Costly medicines for HIV/AIDS

†1812. DR. BHUSHAN LAL JANGDE: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that medicines for HIV/AIDS are very costly and patients are not able to purchase those and get their benefit;

(b) the reasons that Indian drug companies are expressing their inability in manufacturing these medicines; and

(c) whether scientists are making efforts for vaccination measures to check HIV/AIDS?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI SHRIPAD YESSO NAIK): (a) Under National AIDS Control Programme, the ARV Drugs are procured following the process of open tendering and the same ARV Drugs are provided free of costs to the patients.

(b) National AIDS Control Organization procures the Medicines through the process of open tendering. Of late, the medicines are procured through the domestic manufacturers only.

(c) Under the tripartite agreement between Indian Council of Medical Research, International AIDS Vaccine Initiative and National AIDS Control Organization, three phase- 1 trials of HIV vaccine were conducted by National AIDS Research Institute, Pune and National Institute for Research in Tuberculosis, Chennai. Detailed information on vaccine research is given in the Statement.

Statement

Details of vaccine research for prevention of HIV/AIDS

(1) The following trials of HIV vaccine have been conducted in India. Two vaccine candidates were prioritized for Phase I clinical trials in India: tgAAC09, an Adeno-Associated Virus (AAV)-based vaccine, and TBC-M4, a Modified Vaccinia Ankara (MVA) based vaccine. NARI, Pune and NIRT, Chennai have conducted three HIV vaccine trials in the country.

- **A001 trial:** A Phase I trial of using Adeno-Associated Virus (AAV) based HIV-1 subtype C vaccine candidate (tg AAC09) was initiated on February 7, 2005 at the National AIDS Research Institute (NARI), Pune and was completed in December 2006. The vaccine was safe at all the three dosage

†Original notice of the question was received in Hindi.

levels. The vaccine did not stimulate HIV-1 antibodies. The immunological response was observed in 23% individuals. The candidate did not appear to be immunogenic individually and it was felt that it could be evaluated in a prime-boost strategy.

- D001 (MVA) trial: TRC, Chennai conducted the Phase I trial of TBC-M4-Modified Vaccinia Ankara (MVA) candidate has been recently completed. It was found that both the vaccine regimens were safe and immunogenic in more than 90% of the volunteers. However, the response was modest though it persisted in many of the volunteers even 12 months after the last vaccination.
- P001 trial: A Phase I Double-Blind, Placebo-Controlled, Randomized Trial to Evaluate the Safety and Immunogenicity of TBC-M4, a multigenic MVA HIV Vaccine *vs.* ADVAX, a multigenic DNA HIV Vaccine followed by TBC-M4, a multigenic MVA HIV Vaccine. This trial was conducted at NARI, Pune and TRC, Chennai.

(2) DNA Vaccine Project: Generation of HIV 1 subtype C based DNA vaccine and assessment of prime-boost strategy in mouse model (funded by NACO). This was a study carried out for determining the CTL and neutralizing antibody response in mice to the pVAX based gp 150 and full length gag HIV constructs. The findings of the study have generated preliminary data on the neutralization and CTL responses generated by the candidate vaccine. The findings indicate a transient CTL and neutralization response at the 5th week following immunization which disappeared by the 7th week after the initiation of the immunization. The results in the mice were not encouraging.

The present status of each of these research projects

The A001, the MVA (D001) and the P001 trials and the DNA Vaccine Project have been completed. There candidate vaccines used in the A001 and the D001 have been found safe and immunogenic in more than 90% of the human volunteers. The results of the A001 study have been published. In P001 prime-boost trial of DNA followed by Modified Vaccinia Ankara based HIV-1 subtype C vaccine, both the vaccines were found to be safe and well tolerated. The Vaccine Developmental Study has been recently initiated.

Morbidity associated with tobacco usage

1813.SHRI HUSAIN DALWAI : Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether tobacco use accounts for forty per cent of all cancers in India;