GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:4546
ANSWERED ON:19.12.2014
DRUGS EXEMPTED FROM CLINICAL TRIALS
Mahadik Shri Dhananjay Bhimrao;Patil Shri Vijaysinh Mohite;Satav Shri Rajeev Shankarrao;Sule Smt. Supriya Sadanand

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

(a) the details of the drugs in circulation in the country which have been exempted by the Licensing Authority from the requirement of local clinical trial along with the reasons therefor;

(b) whether the Drug Technical Advisory Committee has recently recommended/suggested waiving off of local clinical trials for certain new cancer drugs;

(c) if so, the details thereof and the reasons therefor along with the final decision taken/likely to be taken in this regard;

(d) the steps taken/proposed to be taken by the Government to ensure that clinical trial waiver to such drugs does not have adverse implications for patients; and

(e) the measures being taken by the Government to strengthen the process of approval of new drugs in the country?

Answer

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

(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. However, as per the provisions under Rule 122A(2) & Rule 122B(3) and Para 1(3) of Schedule Y of the Drugs & Cosmetics Rules, 1945, the requirement of submitting the results of local clinical trials may be exempted under certain conditions. The details of new drugs approved for marketing in the country, waiving off local clinical trials in accordance with the provisions/ guidelines during last 5 years and the current year (till November, 2014) are at Annexure-I.

(b) & (c): The Drug Technical Advisory Board is not required to consider matters relating to waiver of clinical trials. Such proposals are considered by the New Drug Advisory Committee (NDAC). From 31.03.2011 onwards, when the NDAC was constituted, 12 anti-cancer drugs have been granted permission/approval for marketing in the country with the waiver of local clinical trials in 10 cases. Further, NDAC has recommended waiver of local clinical trials in respect of the nine anti-cancer drugs, as per details in Annexure-II subject to certain conditions.

(d) & (e): To ensure safety, quality and standards of drugs likely to be exempted from local clinical trials, the applicant is required to submit the technical data including chemical, pharmaceutical, animal pharmacological and toxicological and clinical trial data generated with the drugs outside the country as well as 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. The Government has already made exhaustive provisions for approval of new drugs in the country and these are placed in the public domain.