

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

UNSTARRED QUESTION NO:2606
ANSWERED ON:11.03.2011
STEM CELL RESEARCH AND THERAPY
Kanubhai Patel Jayshreeben

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

- (a) whether the Government has laid down any guidelines and regulatory framework to carry out Stem Cell Research and Therapy in the country;
- (b) if so, the details thereof;
- (c) whether the Government has taken note of cure of blindness with the help of stem cell derived from foetus experiment as claimed by a scientist in USA.
- (d) if so, the details thereof; and
- (e) the steps taken/proposed to promo such research in the country alongwith the details of the developments in the field?

Answer

MINISTER OF THE STATE IN THE MINISTRY OF HEALTH & FAMILY WELFARE (SHRI GHULAM NABI AZAD)

(a) & (b): ICMR jointly with Department of Biotechnology has formulated Guidelines for Stem Cell Research and Therapy (2007). The guidelines are as under:

- (i) Two tier mechanism for review and monitoring of research and therapy in the field of human stem cell.
- (ii) Compulsory registration of all institutions and investigators with National Apex Committee-Stem Cell Research and Therapy (NAC-SCRT).
- (iii) Prior approval of NAC-SCRT or IC-SCRT, as applicable, for conducting any research in human stem cell.
- (iv) All new human stem cell lines to be created with the prior approval of NAC-SCRT or IC-SCRT.
- (v) All established human stem cell lines from any source, imported or created in India should be registered with IC-SCRT and NAC-SCRT.
- (vi) Permission for import/procurement from other Indian laboratories shall be obtained from IC-SCRT.
- (vii) All clinical trials with any stem cell shall have prior approval of IC SCRT, Institutional Ethics Committee and Drug Controller General of India for marketable product; and shall be registered with the NAC-SCRT. International collaborations shall also have prior approval of NAC-SCRT and funding agency as per its procedure/or Health Ministry's Screening Committee.

(c) to (e): As per the news in "The Washington Post" regarding the work of Robert Lonza, Chief Scientific Officer, Advanced Cell Technology Inc. of Marlborough, Mass in the field of Stem Cell research, The Food and Drug Administration, USA (USFDA) approved a second Clinical trial using Human Embryonic Stem Cells requested by Advanced Cell Technology Inc. to inject cells created from Human Embryonic Stem Cells into the eyes of 12 patients suffering from advanced cases of a disease that causes blindness, Stargardt's Macular Dystrophy. The Government has constituted special committees to assess the developments in the fields such as National Apex Committee from Stem Cell Research and Therapy (NAC-SCRT) and Cellular Biology Based Therapeutic Drug Evaluation Committee.