

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

UNSTARRED QUESTION NO:2592
ANSWERED ON:04.12.2009
INHALABLE VACCINE FOR MEASLES
Dhotre Shri Sanjay Shamrao

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

- (a) whether any clinical trials of inhalable vaccine for measles are being conducted in the country;
- (b) if so, the details and the outcome thereof; and
- (c) the time by which the new vaccine is likely to be introduced in the market?

Answer

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

(a) & (b): Yes. Central Drugs Standard Control Organisation (CDSCO) had granted permission to M/s Serum Institute of India Limited, Pune to conduct phase I and Phase II/III clinical trial to evaluate the safety and efficacy of the Measles inhalable vaccine. The permission to conduct Phase II/III Clinical trial was granted after satisfactory evaluation of data generated from Phase I clinical trial. The trials are cosponsored by World Health Organisation.

(c) The permission to market the new vaccine is only granted after submission and satisfactory evaluation of Phase II/III clinical trial data along with other required documents as per the requirements of Drugs and Cosmetics Act and Rules. The marketing approval, therefore, will depend on when company will complete the clinical trial as per approved protocol and submit the study report along with application for new drug permission.