

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

UNSTARRED QUESTION NO:1782

ANSWERED ON:19.11.2010

CLOSURE OF PUBLIC SECTOR VACCINE UNITS

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

- (a) whether any Committee has been constituted to investigate the reasons for the closure of the Public Sector Vaccine units;
- (b) if so, whether the aforesaid Committee has submitted its report to the Union Government;
- (c) if so, the main reasons for suspending the manufacturing licences of these public sector vaccine units;
- (d) the recommendations made by the aforesaid Committee regarding the revival of these public sector vaccine units; and
- (e) the response of the Union Government thereto?

Answer

THE MINISTER OF HEALTH & FAMILY WELFARE (SHRI GHULAM NABI AZAD)

(a) & (b) Yes.

(c) : The manufacturing licenses of these public sector vaccine units were suspended by the Drugs Controller General of India (DCGI) in January, 2008 since they were not found to be compliant with the Good Manufacturing Practices (GMP) as provided under Schedule M of Drugs and Cosmetic Rules, 1945.

(d) & (e): The Committee had submitted its interim report in February, 2010. Its recommendations included—

- (i) The Ministry of Health and Family Welfare to consider revoking the suspension orders issued against the three public sector vaccine manufacturing units in response to the appeals filed under Rule 85(3) of the D&C Rules. The revocation may be made subject to the conditions that the new production line fully compliant with GMP standards be installed and commissioned within a period of three years;
- (ii) The Ministry of Health and Family Welfare to consider directing the units holding finished products to confirm their quality standard and then supply and use them under the UIP before the date of their expiry of the products;
- (iii) The Ministry of Health and Family Welfare to urgently make funds available to the units to complete the remaining upgradation work on the existing production lines.

Central Government in exercise of its powers under Sub rules (3) of Rule 85 of the Drugs and Cosmetics Rules, 1945 have ordered revocation of suspension of the licenses of the these Institutes vide order No. X.11035/2/2010-DFQC dated 26/2/2010. These Institutes have also been asked to ensure that the production line is made fully compliant with GMP standards within three years .

These Institutes were also ordered vide earlier order dated 12.2.2010 to dispose of existing stock of both finished products as well as raw material and to ensure that prior approval of competent authority is obtained to the effect that finished products and raw material for preparation of vaccines are fit for human consumption.

The three vaccine producing units have initiated vaccine manufacturing process.

The Committee has submitted its final report. Its main recommendations include- (i) Ministry to consider making them autonomous by registering them as companies /societies under the Companies Act/Societies Registration Act; (ii) The Government to consider constituting a National Vaccine Security Advisory Board comprising the stakeholders (Public Health Specialists, Pediatricians, Public Health Administrators, Vaccine Technologists, Social Activists etc.) to advise the government on important issues relating to the National Vaccine Security Policy.

Necessary action has been initiated to consider the recommendations of the Committee.