GOVERNMENT OF INDIA MINISTRY OF AYURVEDA, YOGA & NATUROPATHY, UNANI, SIDDHA AND HOMOEOPATHY (AYUSH)

LOK SABHA UNSTARRED QUESTION NO. 4004 TO BE ANSWERED ON 10TH AUGUST, 2018

BGR-34

4004. SHRI RABINDRA KUMAR JENA:

Will the Minister of AYURVEDA, YOGA AND NATUROPATHY, UNANI, SIDDHA AND HOMOEOPATHY (AYUSH) be pleased to state:

- (a) whether the Ministry has approved BGR-34, an Ayurvedic drug designed for treatment of diabetes;
- (b) if so, the details of its supply and distribution by concerned agencies;
- (c) whether clinical trials of the drug have been conducted before its launch and if so, the details thereof;
- (d) whether said clinical trials are included/noted in Clinical Trials Registry India and if so, the details thereof;
- (e) the details of duration of research on BGR-34, the number of people it has been tested upon, the number of peer reviewed journals which have published studies related to the drug; and
- (f) whether a patent for the drug has been acquired by the Government and if so, the details thereof?

ANSWER

THE MINISTER OF STATE (IC) OF THE MINISTRY OF AYURVEDA, YOGA & NATUROPATHY, UNANI, SIDDHA AND HOMOEOPATHY (SHRI SHRIPAD YESSO NAIK)

(a) to (f): Council of Scientific & Industrial Research (CSIR), through its constituent laboratories namely CSIR-Central Institute of Medicinal & Aromatic Plants (CSIR-CIMAP), Lucknow; and CSIR-National Botanical Research Institute (CSIR-NBRI), Lucknow jointly developed scientifically validated herbal product NBRMAP-DB as anti-diabetic, hypoglycemic formulation with hepato-protective and anti-oxidant properties and the knowhow for the product was licensed to M/s AIMIL Pharma Ltd., Delhi who are manufacturing and marketing it as BGR-34.

C	'n	n	t	d				

M/s AIMIL Pharmaceuticals, the licensee carried out the clinical study of BGR-34 and the trial was registered in clinical trial registry of India (Registration number: CTRI/2016/11/007476). The Number of people tested was 64.

The research on the technology was initiated in the year 2010 and the technology was transferred in the year 2015. A separate clinical trial has also been registered (CTRI/2017/09/009709 [Registered on: 11/09/2017]) which has been done on 100 patients. Publication on the said formulation is available in public domain. (Preliminary clinical assessment and non-toxicity evaluation of an Ayurveda formulation BGR-34 in NIDDM published in Journal of Traditional and Complementary Medicine, https://doi.org/10.1016/j.jtcme.2017.11.004, In press).

The patents have been filed for the formulation (0097NF2014/IN and 0097NF2014/WO).