GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH AND FAMILY WELFARE

LOK SABHA
UNSTARRED QUESTION NO. 1203
TO BE ANSWERED ON 9TH FEBRUARY, 2018

WAIVING OFF CLINICAL TRIALS

1203. SHRIMATI VANAROJA R.:

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

(a) whether it is true that the Government is considering to waive off clinical trials in humans for select drugs which are essential for Indian patients and are approved in developed markets;

(b) if so, the details thereof;

(c) whether the Government has received recommendations in this regard from Ranjit Roy Chowdhary Committee; and

(d) if so, the details thereof?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(SHRI ASHWINI KUMAR CHOUBEY)

(a) to (d): As per the existing provisions under the Drugs and Cosmetics Rules, 1945, for new drugs substances approved in other countries, phase III clinical trial is required before granting permission for manufacture/import of finished formulation of the new drug. However, requirements of local Clinical Trial may be waived off / relaxed under certain conditions as per Drugs and Cosmetics Rules depending on nature of drug and diseases for which it is indicated.

In this regard, Prof Ranjit Roy committee recommended that drugs which have already been on the market in well-regulated countries with good post-marketing surveillance (PMS) for more than four years and which have a satisfactory report may be granted marketing licence, subject to strict PMS for four to six years.

In view of the above recommendations, Central Drugs Standard Control Organisation issued an order on 03.07.2014 that waiver of Clinical Trial in Indian population for approval of new drugs, which have already been approved outside India, can presently be considered only in cases of national emergency, extreme urgency, and epidemic and for orphan drugs for rare diseases and drugs indicated for condition/ diseases for which there is no therapy.

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