

(c) Schedule – Y (amended in 2005) of Drugs and Cosmetics Rules, 1945 specifies the guidelines and requirements for conducting clinical trial in the country. This is applicable for both foreign drugs as well as domestic drugs for clinical trial in India. As per the said Schedule, it is also mandatory to conduct clinical trial as per Good Clinical Practice (GCP) guidelines (2001) published by Government of India. Application for clinical trial is required to be submitted in Form-44 along with prescribed fees and chemical and pharmaceutical information, animal and pharmacological, toxicological data, human clinical data of safety and efficacy etc.

Cervical cancer cases

845. SHRIMATI T. RATNA BAI: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

- (a) whether it is a fact that large number of women are suffering from cervical cancer in the country;
- (b) if so, the details thereof and the steps taken so far to contain the same especially in Andhra Pradesh;
- (c) whether the tests have become more accurate to confirm the same;
- (d) if so, the details thereof;
- (e) whether pilot programmes are to be launched in the country aimed at rapid and accurate results having minimal need of infrastructure; and
- (f) if so, details thereof?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRIMATI PANABAKA LAKSHMI): (a) and (b) As per the data collected from Population Based Cancer Registries Programme functioning under the National Cancer Registry Programme of Indian Council of Medical Research (ICMR), the age adjusted incidence rate of cervical cancer in India is between 1.8 to 22.5 per 1 lakh women. The ICMR has already initiated a project in the States of Andhra Pradesh and Gujarat to understand the suitable strategies through existing health infrastructure.

(c) to (f) The screening programmes involve Cytology, Visual inspection and HPV testing. ICMR and International Agency for Research and Cancer (WHO), Lyon, France has conducted research for evaluating the test characteristics of these three modalities of screening. These screening modalities have sufficient sensitivity and specificity (accuracy) to be used as screening tools.

Infant deaths after vaccination

846. SHRIMATI T. RATNA BAI: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

- (a) whether cases of infant deaths after vaccination have been reported recently;
- (b) if so, the details thereof and the reasons therefor; and
- (c) the steps to be taken to protect each and every child at the time of vaccination?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRIMATI PANABAKA LAKSHMI): (a) and (b) Yes Sir, four deaths of infant were reported following