

**GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA**

UNSTARRED QUESTION NO:2928

ANSWERED ON:26.11.2010

GUIDELINES FOR STEM CELL RESEARCH AND THERAPY

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Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

- (a) whether the Indian Council of Medical Research (ICMR) has formulated guidelines for Stem Cell Research and Therapy in the country;
- (b) if so, the details thereof;
- (c) whether cases of violation of these guidelines have been reported in the country;
- (d) if so, the details thereof so far alongwith the action taken/proposed against those found guilty; and
- (e) the present status of treatment using stem cell in the country?

Answer

THE MINISTER OF STATE FOR HEALTH & FAMILY WELFARE (SHRI DINESH TRIVEDI)

(a) & (b): ICMR in collaboration with Department of Biotechnology has formulated Guidelines on Stem Cell Research and Therapy (2007) to help clinicians and scientists working in the field to conduct research in responsible scientific and ethically sensitive manner. The salient features of these guidelines are as under;

- (i) Two tier mechanism for review and monitoring of research and therapy in the field of human stem cells.
- (ii) Compulsory registration of all institutions and investigators with National Apex Committee-Stem Cell Research & Therapy (NAC-SCRT).
- (iii) Prior approval of NAC-SCRT or IC-SCRT, as applicable, for conducting any research in human stem cell.
- (iv) All new human stem cell lines to be created with the prior approval of NAC-SCRT or IC-SCRT.
- (v) All established human stem cell lines from any source, imported or created in India should be registered with IC-SCRT and NAC-SCRT.
- (vi) Permission for import/procurement from other Indian laboratories shall be obtained from IC-SCRT.
- (vii) All clinical trials with any stem cells shall have prior approval of IC-SCRT, institutional Ethics Committee and Drug Controller General of India for marketable product; and shall be registered with the NAC-SCRT. International collaborations shall also have prior approval of NAC-SCRT and funding agency as per its procedure/ or Health Ministry's Screening Committee.

(c) to (e): These guidelines are advisory in nature. At the moment, there is no system in place to take note of violation of these guidelines or take action against the agencies found violating these guidelines. Currently there is no approved indication for Stem Cell therapy as a part of routine medical practice, other than Bone marrow Transplantation (BMT).