GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH RESEARCH

LOK SABHA
UNSTARRED QUESTION NO. 2528

TO BE ANSWERED ON 11TH MARCH, 2016

STEM CELL THERAPY

2528. SHRI LAKHAN LAL SAHU:

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

(a) whether the treatment through stem cell has been started in the country and if so, the details thereof;

(b) the details of the hospitals in the country providing treatment through stem cell therapy; and

(c) the details of the guidelines prepared/ issued by the Government to give permission for starting stem cell research and treatment in the country?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(SHRI SHRIPAD YESSO NAIK)

(a) to (c): No treatment regime using Stem Cells has been established yet, however, treatment using Stem Cell is only valid for diseases like Cancer. All India Institute of Medical Sciences (AIIMS), New Delhi, is providing treatment through Stem Cell Therapy to Cancer patients only.

The Indian Council of Medical Research (ICMR), in collaboration with the Department of Biotechnology, has prepared the National Guidelines for Stem Cell Research in the year 2013. These guidelines 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. The details are at **Annexure**.

As per the Indian Council of Medical Research (ICMR) National Guidelines for Stem Cell Research (2013), there are no approved indications for Stem Cell Therapy other than the Hematopoietic Stem Cell Transplantation (HSCT) for hemological disorders.

ANNEXURE

Salient features of the guidelines

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 the national level. A National Apex Committee for Stem Cell Research and Therapy (NAC-SCRT) will monitor and oversee activates 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 institute have fulfilled the criteria and have been granted registration. The status of registration of these organizations is available at NACSCRT website.

Clinical Research/Trial

Clinical trials using human stem cells should be in compliance with Schedule Y of Drugs and Cosmetics Act and GCP Guidelines of CDSCO (www.cdsco.nic.in)as well as ICMR Ethical Guidelines for Biomedical Research involving Human Participants (http://www.icmr.nic.in/ethical guidelines.pdf). Clinical trial protocol shall be formulated as per the format given in Annexure-II. The clinical research on stem cells must be performed only by appropriately qualified medical practitioners and in medical institutions with adequate infrastructure licensed by appropriate authority as per existing regulations (Clause 7.1). Reagents used for the derivation of humans ES or iPS cell lines, or expansion/enrichment of SSCs, for purposes of clinical trials should be of clinical – grade. The patient information sheet and the informed consent form shall specifically address:

a) Information regarding the present status of use of stem cells in the given condition, experimental nature of the proposed clinical study and its possible short and long term risks.
b) Information stating irreversibility of the intervention.
c) Information regarding source and characteristics of stem cells and degree of their ex-vivo manipulation, if any.
d) Information on the established standard of care for a given condition
e) Information on the sample size and duration of study
f) The information sheet and the consent form should be approved by IEC and IC-SCR and the same should be clearly mentioned in these documents.

Regulatory Approvals:-

1. All clinical trials using stem cells shall be registered with CTRI http://ctri.nic.in/Clinicaltrials/longin.php
2. Clinical trial proposals using minimally manipulated autologous SSCs hall be approved by IC-SCR and IEC.