

(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

administration of measles vaccine from Thiruvallur district of Tamil Nadu on 23rd April, 2008 and four deaths were reported from Waghola village of Aurangabad district of Maharashtra on 27th September, 2008.

As per the clinico-epidemiological investigations, the probable cause of death could be due to Toxic Shock Syndrome (TSS).

(c) Effective supervision at outreach clinics, monitoring, reporting and management of adverse events following immunization would prevent/minimize the consequences of serious adverse events that may rarely occur. Vaccinator's training for taking all necessary precautions during vaccination will also minimize occurrence of serious adverse events.

#### **Upgradation of medical colleges**

847. SHRI DHARAM PAL SABHARWAL: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether according to Pradhan Mantri Swasthya Suraksha Yojana (PMSSY), several medical colleges in the country have been upgraded by providing central financial assistance;

(b) if so, what are the reasons that the oldest medical institution at Amritsar, Punjab has not been included under PMSSY scheme of upgradation; and

(c) the steps being taken to include Amritsar Medical College under PMSSY and sanction of special grants to this institution?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRIMATI PANABAKA LAKSHMI): (a) to (c) In the first phase of PMSSY, 13 existing Government medical college institutions are being upgraded. List of institutions being upgraded is given in the Statement (*See below*).

Since Government of India is running PGIMER, Chandigarh, no existing Government medical college institution in the States of Punjab, Haryana and Himachal Pradesh were taken up for upgradation in the first phase of PMSSY. However, of late there has been considerable increase and over crowding of referral patients to PGIMER, Chandigarh. Taking into account the fact and request of State Government of Punjab, it is proposed to upgrade Government Medical College, Amritsar, in the second phase of PMSSY. The Planning Commission has accorded 'in principle approval'. Necessary approvals are being obtained.

Gap analysis/assessment of requirements in Government medical college, Amritsar in terms of civil construction and provision of equipment was carried out by Central technical team comprising of MoHFW officials, CDB architects, Engineers and PGIMER faculty members in September, 2008. Government Medical College, Amritsar/ Government of Punjab have been advised to prepare a Project Report, based on the inputs received from the technical team.

#### ***Statement***

##### ***List of medical college institutions upgraded in the first phase of PMSSY***

1. Govt. Medical College, Jammu (J&K)
2. Govt. Medical College, Srinagar (J&K)
3. Kolkata Medical College, Kolkata (W.B.)