

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

STARRED QUESTION NO:178

ANSWERED ON:08.03.2013

TUBERCULOSIS VACCINE

Das Gupta Shri Gurudas;Viswanathan Shri P.

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

(a) whether the Government has taken note of various international research projects to develop a vaccine to protect infants and children against tuberculosis, particularly drug-resistant tuberculosis;

(b) if so, the details thereof;

(c) the steps taken/proposed by the Government to support research in this regard including the outcome thereof;

(d) whether the Government has received any request to allow entry of new TB drug Bedaquiline into India for the benefit of patients suffering from drug resistant tuberculosis; and

(e) if so, the details thereof along with the action taken/proposed by the Government thereon?

**Answer**

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD)

(a)to(e): A statement is laid on the Table of the House.

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO.178 FOR 8TH MARCH, 2013

(a)&(b): Yes, Madam. The Government has taken note of various international projects to develop a vaccine against tuberculosis. There are 12 TB vaccine candidates in various stages of development and two of them are in phase IIb trials. The vaccine candidates are designed to protect against infection or reactivation of TB disease, both drug sensitive and drug resistant TB. Recently, results of a vaccine trial (using MVA 85A antigen) carried out in a rural region near Cape Town S. Africa was published (Lancet published online Feb. 4, 2013) and showed lack of significant protection against TB in young infants. No effective vaccine has yet been developed to protect infants and children against tuberculosis, particularly drug resistant tuberculosis.

(c): The Government is supporting the development of indigenous vaccines in tuberculosis by funding research in this area. The Indian Council of Medical Research (ICMR) as well as Department of Biotechnology (DBT) and Department of Science & Technology (DST) are funding various research groups in the country to identify and test suitable vaccine candidates. Animal studies showed good protective efficacy.

(d) & (e): No request has been received under the Drugs and Cosmetics Act to allow entry of new TB drug Bedaquiline into India. A new drug can only be introduced in the Indian market after due approval from Drugs Controller General of India (DCGI).

However, the ICMR and Central TB Division of DGHS have convened an expert group to discuss the introduction of new TB drug Bedaquiline in India. It is proposed to introduce the drug in India under controlled conditions at 4-5 DOTS Plus sites to assess its impact on Multidrug and extensively drug-resistant TB (M/XDRTB).