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

UNSTARRED QUESTION NO:2836
ANSWERED ON:26.11.2010
QUALITY OF IMPORTED DRUGS
Das Shri Bhakta Charan;Semmalai Shri S. ;Singh Shri Radhey Mohan

**Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:**

(a) the steps taken/proposed by the Government to ensure quality and efficacy of imported as well as indigenously manufactured drugs;

(b) whether the Government proposes to make it mandatory for the drug manufacturing companies to have Good Manufacturing Practice (GMP) laboratories and research centres;

(c) if so, the details thereof and if not,the reasons therefor;

(d) whether the Government has received complaints regarding irregularities and malpractices in carrying out clinical trials of imported and also indigenously developed drugs;

(e) if so, the details thereof; and

(f) the action taken by the Government against those found guilty?

## Answer

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

(a): The quality, safety and efficacy of imported as well as indigenously manufactured drugs are regulated under the provisions of Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945 made thereunder. Quality of drugs is regulated through a system of testing, inspection and licensing under the said Act. In addition, samples of imported drugs are collected randomly at port offices for the purpose of test/ analysis for monitoring their quality. The said Act also contains stringent penal provisions which work as a deterrent against violation/non-adherence to the provisions of the Act relating to quality, safety and efficacy of drugs.

(b) & (c): The manufacturing facilities of drugs are required to comply with the requirements of Good Manufacturing Practices (GMP) as provided under Schedule M and Good Laboratory Practices under Schedule -L1 of the Drugs and Cosmetics Rules, 1945.

(d) to (f): Some cases of alleged irregularities in clinical trial as reported in media are as follows.

1. Alleged irregularities in the conduct of a trial with Human Papilomavirus (HPV) vaccine in a post licensure observational study trial in Gujarat and Andhra Pradesh. ICMR has suspended the trial and Hon'ble HFM has set up a high power enquiry committee to investigate the matter.

2. Alleged irregularities in drug trials conducted in Bhopal and Indore. A team of officials of CDSCO carried out inspection from 10-08-2010 to 12-08-2010. Finding of the inspection show some deficiencies for which the Principal Investigator and M/s Quintiles ltd., Bangalore (CRO) was asked to explain their position vide letter dated 28-09-2010.