

**GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS**

LOK SABHA
UNSTARRED QUESTION No. 1707
TO BE ANSWERED ON THE 2nd July, 2019

Pharmaceutical Research

1707. SHRI PARVESH SAHIB SINGH:

Will the Minister of **CHEMICALS AND FERTILIZERS** be pleased to state:

- (a) whether there is any disease/virus/ epidemic in the country for which there is no drug/antidote available in the country as of June 2019 and if so, the details thereof;
- (b) the details of exclusive pharmaceutical research/inventions carried out in the country during the last five years; and
- (c) the total funds allocated for pharmaceutical research during the said period and the steps taken for promotion of pharmaceutical research and inventions in the country?

ANSWER

MINISTER IN THE MINISTRY OF CHEMICALS AND FERTILIZERS
(SHRI D. V. SADANANDA GOWDA)

(a): The Department of Pharmaceuticals has no data regarding any disease/virus/epidemic in the country for which there is no drug/antidote available in the country.

(b) & (C): The details of research and development activities being undertaken in the field of pharmaceuticals research is given at Annexure.

Annexure referred to in part (b) & (c) of Lok Sabha Unstarred Question No. 1707 for reply on 02.07.2019 raised by Shri Parvesh Sahib Singh regarding 'Pharmaceutical Research'.

(b) & (c): The details of research and development activities being undertaken in the field of pharmaceuticals research is as following:

- **Council of Scientific & Industrial Research (CSIR)** is implementing a Mission Mode Project on Active Pharmaceutical Ingredients to develop innovative and novel processes for soon to be generic nationally important APIs and also for key starting materials and intermediates for which Indian pharmaceutical industry is mainly dependent on China for its requirement. Selected molecules are: Daclatasvir; Ledipasvir; Nilotinib; Nicergolin; alpha-Lipoic acid; Sitagliptin; Sacubitril; Azelaic Acid; Paracetamol; Ibuprofen; Dolutegravir; Boscalid; Pregabalin; Avibactam.
- CSIR is implementing Phytopharmaceuticals Mission under which phytopharmaceutical development is being pursued along with related activities such as captive cultivation of medicinal plants including rare and endangered medicinal plants and technology for preparation of standardized extracts. The phytopharmaceutical development is being pursued as per regulatory guidelines of DCGI/AYUSH. Phytopharmaceutical development of *Cassia occidentalis* for Glucocorticoid-induced osteoporosis, *Murraya koenigii* for Cervical cancer, *Dysoxylum binectariferum* for Rheumatoid arthritis and *Picrorhiza kurroa* for Liver fibrosis is being pursued as per regulatory guidelines of DCGI(I). Phytopharmaceutical development of *Glycyrrhiza glabra* for Diabetes, *Cissampelos pareira* for Anti-venom, *Tinospora cordifolia* for Cognitive impairment and *Bergenia ciliate* for Pain in Rheumatoid arthritis is being pursued as per regulatory guidelines of AYUSH.
- CSIR is also implementing Sickle Cell Anaemia Mission for Managing Genetic Burden of Sickle Cell Anaemia and Understanding Genetic Basis of Differential Response to Hydroxyurea Therapy; Drug discovery and development for management of SCA; Genome editing and stem cell research approach for the treatment of SCA; and Development and on-ground implementation of an affordable, accurate and accelerated diagnostic kit.
- Standardized extract of *Dalbergia sissoo* for fracture healing and management of post-menopausal osteoporosis has been launched for marketing on 17 Feb 2016 by our licensee M/s. Pharmanza Herbals Ltd., Gujarat. It is being marketed with brand name Reunion, an Ayurvedic Medicine.
- Technology of novel osteo-inductive agent CDRI S008-399 as medicated bone implant material for fracture healing has been transferred to M/s. OrthoRegenics Pvt., Ltd., Hyderabad.
- IND has been filed for the Antithrombotic candidate drug S007-867
- Advanced level pre-clinical regulatory studies are ongoing for the fracture healing agent CDRI S007-1500. IND to be filed shortly.
- Development of Non-invasive Premature Birth Prediction Kit
- Development of a biosimilar of Adalimumab for treatment of rheumatoid arthritis: scaling-up of upstream and downstream mAb production processes

As per the information received from CSIR, detail of their allocation on pharmaceuticals research is given below:

(Rs. In Lakh)					
Year	2015-16	2016-17	2017-18	2018-19	19-20 (till date)
R&D Budget	6063	4608	7747	9227	5252

The Department of Science and Technology under Ministry of Science and Technology has been implementing a Plan Scheme (Drugs & Pharmaceuticals Research Programme – DPRP) since 1994-95 for promoting R&D in Drugs & Pharmaceutical Sector with the following objectives:

- To synergise the strengths of publicly funded R&D institutions and Indian Pharmaceutical Industry;
- To create an enabling infrastructure, mechanisms and linkages to facilitate new drug development;
- To stimulate skill development of human resources in R&D for drugs and pharmaceuticals;

Under this programme grants-in-aid is extended to Indian Pharmaceutical industries for clinical trials – Phase-I, II and III for neglected diseases such as Tuberculosis, Malaria, Kala-Azar, Filariasis, etc. Since 2008-09, this programme supported four grants-in-aid projects to Indian Pharma industries for conducting trials in neglected diseases such as malaria, kala-azar etc.

The total funds allocated to the Drugs & Pharmaceuticals Research Programme (DPRP) during the last five years is 100 Crores

Indian Council for Medical Research (ICMR) has supported a total number of 20 pharmaceutical research projects during last five years. ICMR has set up Technical Advisory group for guidance of taking forward leads of research for product development.

ICMR has released Rs. 2.57 crores for pharmaceutical research.

XXXXX