

1	2	3	4
Uttar Pradesh	Allahabad	12	3
	Kanpur	28	14
	Lucknow	18	9
	Meerut	16	2
West Bengal	Kolkata	12	5
Chandigarh (UT)	Chandigarh	7	5
TOTAL		481	134

Directions for clinical trials of all new drugs

546. SHRI T.M. SELVAGANAPATHI: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that every month one drug is being approved without trial;

(b) whether it is also a fact that in many cases even the mandatory Phase-III clinical trials had not been conducted;

(c) if so, the reasons therefor;

(d) whether Government has given any direction to conduct clinical trials for all drugs without fail; and

(e) if so, the details thereof?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD): (a) No. New drugs are approved in the country based on non-clinical data, clinical data of safety and efficacy of drug, regulatory status in other countries etc. as per the requirements and Guidelines specified in Rules 122A, 122B, 122D and Schedule Y of the Drugs and Cosmetics Rules, 1945.

(b) to (e) As per the Schedule Y, for new drug approved outside India, phase III clinical trials need to be carried out primarily to generate evidence of efficacy and safety of the drugs in Indian patients when used as recommended in the prescribing information. However, as per Rule 122 A (2) and Rule 122 B (3), the

requirement of such local clinical trial may not be necessary if the drug is of such a nature that the Licensing Authority may, in public interest, decide to grant permission to import/manufacture the new drug on the basis of data available from other countries.

Further, as per clause 1 (3) of Schedule Y, for drugs indicated in life threatening/serious diseases or diseases of special relevance to the Indian health scenario, clinical data requirements may be abbreviated, deferred or omitted, as deemed appropriate by the Licensing Authority.

Malnutrition problem in Bihar

†547. SHRI RAM VILAS PASWAN: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether Government is aware that according to a committee appointed by the Supreme Court, 55 per cent population in Bihar is suffering from malnutrition and 70 per cent population of women and children is suffering from anaemia; and

(b) if so, the action being taken by Government in this direction?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD): (a) As per National Family Health Survey (NFHS-III) 2005-06 report in Bihar, 55.9% children under age five years are underweight and 45.1% women in the age group 15-49 years have chronic energy deficient (BMI below 18.5). Prevalence of anaemia in women of 15-49 years & children under age five years is 67.4% & 78.0 % respectively.

(b) Government has taken the following measures to improve the health and nutritional status of vulnerable population including women and children of the country:

1. Prime Minister's National Council on India's Nutrition Challenges was set up in October, 2008 for policy direction, review & effective coordination between Ministries which all will have a sectoral responsibility for the challenge of Nutrition.
2. A National Nutrition Policy has been adopted in 1993 and a National Plan of Action for Nutrition (1995) is being implemented through various Departments of Government.

†Original notice of the question was received in Hindi.