

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

UNSTARRED QUESTION NO:766
ANSWERED ON:27.02.2015
STEM CELL RESEARCH AND THERAPY
Maragatham Smt. K.;Trivedi Shri Dinesh

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

- (a) whether the National Guidelines for Stem Cell Research prohibit stem cell therapy and consider its use for any other purpose outside the domain of clinical trial unethical in the country;
- (b) if so, the details and the reasons therefor indicating the ethical concerns present in use of embryonic stem cells for research purposes;
- (c) the other salient features of the aforesaid National Guidelines for Stem Cell Research and the mechanism put in place to regulate and oversee related activities in the country;
- (d) the steps taken and proposed to be taken by the Government for the promotion of stem cell research and treatment through stem cell therapy along with the funds earmarked, allocated and utilized by the Government for the above purpose during each of the last three years and the current year; and
- (e) whether the Government is evaluating a proposal to create a registry to have an official database on stem cell donors and recipients, and if so, the details thereof?

Answer

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI JAGAT PRAKASH NADDA)

(a): Yes. As per the National Guidelines for Stem Cell Research (2013), at present, there are no approved indications for stem cell therapy other than the hematopoietic stem cell transplantation (HSCT) for hematological disorders. Accordingly, all stem cell therapy other than the above shall be treated as investigational and conducted only in the form of a clinical trial after obtaining necessary regulatory approvals. Use of stem cells for any other purpose outside the domain of clinical trials will be considered unethical and hence is not permissible.

(b): Indian Council of Medical Research (ICMR) has informed that the research on embryonic stem cell involves creating embryonic stem cell lines, which may lead to commoditization of human tissue and cells with inherent risk of exploitation of individuals, particularly those belonging to underprivileged groups. Another concern is the misuse of the material for germline engineering and reproductive cloning. Hence, the research involving embryonic stem cells requires very close monitoring by the local committees. The details on Ethical considerations in use of embryonic stem cells are appended as Annex I.

(c): National Guidelines for Stem Cell Research(2013) apply to all stakeholders including individual researchers, organizations, sponsors, oversight/regulatory committees and any others associated with both basic and clinical research on all types of human stem cells and their derivatives.

As per the National Guidelines for Stem Cell Research (2013), an additional layer of oversight, besides the institutional Ethics Committee (IEC), in the form of Institutional Committee for stem cell research (IC-SCR) and National Apex Committee for Stem Cell Research and Therapy (NAC-SCRT) has been introduced to review and monitor stem cell research at the institutional as well as National level. A National apex committee for stem cell research and therapy (NAC-SCRT) will monitor and oversee activities at national level and institutional Committee for stem cell research (IC-SCR) at institutional level. These oversight committees shall ensure that review, approval and monitoring of all research projects in the field of stem cell research are done rigorously and effectively as per the National Guidelines. This mechanism of additional review has been accepted by the scientific community in the country and the NAC-SCRT has become operational after its notification by Department of Health Research (DHR) on 29th October 2012. Till date, 82 organizations/ Institutes across the country have applied for registration of their IC-SCRs with NAC-SCRT, out of which only 5 institutes have fulfilled the criteria and have been granted registration.

(d): ICMR is promoting activities under the area of Stem Cell Research. Besides promotion of basic/clinical research, ICMR is also involved in framing guidelines for stem cell research for scientists and clinicians working in the field. However, the details of funds allocated and utilized during past three years and current year in respect of ICMR, Department of biotechnology, Department of Science and Technology and AIIMS are given in the statement at Annexure-II.

(e): No.

