GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:4688
ANSWERED ON:21.02.2014
STEM CELL RESEARCH AND THERAPY
Reddy Shri Modugula Venugopala

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

(a) the details of the guidelines formulated by the Government to regulate stem cell research and therapy in the country;

(b) whether the Government has put in place any mechanism to take care of the violationsof the aforesaid guidelines and regulations;

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

(d) if not, the reasons therefor; and

(e) the measures taken/proposed by the Government to formulate mandatory guidelines and a regulatory framework for stem cell research and therapy and ensure their propers enforcement/compliance in the country?

Answer

THE MINISTER OF HEATH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD)

(a): Indian Council of Medical Research and Department of Biotechnology jointly released guidelines in 2007 for Stem Cell Research and Therapy. Considering the developments in the field and the views of the stake holders, the 2007 guidelines were revised and finalized in December 2013 and named as National Guidelines for Stem Cell Research. The details of the guidelines are given in the Annexed.

(b): National Guidelines for Stem Cell Research envisage setting up of a National Apex Committee for Stem Cell Research and Therapy (NAC-SCRT) to monitor and oversee activities at national level and Institutional Committee for Stem Cell Research (IC-SCR) at institutional level. These Committees shall ensure that review, approval and monitoring of the research projects in the field of Stem Cell Research are done rigorously and effectively as per the National guidelines.

(c) & (d): Few cases of violations have been received by NAC-SCRT. After deliberations, these cases have been forwarded to concerned regulatory authorities/agencies for necessary action.

(e): Ministry of Health and Family Welfare vide order dated 01-09/2010 constituted a Core Investigational New Drug 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 of General (India) Ministry of Health and Family Welfare, Govt. of India vide order dated 16.03.2012 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.