.