

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

UNSTARRED QUESTION NO:4593  
ANSWERED ON:20.08.2010  
NATIONAL INSTITUTE OF BIOLOGICAL  
Ram Shri Purnmasi

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

- (a) the objectives and functions of National Institute of Biologicals (NIB);
- (b) whether the Institute has lacked in ensuring the quality of biological products for consumption in the country and biological products are released without independent quality assurance test;
- (c) if so, the details thereof and the reasons therefor;
- (d) whether serious scientific lapses and malpractices have been observed therein; and
- (e) if so, the remedial measures taken by the Government in this regard?

**Answer**

MINISTER OF THE STATE IN THE MINISTRY OF HEALTH & FAMILY WELFARE (SHRI DINESH TRVEDI)

(a) to (e) The National Institute of Biologicals (NIB) was established with the overall objective to carry out quality control tests of biological products, train personnel and prepare reference standards for biologicals. Samples of biologicals for batch lot release forwarded by the drug regulatory authorities are tested at the Institute as per the pharmacopoeia specifications and protocol scrutiny. Due to administrative problems in the Institute, which affected the quality of working, the Central Drugs Standard Control Organisation (CDSCO) stopped sending of samples of diagnostic kit and blood products to NIB in July, 2007 after the inspection by the WHO. Government has since taken several corrective measures, including change in the management of the Institute. Steps have been taken to test the biological products by the parameters specified in the pharmacopoeia / other guidelines and protocols, with proper documentation.