

**GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA**

UNSTARRED QUESTION NO:3576
ANSWERED ON:11.12.2009
TRIAL OF PNEUMONIA VACCINE
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Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

- (a) whether deaths of some infants during the trial of Pneumonia Vaccine have been reported in the country;
- (b) if so, the details thereof; and
- (c) the action taken by the Government thereon?

Answer

THE MINISTER OF STATE FOR HEALTH & FAMILY WELFARE(SHRI DINESH TRIVEDI)

(a) & (b): There was a report of serious adverse events regarding death of a subject involved in a clinical trial of 13-valent pneumococcal conjugate vaccine at one of the site in the country.

(c) A team was constituted by the Central Drugs Standard Control Organisation (CDSCO) to investigate the matter. The team conducted the inspection on 13th December & 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 actions 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. The CDSCO, after scrutiny of the same, decided to revoke the suspension of 23-04-2009 from all the sites except the inspected site. Further the 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.