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

LOK SABHA UNSTARRED QUESTION NO. 4850 TO BE ANSWERED ON 1st APRIL, 2022

STEM CELL RESEARCH

4850 SHRI SUNIL DATTATRAYTATKARE: DR. SUBHASH RAMRAO BHAMRE: SHRI ANURAG SHARMA: SHRIMATI SUPRIYA SULE: DR. AMOL RAMSING KOLHE: DR. DNV SENTHILKUMAR. S.:

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

(a) the details of 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 violations of the aforesaid guidelines and regulation and if so, the details thereof and if not the reasons therefor;

(c) the funds allocated and utilized for the purpose of Stem Cell Research and Therapy in the country during each of the last three years and the current year, State/UT-wise along with the achievement made in the field;

(d) whether Stem Cell Research Therapy are being carried out in Government Medical Colleges and Hospitals in the country and if so, the details thereof and if not the reasons therefor; and

(e) whether the facility of molecular diagnostic is available in the Government hospitals in the country and if so, the details of the hospitals where such facility is available?

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

(a) & (b): Ministry of Health & Family Welfare has notified New Drugs and Clinical Trials Rules, 2019 under Drugs and Cosmetics Act 1940. "Cell or stem cell derived product" is covered under the definition of "New Drugs" under the said rules. As and when complaint is received with respect to violation of New Drugs and Clinical Trials Rules, 2019 the matter is taken up for appropriate action as per the rules.

Besides, Indian Council of Medical Research (ICMR), an Autonomous Body under Department of Health Research has issued National Guidelines for Stem Cell Research (NGSCR-2017).They provide guidance to all stakeholders including scientists, clinicians and industry and can be accessed online at:

https://main.icmr.nic.in/sites/default/files/guidelines/Guidelines_for_stem_cell_research_2017.p df.

(c) Funds released during last three years (till date) under Stem Cell research may be seen at Annexure.

As informed by Department of Bio-Technology, support has been provided for projects on 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. In the programme on accelerating the application of stem cell technology in Human diseases, a novel hematopoietic stem cell based lentiviral vector mediated gene therapy product for possible treatment of Haemophilia A has been developed.

(d) Stem Cell Research is carried out in some Government Medical Colleges and Hospitals in the country. Stem Cell Therapy is offered only in approved disease conditions i.e hematological cancers and disorders. Therapeutic use of stem cells for other diseases is experimental and not standard of care, so same has to be done only under the purview of clinical trials to establish scientific evidences with its safety and efficacy.

(e) National Medical Commission in the Minimum Standards Requirements for Admissions Annually Regulations 1999 provide for setting up of a BSL-2 level, RTP-CR facility laboratories in the Deptt of Microbiology in all the Medical Colleges. The molecular labs, testing for COVID – 19, including those in Government Hospitals are listed in ICMR website at https://www.icmr.gov.in/pdf/covid/labs/COVID_Testing_Labs_29032022.pdf

Funds Released

ICMR

Year	Total funds released (in Rs)	
2019	4,36,19,531/-	
2020	68,82,564/-	
2021	3,08,34,008/-	
2022 (As on 28 th March)	10,00,000/-	

DBT

(Rs in Lakhs)

			Y	
State/UT	2021-22	2020-21	2019-20	2018-19
Andhra Pradesh	-	-	14.49	
Assam	-	-	-	6.36
Chandigarh (UT)	-	4.99	5.85	7.16
Delhi (UT)	141.80	30.59	103.71	84.35
Gujarat	-	-	18.89	-
Haryana	13.30	38.52	16.32	-
Karnataka	-	1566.89	2718.55	821.58
Kerala	15.00	14.61	14.79	36.25
Maharashtra	74.22	86.42	98.12	65.93
Odisha	-	-	6.58	8.01
Punjab	21.81	-	15.95	7.82
Tamilnadu	96.29	688.06	560.61	42.92
Telangana	29.54	17.35	9.33	35.38
Uttar Pradesh	-	22.99	13.07	12.40
West Bengal	-	-	16.85	37.85
