

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

STARRED QUESTION NO:258

ANSWERED ON:13.03.2015

TRACK AND TRACE MECHANISM FOR SAFE MEDICINES

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

- (a) whether the Government proposes to launch a `track and trace` mechanism through which patient will be able to check the safety and authenticity of the medicine;
- (b) if so, the details and the objective thereof along with the cost to be incurred on the said mechanism for the domestic market;
- (c) the time by which the `track and trace` mechanism is likely to be launched and the manner in which it is likely to be made operational in the country; and
- (d) the other steps being taken by the Government to provide quality and standard medicines to the consumers?

Answer

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI JAGAT PRAKASH NADDA)

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

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 258 FOR 13TH MARCH, 2015

(a) Yes.

(b) A 'Track and Trace' mechanism has been developed with the objective of authenticating that the medicines being sold and stored in the country are the genuine products of the manufacturer. Under the system, the primary, secondary and tertiary packs of medicines will have a unique bar code allotted to a particular manufacturer. The data relating to all medicinal products will be available on the internet and any person having access to internet would be able to cross check the authenticity of the medicines.

(c) Rules for implementing the Track and Trace mechanism will be framed and will be operationalized after allowing a reasonable period for transition. Compliance with the requirements of this mechanism will be mandatory for all manufacturers of drugs.

(d) The Drugs and Cosmetics Act, 1940, provides stringent penalties for manufacture of spurious and adulterated drugs. Certain offences have also been made cognizable and non-bailable. The inspectorate staff of Central Drugs Standard Control Organisation also keeps a vigil and draws samples of drugs for test and analysis to monitor the quality of drugs in the country.