

F.No. X-11026/138/2023-BD
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Biological Division)

FDA Bhawan, Kotla Road,
New Delhi 110002

Dated: .

19 OCT 2023

To
All State/UTs Drugs Controllers.
All Zonal/Sub-Zonal/Port Offices of CDSCO.

Subject: Stem Cell Treatment and Advertisements for various diseases-Reg.

Sir/Madam,

This office has received various representations from time to time regarding Stem Cell treatment offered in various diseases like autoimmune degenerative and metabolic diseases, osteoarthritis, juvenile diabetes, spinal cord injury etc. Further, there are cases filed by stake holders in the court citing the use of stem cells, which are still under research but offered as treatment and that advertisements or promotion of such stem cell therapy by hospitals/clinics/doctors is to be prohibited to avoid widespread dissemination of such therapies.

As per the New Drugs and Clinical Trials Rules, 2019, "a vaccine, recombinant Deoxyribonucleic Acid (r-DNA) derived product, living modified organism, monoclonal anti-body, cell or stem cell derived product, gene therapeutic product or xenografts, intended to be used as drug" are considered under the definition of New Drug.

Subsequently, a direction under section 33P of the Drugs & Cosmetics Act, 1940 for clarification on '**stem cell derived product**' as defined under New Drugs and Clinical Trials Rules, 2019 was issued by the Central Govt. to the Principal/ Health Secretaries of all States/ Union Territories vide letter dated 09.02.2021 for regulation of manufacture, sale and distribution of such new drugs under the Drugs & Cosmetics Act, 1940 and rules thereunder. (Copy enclosed).

As per the clarification, "**Stem cell derived product**" means a drug which has been derived from processed stem cells and which has been processed by means of substantial or more than minimal manipulation with the objective of propagation and/ or differentiation of a cell or tissue, cell activation and production of a cell-line, which includes pharmaceutical or chemical or enzymatic treatment, altering a biological characteristic, combining with a non-cellular component, manipulation by genetic engineering including gene editing & gene modification.

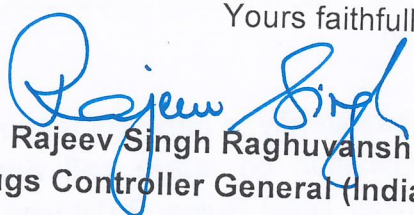
For the above purpose:

- (i) Substantial or more than minimal manipulation means ex-vivo alteration in the cell population (T-Cell depletion, cancer cell depletion), expansion, which is expected to result in alteration of function.
- (ii) The isolation of tissue, washing, centrifugation, suspension in acceptable medium, cutting, grinding, shaping, disintegration of tissue, separation of cells, isolation of a specific cell, treatment with antibiotics, sterilization by washing or gamma irradiation, freezing, thawing and such similar procedures are regarded as minimal manipulation and are not considered as processing by means of substantial or more than minimal manipulation.
- (iii) Stem cells removed from an individual for implantation of such cells only into the same individual for use during the same surgical procedure should not undergo processing steps beyond rinsing, cleaning or sizing and these steps shall not be considered as processing.

Further, the cell based products and tissue based products which have been processed by means of substantial or more than minimal manipulation as per criteria mentioned above are also covered under the New Drugs and Clinical Trials Rules, 2019.

In view of above facts and circumstances, you are hereby requested to sensitize your Inspectorate staff under your control to keep a strong vigil on such activities and advertisements for taking appropriate action under Drugs and Cosmetics Act, 1940 and rules thereunder.

Yours faithfully,


(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)