DCA
DRUGS CONTROL ADMINISTRATION
TELANGANA

GOVERNMENT OF TELANGANA
DRUGS CONTROL ADMINISTRATION

Circular Memo No.363/2021, **Dated:22-06-2021**

CIRCULAR

Sub: Drugs and Cosmetics Act, 1940 & New Drugs and Clinical Trial Rules, 2019 -Direction under Section 33P of the Drugs & Cosmetics Act, 1940 for issuance of clarification on 'Stem cell derived products' as defined under New Drugs and Clinical Trial Rules, 2019 – Clarification issued by MH&FW, Govt. of India –Communicated – Regarding.

Ref: 1. Memo No.1930/G/2021-1 dated: 25-02-2021 of Joint Secretary, HM&FW, Govt. of Telangana (enclosing reference 2nd cited)
2. Letter dated: 09-02-2021 in F. No. X.11014/21/2017-DRS to the Principal/Health Secretaries of the States/UTs

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It is hereby communicated that Ministry of Health and Family Welfare, Govt. of India issued direction under Section 33P, vide reference 2nd cited, for issuance of clarification regarding the term 'Stem Cell Derived Product' as defined under New Drugs and Clinical Trial Rules, 2019 to streamline the understanding for regulation under the provisions of said rules.

Accordingly, the clarification issued (ref. 2nd cited enclosed) shall be utilized for regulation of manufacture, sale and distribution of "Stem Cell Derived Products" under the Drugs and Cosmetics Act and rules thereunder.

22/6/2021

JOINT DIRECTOR (I/c)
DRUGS CONTROL ADMINISTRATION
TELANGANA STATE

To
All the Stakeholders in Telangana State

Encl: Reference 2nd cited

No. X.11014/21/2017-DRS
Government of India
Ministry of Health and Family Welfare
Department of Health & Family Welfare
(Drugs Regulation Section)

Nirman Bhawan, New Delhi
Dated the 9th February, 2021

To

The Principal / Health Secretaries of all States / Union Territories

Subject: Direction under section 33P of the Drugs & Cosmetics Act, 1940 for issuance of clarification on 'stem cell derived products' as defined under New Drugs and Clinical Trials Rules, 2019 - Reg.

Sir / Madam,

1930
23/02/2021.

The regulatory control over the manufacture and sale of drugs is exercised by the State Licensing Authorities appointed by the State Governments under the provisions of the Drugs and Cosmetics Act, 1940.

2. As per the New Drugs and Clinical Trials Rules, 2019, "new drug" includes "stem cell derived product" intended to be used as drug.

3. In light of the above and as a number of representations have been received, it has been felt necessary to provide clarification for streamlining regulation of such new drugs in the country.

4. To clarify the term "stem cell derived product", the matter was deliberated in the 84th meeting of the Drugs Technical Advisory Board (DTAB) held on 27.08.2019 wherein one of the agenda items was "Consideration of the proposal to incorporate definition for 'stem cell derived product' under the New Drugs and Clinical Trials Rules, 2019". After detailed deliberation on clarification of the term, DTAB agreed to the proposal in principle. Further, in the 85th DTAB meeting held on 29.07.2020, while discussing the Action Taken Report on the recommendations of 84th meeting, the Board recommended that the matter relating to "issuance of the clarification" for stem cell derived products as already decided needs to be expedited considering the urgency.

5. Accordingly, it is considered important to issue a clarification on such products to streamline the understanding for regulation under the provisions of New Drugs and Clinical Trials Rules, 2019.

6. In pursuance of the provisions contained in section 33P of the Drugs and Cosmetics Act, 1940, the Central Government hereby directs all the States/Union Territory Governments to utilize the following clarification for regulation of manufacture, sale and distribution of

such new drugs under the Drugs & Cosmetics Act, 1940 and rules thereunder:

"It is clarified that "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."

Yours faithfully,

Signed by Bikash R Mah
Date: 09-02-2021 10:54:
Reason: Approved

(Bikash R Mahato)
Under Secretary to the Government of India
Tel: 011-2306 1141

Copy to: Drugs Controller General (India), Central Drugs Standard Control Organization, FDA Bhawan, New Delhi