

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

STARRED QUESTION NO:46

ANSWERED ON:18.02.2009

PUBLIC SECTOR VACCINE MANUFACTURING UNITS

Adhalrao Patil Shri Shivaji;Kharventhan Shri Salarapatty Kuppusamy

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

(a)whether the Government proposes to reverse its earlier decision to close down Public Sector vaccine units as reported in The Times of India dated 22 January, 2009;

(b)if so, the details thereof alongwith the reasons therefor;

(c)the steps taken by the Government to produce vaccine as per the standards fixed by World Health Organisation; and

(d)the time by which the production is likely to be commenced?

Answer

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. ANBUMANI RAMADOSS)

(a)to(c): A statement is laid on the Table of the House.

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 46 FOR 18TH FEBRUARY, 2009

The Government has not taken any decision to close down the three Public Sector Vaccine Manufacturing Units, namely, the Central Research Institute, Kasauli, Himachal Pradesh, the Pasteur Institute of India, Coonoor, Tamil Nadu and the BCG Vaccine Laboratory, Chennai, Tamil Nadu. The manufacturing licenses of these three Institutes were suspended by the Drugs Controller General of India (DCG(I)) in January, 2008, since they were not found? in compliance with the Good Manufacturing Practices(GMP) as provided under Schedule M of Drugs and Cosmetic Rules,1945.

An Expert Committee under the chairmanship of DCG(I) was constituted by the Government in April, 2008, to study, inter alia, the existing infrastructure/facilities available with these institutes and explore the feasibility of conversion of existing laboratories into testing laboratories, utilisation of the existing facilities for setting up a residential training facility, and having some of the vaccines/anti-sera production at these institutes complying with GMP.

The Expert Committee has submitted its report.? In so far as PII is concerned, the Committee has recommended production of Tissue Culture Anti Rabies Vaccine (TCARV) and Anti Sera like Anti Snake Venom Serum (ASVS), Anti Tetanus Serum (ATS), Anti Diphtheria Serum (ADS), Anti Rabies Serum (ARS), etc.? The Committee also recommended development of the Institute as a Central Testing Laboratory for testing of medical devices and training centre for training in production and testing of Anti Serum etc.? In so far as CRI is concerned, the Committee has recommended? new manufacturing facilities for Yellow Fever vaccine, Influenza vaccine (Seasonal and Pandemic), Acetone Killed Typhoid Vaccine and Tissue Culture Anti Rabies Vaccine (TCARV), new anti-sera facility, developing measles surveillance centre in addition to existing Polio, Influenza and Rabies surveillance centre,? expansion and modernization of existing Animal House as National Animal Breeding Centre, expansion of Central Drugs Laboratory (CDL) to have separate wings for bacterial and viral vaccines by utilizing area used for production of vaccines;? independence of CDL for administrative and financial powers.? In so far as BCGVL is concerned, the Committee has recommended conversion to Central Drugs Laboratory for BCG vaccine testing under CDL Kasauli, development as a Central Testing Laboratory for testing of Cosmetics, expansion and modernisation of the existing Animal house for supply of animals to various research institutes in the country, training centre for BCG production and testing.

A proposal for upgradation of the facilities at CRI Kasauli to make them GMP compliant has now been received. This proposal is currently under consideration of the Government.