GOVERNMENT OF INDIA HEALTH AND FAMILY WELFARE LOK SABHA

UNSTARRED QUESTION NO:1516 ANSWERED ON:27.11.2009 STEM CELL RESEARCH AND THERAPY Devappa Anna Shri Shetti Raju Alias

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

- (a) the details of the guidelines issued in respect of Stem Cell Research and therefor in the country;
- (b) whether Stem Cell Research Therapy and are being carried out in the Government Medical Colleges and Hospitals in the country;
- (c) if so, the details thereof and if not the reasons therefor;
- (d) whether the facility of molecular diagnostic is available in the Government hospitals in the country; and
- (e) if so, the details of the hospitals where such facility is available?

Answer

MINISTER OF THE STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI S. GANDHISELVAN)

- (a) Indian Council of Medical Research in collaboration with Department of Bio-Technology has formulated guidelines for Stem Cell Research Therapy. The salient features of these guidelines are as under;
- (i) Two tier mechanism for review and monitoring of research and therapy in the field of human stem cells, one at the national level and an other at institutional level.
- (ii) Compulsory registration of all institutions and investigators with NAC-SCRT through IC-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 shall be created with the prior approval of NAC-SCRT or IC-SCRT, as the case may be.
- (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 cells 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.
- (b) to (e) Information is being collected and will be laid on the Table of the House.