

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

**LOK SABHA
UNSTARRED QUESTION NO. 1830
TO BE ANSWERED ON 11TH FEBRUARY, 2022**

RESEARCH IN REGENERATIVE MEDICINE

**1830. SHRI C.N. ANNADURAI:
SHRI ANURAG SHARMA:
SHRI SELVAM G:
SHRI GAJANAN KIRTIKAR:
SHRI GAUTHAM SIGAMANI PON:
SHRIMATI MANJULATA MANDAL:
SHRI DHANUSH M. KUMAR:**

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

- (a) whether the country is lagging in research and development of medicine and if so, the details thereof and the reaction of the Government thereto;
- (b) whether the Government needs to increase the pace of research in regenerative medicine to come up to the global level, especially in the area of clinical trials and regulatory requirement and if so, the details thereof;
- (c) whether the Government has prepared any plan of action in this regard with fixed targets and if so, the details thereof;
- (d) the funds allocated for the purpose during the last three years and the current year;
- (e) the extent to which the Government has achieved the target and goals so far in this regard; and
- (f) whether the Government has entered into any agreement with other countries for research and development of medicines and if so, the details thereof?

**ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(DR. BHARATI PRAVIN PAWAR)**

(a) to (f) The Government of India has conducted stem cell research through various Departments/ Institutions by supporting basic as well as clinical research through national funding agencies like the Indian Council of Medical Research (ICMR), Department of Biotechnology (DBT) and Department of Science and Technology (DST). The work done in this field has resulted in the establishment of state-of-art infrastructure at over 40 premier health research and educational institutes in addition to supporting industry initiatives in India.

ICMR has released the National Guidelines for Stem Cell Research (NGSCR) 2017 which were framed in harmonization of international guidelines. Government has supported the ethical and scientific conduct of stem cell research through guidelines for stem cell research. Government supports using hematopoietic cell transplantation (HCT) for hematological disorders, as standard of care, as per NGSCR-2017.

ICMR has also released Evidence Based Status of Stem Cell Therapy for Human Diseases for creating awareness and understanding regarding experimental use of stem cells under the purview of clinical trial and the document is available at the following link:

https://main.icmr.nic.in/sites/default/files/upload_documents/Evidence_Based_Status_of_Stem_Cell_Therapy_for_Human_Diseases_v1.pdf.

The Government has notified the New Drugs and Clinical Trial Rules, 2019 for regulation of clinical trials and New Drugs including cell & stem cell derived product, gene therapeutics product and xenografts for human use, which contains various provisions for improving transparency and accountability for the approval process and to promote research and development of the new drugs.

The total funds released by Indian Council of Medical Research (ICMR) during last three years under Stem cell research in fellowships and Ad-hoc project, are as below:

| Year | Total funds released (In Rs.) |
|-------------|--------------------------------------|
| 2019 | 4,36,19,531/- |
| 2020 | 68,82,564/- |
| 2021 | 3,08,34,008/- |

The Department of Biotechnology (DBT) has supported projects for basic biology of stem cells; early and late translational research; developing gene editing technology for potential therapeutic applications and creation of animal models for various human diseases. The funds released by the DBT during the last three years and the current year in this area is Rs. 7345.58 Lakh.
