

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

STARRED QUESTION NO:614

ANSWERED ON:07.05.2010

DRUGS FOR TUBERCULOSIS

Kanubhai Patel Jayshreeben;Singh Alias Pappu Singh Shri Uday

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

- (a) whether the government has examined the quality and effectiveness of the various drugs including resorine for the treatment of tuberculosis in the country;
- (b) if so, the details thereof;
- (c) whether the Government has recently withdrawn the stock of the drug being administered under the Revised National Tuberculosis Control Programme (RNTCP);
- (d) if so, the details thereof and the reasons therefor; and
- (e) the action taken/proposed to be taken by the Government to ensure the supply of quality drugs under the said programme?

Answer

MINISTER OF THE STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NAM 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.614 FOR 07-05-2010

(a) & (b): Various anti-TB drugs like Rifampicin, Isoniazid, Pyrazinamide, Ethambutol, Streptomycin etc. and combination of such drugs, including Resorine have been approved for marketing in the country as per the provisions of the Drugs and Cosmetics Act and Rules. These drugs are effective if taken as recommended.

(c) & (d): There is a system of routine quality surveillance of anti-TB drugs supplied under the Revised National TB control Programme (RNTCP). Based on the results of routine surveillance and the advice of the Expert Committee of the Ministry, four batches of anti-TB drugs were withdrawn in June 2009. These anti-TB drugs were supplied in 2007, after having been fully compliant with Indian Pharmacopoeia (IP)-1996, the standards prevailing at that time. The Indian Pharmacopoeia-2007 standards came into force in July 2008. During the tests conducted in May 2009, these drugs were found to be not fully compliant with new standards. Therefore, on the advice of the Expert Committee, the drugs in question were withdrawn.

(e): With a view to ensuring supply of quality drugs, the Revised National TB Control Programme (RNTCP) has put in place a quality assurance protocol. The procurement of anti-TB drugs is carried out with the help of a professional procurement agency and through a competitive bidding process. Prior to dispatch of drugs to the consignees, each batch is subjected to inspection for quality testing at the supplier's premises. In addition, as an additional safeguard for continued stability and quality of these drugs under actual field conditions, random samples are lifted from the field units and tested by NABL accredited independent laboratories identified by the Ministry.