

serious patients, with multifarious ailments come directly to AIIMS OPD/ Emergency for treatment.

(e) and (f) The AIIMS is involved in research activities and the faculty of AIIMS on their own are able to attract research funds from various funding agencies, like Department of Biotechnology, Department of Sciences & Technology, Indian Council of Medical Research, etc. The Institute was able to attract Rs. 20.3 crores of research grant in the year 2003-04 from outside agencies.

Illegal and unethical drug trials

121. SHRI EKANATH K. THAKUR: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether Government are aware that global pharma companies are treating India as a convenient laboratory for testing their drugs and using Indians as unsuspecting guinea pigs;

(b) whether Government are aware that illegal and unethical drug trials are carried out in the country in spite of the stringent laws governing clinical trials; and

(c) if so, the steps Government propose to take to monitor the implementation of laws governing clinical trials?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRIMATI PANABAKA LAKSHMI): (a) and (b) No Sir, there are no instances of Global Pharma Companies treating India as convenient laboratory for testing their drugs and using Indian as unsuspecting guinea pigs. All clinical trials are required to be conducted as per norms prescribed under Drugs and Cosmetics Rules. For every trial, approval is also to be taken from Ethics Committee of the concerned, institution.

Further, this Ministry is amending the Drugs and Cosmetics Rules to strengthen the norms for undertaking clinical trials in the country so that the safety of the patients and ethics are strictly followed. This includes, publication of Good Clinical Practices (GCP) guidelines, revision of Schedule-Y to Drugs and Cosmetics Rules & publication of ICMR's "Ethical Guidelines for Biomedical Research on Human Subjects" etc.

[9 July, 2004]

RAJYA SABHA

The revised Schedule-Y, which is soon to be published provides for-

- (1) Specific responsibilities of
 - Clinical Investigator
 - Sponsors
 - Ethics Committees
- (2) Patient consent form has been made very elaborate to ensure transparency in enrolling the willing patients.
- (3) It has been clearly specified that while conducting any clinical trial, norms of GCP guidelines published by Government and Indian Council of Medical Research's "Ethical guidelines for biomedical research on human subject" are to be followed.
- (4) No first time human trial for drug developed outside India, to be permitted, as was the case earlier.

UNICEF's World Children Report 2004

122. SHRIMATI N.P. DURGA : Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that the recently released World's Children Report, 2004 of the UNICEF reveals that under-developed countries like Bangladesh and Sri Lanka look after their children far better than India in terms of health care and education;

(b) whether it is also a fact that in terms of infant mortality, India is going only a little better than sub-Saharan African countries; and

(c) if so, the reasons behind this and action taken by Government on the contents of the Report?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRIMATI PANABAKA LAKSHMI): (a) According to the UNICEF report, state of the World's children 2004 the infant mortality rate for India has declined from 146/1000 live births in 1960 to 67/1000 live births in 2002. The infants mortality rate in Bangladesh is 51/1000 live births and for Sri Lanka it is 17/1000 live births. The percentage of under fives suffering from under weight is 47 for India and 48 for Bangladesh and 29 for Sri Lanka. The percentage of infants with low birth rate is 30 for India and 30 for Bangladesh and 22 for Sri Lanka.