GOVERNMENT OF INDIA
MINISTRY OF SCIENCE AND TECHNOLOGY
DEPARTMENT OF SCIENTIFIC AND INDUSTRIAL RESEARCH

LOK SABHA
STARRED QUESTION No. *373
(TO BE ANSWERED ON 21.03.2018)

ALLOCATION OF FUND TO CSIR

*373. SHRI PREM DAS RAI:

Will the Minister of SCIENCE AND TECHNOLOGY be pleased to state:

(a) the percentage hike in allocation to CSIR under the Union Budget 2018;
(b) whether the budgetary allocation to CSIR is sufficient to fund the research in new drugs for kala-azar, filaria, leprosy and tuberculosis;
(c) if so, the details thereof and if not, the manner in which the Government proposes to fund and support such research; and
(d) the achievements made by CSIR in making affordable drugs for the above diseases?

ANSWER
MINISTER OF SCIENCE AND TECHNOLOGY AND EARTH SCIENCES
(DR. HARSH VARDHAN)

(a) Madam, the Council of Scientific and Industrial Research (CSIR) has been allocated Rs. 4734.71 crore (Budget Estimate) for the Financial Year (FY) 2018-19. The budget for FY 2017-18 was Rs. 4582.12 crore (Revised Estimate). This corresponds to a budgetary hike of 3.33% compared to that in 2017-18.

(b), (c)&(d) Yes, Madam, considering the spectrum and quantum of R&D activities being pursued by the CSIR constituent laboratories which range from studies that lead to better understanding of molecular mechanisms to identifying potential drug targets to new disease diagnostics to drug molecules and new formulations.

CSIR laboratories carry out focused R&D efforts in the infectious disease area, particularly tuberculosis and leishmaniasis (Kala-azar), and to a smaller extent in the area of filariasis.

An important intervention developed for tuberculosis by CSIR jointly with Cadila Pharmaceuticals, Ahmedabad, is a drug named Risorine. It is a novel formulation of Rifampicin with piperine, the bio-enhancer based on knowledge derived from Ayurveda. The drug is marketed by Cadila Pharmaceuticals Ltd, Ahmedabad since 2009. The cost of a single day dose of Risorine kit (Rifampicin-200mg, Isoniazid-300mg, Piperine-10mg,

Ethambutol-800mg, Pyrazinamid-750mg) is Rs. 14.50. The annual sales (2015 and 2016) of RISORINE CAP 10X6 CAP and RISORINE KIT 30X1 KIT is about Rs 100 lakhs, each.

Under the CSIR-NMITLI programme, a battery operated hand held microPCR for diagnosis of various diseases has been developed. The diseases which can be diagnosed are: Tuberculosis, Malaria, Dengue, Chikungunya, Hepatitis B and H1N1. The product is available in Indian and global markets.

An anti-leishmanial lead compound 96/261 has been identified for further development.

No new drug candidate for filariasis is currently being pursued by the CSIR.

Some key achievements of CSIR in the areas related to tuberculosis, leishmaniasis and filariasis from recent past are given at Annexure-1.

Key achievements of CSIR in the areas related to tuberculosis, leishmaniasis and filariasis from recent past

- **Tuberculosis:**
  - **Developed a metabolite (non-nucleic acid) biomarker based novel TB diagnostic kit for sensitive M. tuberculosis (can detect Mtb missed by smear microscopy) and specific (to Mtb in sputum samples). The technology has been licensed to a start-up company (Annweshan SciTech Pvt. Ltd.) for further development;**
  - **Developed a viable new process for Bedaquiline, a drug for treating multi-drug-resistant tuberculosis (TB);**
  - **Identified novel-protein-protein-interactions essential for virulence regulation of Mtb which can be pursued as unique targets of anti-mycobacterial drugs/ entities;**
  - **Shown that (a) biofilm harbours a population of phenotypically drug-resistant Mtb and (b) cellulose is a major component of the Mtb biofilms;**
  - **Generated fusion constructs expressing reporter protein along with virulence factors for tuberculosis;**
  - **Identified miRNA and cytokine signatures in body fluids for TB diagnostics; and**
  - **Identified new hits/leads:**
    - ✓ **Nano-molar MmpL3 transporter protein inhibitors: NDS-100244 and NDS-100529;**
    - ✓ **10-α/β-D-arabinofuranosyl-undecenes based nanomolar cell-wall synthesis inhibitor;**
    - ✓ **11 leads (IICT-1 to IICT-11) - pursuing 3 leads (IICT-3, IICT-4, and IICT-8) for further investigations;**
    - ✓ **IIIM/019/Dinitroimidazole derivative for treatment of MDR tuberculosis;**
    - ✓ **IIIM/1132+rifampicin combination for improved bioefficacy;**
- **Leishmaniasis:**
  - **Developed serum and urine-based kits for diagnosis of human and canine visceral leishmaniasis (VL) and post kala-azar dermal leishmaniasis (PKDL);**
    - ✓ **A colloidal gold-based LFT for detecting serum and urine antibodies specific to *L. donovani* purified antigen, Lag has been developed. The LFTs are undergoing validation in the clinical settings;**
  - **Identified new hits/leads:**

- ✓ **Identified anti-leishmanial lead compound 96/261: Has potent activity against *Leishmania donovani* both *in vitro* and *in vivo*. Dose-dependent response in the hamster- L. donovani model has been seen and pharmacokinetic analysis has been carried out. Early toxicity studies indicate a high tolerated dose suggesting a good safety margin;**
- ✓ **Anti-leishmanial lyophilized liposomal amphotericin B (AmB) formulation: detailed toxicity, immunomodulation and anti-leishmanial studies need to be carried out;**

- **Identification and development of META1 as a druggable target against leishmaniasis: Possibly essential for Leishmania survival; Potential virulence factor; Role in deciding which tissue to infect/modulates secretary process and reversible changes in leishmania morphology;**
- **Generated a clear understanding of the virulence of leishmaniasis through regulation of parasite genes; and**
- **Developed a novel liposomal adjuvant formulation for induction of long term protective response in leishmaniasis;**

- **Filariasis:**
  - **Mapped the genome (draft) of parasitic nematode, *Setaria digitate* (filariasis).**

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