

Awareness generation on consumption of nutritious food is being done through the Village Health and Nutrition Days.

Death during clinical trial of drugs

2843. SHRIMATI BRINDA KARAT: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

- (a) whether it is a fact that a death was reported during clinical trial of a vaccine manufactured by an MNC;
- (b) if so, what is the name of the company and the drug; and
- (c) what action is being taken against the company and the sponsors of the trial?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRIDINESH TRIVEDI): (a) and (b) Yes. There was report of serious adverse event regarding death of a subject involved in a clinical trial of 13-valent pneumococcal conjugate vaccine being developed by M/s Wyeth Pharmaceuticals at one of the sites in the country.

(c) A team was constituted to investigate the matter. The team conducted the inspection on 13th December and 14th December, 2008. The inspection revealed various Good Clinical Practices (GCP) violations. Therefore, the concerned investigator, sponsor and monitor were issued warning letters asking corrective action to be taken by them to prevent such violation in future. The clinical trial remained suspended at all the twelve sites from 06-11-2008 to 22-04-2009. The sponsor submitted various corrective actions taken to ensure GCP compliance. Central Drugs Standard Control Organisation (CDSCO) scrutinized the same and decided to revoke the suspension on 23.04.2009 from all the sites except the inspected site. Further, monitor and investigator of the inspected site also submitted details of corrective action taken by them, based on which the suspension from the inspected site was also revoked on 02.06.2009.

Infant mortality

2844. SHRI Y.P. TRIVEDI: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

- (a) whether it is a fact that over 20 per cent of the world's child deaths occur in India, 20 lakhs children die before reaching their fifth birthday, one in three malnourished children in the world lives in India, around 46 percent of Indian children under three years are underweight and India's record on newborn (72 per 1000 live birth); and the child mortality fare worse than Bangladesh and Sri Lanka;
- (b) if so, the reasons therefor; and
- (c) the action taken to prevent the same by Government?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI DINESH TRIVEDI): (a) As per the UNICEF State of World Children 2009 report India contributes 20% of the global burden of child deaths with 20 lakh children dying in India every year. As per this report, one in three malnourished children in the world lives in India and around