

Efforts on Population stabilization very much required strengthening of the primary health care system as there is a very strong correlation between health indicators like Maternal Mortality rate and Infant Mortality Rate to the population stabilization. As such in line with the National Population Policy, 2000 the Government has launched the National Rural Health Mission (NRHM) on 12th April, 2005 throughout the country to address the strengthening of primary health care system. The approach to population stabilization under NRHM is providing through quality health services in remote rural areas along with a wide range of contraceptive choices to meet the unmet demands for these services which includes delivery, safe abortions, treatment of reproductive tract infections and Family Planning Services while ensuring full reproductive choices to women. The strategy also is to promote male participation in Family Planning.

The new initiative of NRHM of Community Health Workers (ASHAs) in every village has positively contributed towards household seeking health and family planning services and also has strengthened the public awareness campaign for family planning services.

#### **Excessive control of MCI on medical education**

3111. SHRIMATI JAYA BACHCHAN: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that medical education in India is in the hands of a small but powerful group of doctors and officials headed by MCI president; and

(b) if so, the steps Government has taken to wean away the excessive control from the group?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD): (a) and (b) This Ministry has proposed to set up a National Council for Human Resources in Health as an overarching regulatory body for the health sector to reform the current regulatory framework and enhance supply of skilled personnel. A Task Force under the chairmanship of Union Secretary (Health and Family Welfare) has been constituted to deliberate upon the issue of setting up the proposed National Council. The Task Force shall submit its report to the Ministry by 31st July, 2009.

#### **Closed vaccine PSUs**

3112. SHRI RAJKUMAR DHOOT:

SHRI RAHUL BAJAJ:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state whether it is true that some Public Sector Units manufacturing vaccines have been closed down in the last 5 years and if so, why was such a step taken and how has it impacted availability and cost of vaccines in the country?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD): No. Public Sector Units manufacturing vaccines have not been closed down. However, the manufacturing licenses of three Vaccine Institutes *i.e.* the Central Research Institute, Kasauli, Himachal Pradesh, the Pasteur Institute of India, Coonoor, Tamil Nadu and BCG Vaccine Laboratory, Chennai, Tamil Nadu, which are under the administrative control of the Ministry, were suspended by the Drug Controller General of India in January, 2008 since they were not found in compliance with the Good Manufacturing Practices (GMP) as provided under Schedule M of Drugs and Cosmetic Rules, 1945.

For some months in 2008, there were shortages of Diphtheria-Pertussis-Tetanus (DPT), Tetanus Toxoid (TT) and Diphtheria Tetanus (DT) in some States due to non-fulfillment of supply commitments by manufacturers. These were overcome by October, 2008. Since then there has been no shortage.

There was an increase in the costs of the vaccines, namely, BCG, DPT, DT and TT procured by the Ministry, after the suspension of licenses of these three Vaccine Manufacturing Units.

#### **Clinical trials**

3113. SHRI B.K. HARIPRASAD: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether to bring the human clinical trial industry under a regulatory mechanism the Government has mandated all such trials being conducted in the country be registered with the ICMR;

(b) whether Government is in the process to bring in a separate provision for clinical trials in the Drugs and Cosmetics Act to deal with offenders of un-ethical clinical trials; and

(c) if so, the details thereof?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD): (a) Prior to 17th November, 2008, registration of clinical trial was voluntary. For all clinical trials, permission of which were granted between 17th November, 2008 to 14th June, 2009, applicants were advised to get the trials registered at ICMR registry at [www.ctri.in](http://www.ctri.in). However from 15th June, 2009, it has been made mandatory to register all clinical trials permitted to or after the said date at Indian Council of Medical Research (ICMR) registry at their said web site before enrolling first patient in the study.

(b) and (c) The Drugs and Cosmetics (Amendment) Bill 2007 introduced in the Rajya Sabha on 21.8.2007 contains separate regulatory provisions for clinical trial.