

**GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA**

STARRED QUESTION NO:325
ANSWERED ON:04.02.2004
DRUG FOR DIABETES
M. JAGANNATH;VSM (RETD.) COL. CHOUDHARY

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

- (a) whether a new wonder drug for diabetes has been developed by an Indian researcher as reported in the Times of India dated January 20, 2004;
- (b) if so, the facts of the matter reported therein;
- (c) whether this wonder drug has won an award in US;
- (d) whether it is slated for global launch during March 2004;
- (e) if so, whether the Government has given the clearance for launch of this drug in the country;
- (f) if not, the reasons therefore; and
- (g) the time by which the Government proposes to give clearance for launch of this drug?

Answer

MINISTER OF HEALTH AND FAMILY WELFARE AND PARLIAMENTARY AFFAIRS (SMT. SUSHMA SWARAJ)

(a) to (g): A Statement is laid on the Table of the House.

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 325 FOR 04.02.2004

A Bangalore based firm M/s German Pharmaceutical Ltd. had approached DCG(I)'s office in September, 1999, with request for permission to carry out clinical trial with the product Diabetes Entoxin-N on Indian patients suffering from Type-II Diabetes Mellitus. The product was to be imported from Germany. Since the reference to this product for treatment of diabetes is not available in any standard medical texts, the proposal was referred to the Director, CDRI, Lucknow and ICMR in February/ March, 2000 respectively by the office of DCG(I), along with the protocol submitted by the applicant, for expert opinion on the essentiality and desirability of granting permission for conducting clinical trial with Diabetes Entoxin-II in Diabetes Mellitus in the country as per the protocol submitted by the firm. On receipt of the comments of ICMR, the firm was requested to furnish relevant data with regard to its chemistry, pre-clinical toxicology and efficacy in September 2000.

In response in March, 2003, the applicant informed that they have conducted study on this German Phyto Pharmaceutical Drug through American Prosthetics for Diabetics Foundation which resulted in 98.28 success and that Dr. Jyoti Ghosh of German Pharmaceutical Ltd., Bangalore, who has developed this drug, has been chosen for an award carrying prize money of US\$ 0.5 million. Dr. Jyoti Ghosh has further informed DG, ICMR that his product, since named in the patent application in USA, as Arogya-2 (under production in Germany) is a modern complementary medicine with five botanical extracts and Chromium group supplements. However, the firm did not enclose the required data with regard to chemistry, pre-clinical toxicology and efficacy.

ICMR have now informed that on evaluation of the information submitted, it appears that the drug has the potential to be used for treatment of Diabetes in India. However, detailed information regarding formulation, pre-clinical safety and pharmacological data and protocol for clinical trial along with details of the earlier clinical trial results is required to be furnished by M/s German Pharmaceutical Ltd. for further examination by the expert group set up by ICMR. The same is awaited.

This Ministry has no information, from published literature, that this product is slated for global launch during March, 2004, as a drug for treatment of Diabetes.