GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

STARRED QUESTION NO:200
ANSWERED ON:05.12.2014
EXEMPTION OF DRUGS FROM CLINICALTRIALS
Chavan Shri Ashok Shankarrao;Singh Shri Kunwar Haribansh

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

(a) The details of the provisions/ guidelines laid down by the Government with regard to clinical trials of new drugs for grant of licences for their import, manufacture and sale in the country;

(b) Whether the Government proposes to exempt certain new drugs for serious and life-threatening diseases and ailments from local clinical trials;

(c) If so, the details of the exemption criteria drawn up/to be drawn up along with the reasons therefor; and

(d)The steps taken/proposed to be taken by the Government to ensure safety, quality and standards of drugs likely to be exempted from local clinical trials?

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. 200 FOR 05TH DECEMBER, 2014

(a): Rule 122A, 122B, 122D, 122E and Schedule-Y of Drugs & Cosmetics Rules, 1945 specify the requirements and guidelines for conducting clinical trials for marketing of new drugs in India. As regards new drugs approved in other countries, phase III clinical trial is required to be conducted in the country before granting permission to manufacture / import of finished formulation of the new drug.

(b) & (c): As per the provisions under Rule 122A (2) & Rule 122B(3) of the Drugs & Cosmetics Rules, 1945, the requirement of submitting the results of local clinical trial may be exempted if the Licensing Authority decides in public interest to grant such permission on the basis of data available from other countries. Further, as per Para 1 (3) of Schedule Y of the Drugs & Cosmetics Rules, 1945, clinical trial data requirements may be either abbreviated or deferred or omitted, as deemed appropriate by the Licensing Authority, in case of drugs for life threatening / serious diseases or diseases of special relevance in the Indian health scenario.

(d): To ensure safety, quality and standards of drugs likely to be exempted from local clinical trials, the applicant is required to submit technical data including chemical pharmaceutical information, animal pharmacological and toxicological data, and clinical trial data generated with the drug outside the country as well as the local clinical trial data. Besides, waiver of local clinical trial is also considered for approval of such new drugs which have already been approved in other countries.