GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

STARRED QUESTION NO:328
ANSWERED ON:27.04.2012
STEM CELL RESEARCH AND THERAPY
Ahir Shri Hansraj Gangaram

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

(a) the details of the guidelines and regulations formulated for stem cell research and therapy in the country;

(b) whether the Government has put in place any mechanism to take note of the violations of these guidelines and regulations;

(c) if so, the details thereof alongwith the number of cases of violation of these guidelines reported and action taken against the emng agencies during the last three years;

(d) if not, the reasons therefor; and

(e) the further measures taken/proposed to formulate mandatory guidelines and a regulatory framework to cany out stem cell research and therapy and ensure their proper compliance in the country?

Answer

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NAB1 AZAD)

(a)to(e): A statement is laid on the Table of the House.

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 328 FOR 27 APRIL, 2012

(a) ICMR jointly with Dept. of Biotechnology has formulated Guidelines for 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. Understanding the recent advances in the field, the guidelines are being revised in 2012. The draft guidelines are available on ICMR website (www.icmr.nic.in).

(b)to(d) As suggested in the guidelines, all the Institutes working in the field of Stem Cells Research and therapy have to constitute Institutional Committee for Stem Cell Research and Therapy (IC-SCRT) to oversee the activities and proper implementation of all guidelines. The guidelines have also suggested having National Apex Committee for Stem Cell Research and Therapy i.e. (NAC-SCRT) to oversee the activities at National level, where all the IC-SCRTs will be registered. Guidelines do suggest the responsibility of investigator and IC-SCRT to oversee activities at institution level and report to NAC-SCRT in case of violation/unethical practices. So far council has not received any complaints at institutional level,

Till recently, there was no mechanism in place to take note of the cases violating these guidelines or take action against the agencies found violating these guidelines. In a step towards this direction, 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 Xenotransplantation 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): Following steps were taken :

@ Constitution of National apex Committee

Dept. of Health Research has notified the constitution of NAC-SCRT on 29th October 2010.

NAC-SCRT has initiated the process of registration for IC-SCRTs.

NAC-SCRT has determined that `Given the current state of knowledge and evidence, only hematopoietic stem cell transplants for blood diseases and limbal stem cell transplants for comeal diseases can be performed as standard therapy outside of clinical trials in India.

All other forms of stem cell transplants, including those with blood or marrow derived stem cells, cord blood stem cells, mesenchymal stem cells and any embryonic stem cell derived tissue should only be used within an appropriately reviewed and monitored clinical trial that has been registered on the JCMR clinical registry (www.ctri.nic.in) and in accordance with current national guidelines`. This has already been put on ICMR website

http://www.icmr.nic.iri/icmrnews/NAC.htm