

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

UNSTARRED QUESTION NO:1230
ANSWERED ON:18.07.2014
TREATMENT THROUGH STEM CELL THERAPY
Singh Shri Ganesh

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

- (a) whether treatment through stem cell therapy has started in the country;
- (b) if so, the details thereof along with the time since when the said treatment is being practiced in the country;
- (c) the details of the hospitals in which treatment through stem cell therapy is being carried out in the country;
- (d) the details of the guidelines formulated by the Government with regard to permission to begin stem cell research and therapy and the mechanism put in place to regulate and oversee related activities in the country; and
- (e) the funds earmarked, allocated and utilized by the Government on various activities relating to stem cell research and therapy along with the outcome thereof during each of the last three years and the current year in the country?

Answer

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. HARSH VARDHAN)

(a)&(b): ICMR has stated that at present, there are no approved indications for stem cell therapy other than the hematopoietic stem cell transplantation(HSCT) for a haematological 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 trial will be considered unethical and hence is not permissible

(c):ICMR has informed that they have no information regarding the hospitals offering Stem Cell Therapy in the country.

(d): In 2007, the Indian Council of Medical Research and the Department of Biotechnology jointly released Guidelines for Stem Cell Research and Therapy. Taking into consideration the developments in the field and the views of the stakeholders the 2007 guidelines were revised and finalized in December 2013 and named as National Guidelines for Stem Cell Research. The salient features of the said guidelines are at Annexure-I.

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) have been introduced to review and monitor stem cell research at the institutional as well as the 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 and the required NAC-SCRT has become operational after its notification by Department of Health Research (DHR) on 29th October 2012.

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.

In order to take note of the cases violating these guidelines or take action against the agencies found violating these guidelines, Ministry of Health and Family Welfare (Govt. of India) vide order dated 1st September 2010 constituted a Core Investigational New Drug (IND) Panel of Experts namely "Cellular Biology Based Therapeutic Drug Evaluation Committee (CBBTDEC) under the chairmanship of Director General, ICMR & Secretary, DHR to advice DCGI in matters pertaining to regulatory pathways leading to the approval of clinical trials and market authorization for the "Therapeutic products derived from Stem Cell, human Gene manipulation and Xeno transplantation technology". CBBTDEC has deliberated on the need for strengthening the regulatory agency (DCGI) by establishing separate wing for Stem Cell Research supported with knowledge and capacity to regulate the activities in the country.

Accordingly, Directorate General of Health Services, Office of Drugs Controller General (India) Ministry of Health and Family Welfare, Government of India vide order dated 16-3-2012 has established Stem Cell Division within Biological Division in Central Drugs Standard Control Organization (HQ) for the internal evaluation of all proposals including stem cell concerning with clinical trial and marketing authorization before referring to CBBTDEC.

(e): ICMR is promoting activities under the area of Stem Cell Research. There was no separate grant/funds earmarked for Stem Cell Research. Besides promotion of basic/ clinical research, Besides ICMR, Department of Biotechnology (DBT) and Department of Science and Technology (DST) are also promoting research activities in the field of stem cell research.

The details of funds allocated and utilized during the past three years and current year is at Annexure-II.

The projects funded in the field of stem cell research are basic science nature. Outcome of the studies completed by 2013 is at Annexure- III, and IV.