

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

UNSTARRED QUESTION NO:3875

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AVAILABILITY COST OF VACCINES

Lingam Shri P.;Panda Shri Prabodh;Vinay Kumar Alias Vinnu Shri

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

(a) whether adherence of World Health Organisation (WHO) good Manufacturing practices and standards, coupled with the closure of public sector companies has impacted the availability and price of commonly used vaccines;

(b) if so, the details thereof; and

(c) the corrective action taken in the matter, including assisting Public Sector Undertakings (PSUs) to follow WHO's standard manufacturing practices?

Answer

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

(a) & (b) Adherence to World Health Organization (WHO) good manufacturing practices and standards are followed only for those vaccines which are procured from External Aided Component (EAC). In case of domestic procurement, only good manufacturing practices (GMP) are followed. The manufacturing licenses of the three vaccine manufacturing units, namely, the Central Research Institute at Kasauli, the Pasteur Institute of India at Coonoor and BCG Vaccine Laboratory at Chennai were suspended by the Drug Controller General of India (DCGI) 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. The impact in terms of availability and price of commonly used vaccines is as under :

i) During April to October 2008, there was some shortage of Diphtheria- Pertussis-Tetanus (DPT), Tetanus Toxoid (TT) and Diphtheria Tetanus (DT) in some States. However, there was no shortage of Bacillus Calmette-Guérin (BCG), Measles and Polio (OPV) vaccines. The reason was that the Public and Private vaccine manufacturers defaulted on their supply by staggering their delivery in some states. However, stock out situation was averted by releasing the buffer stock from GMSDs to these States. Therefore, the dislocation was only temporary and the Immunization Programme as such was not hampered.

ii) Vaccines being procured now are supplied along with Vaccine Vial Monitor (VVM), Temperature Monitoring Device and with International Packaging. However, these features were not included in earlier supply made by Departmental Vaccine Institutes.

(c) The actions taken in the matter are as under :-

1) Approval of the Competent Authority has been obtained for revival and upgradation of BCG vaccine manufacturing facility as per cGMP norms at BCG VL, Guindy at an estimated cost of Rs. 58.52 crore plus Project management consultancy fee.

2) Approval of the Competent Authority has also been obtained for upgradation of DPT group of vaccine manufacturing facilities at PII, Coonoor with an estimated cost of Rs. 137.02 Crore plus Project management consultancy fee.

3) Upgradation and revival of manufacturing of DPT group of vaccine facilities, as per cGMP norms, at CRI, Kasauli has almost been completed.