

(b) if so, the details thereof; and

(c) if not, the reasons therefor?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD): (a) No.

(b) Does not arise.

(c) At the time of preparation of the National List of essential medicines 2003, the concept of the poly drug, combination of Aspirin, Statin and ACE-Inhibitor was not introduced/approved.

#### **Failure to clear toxicity test**

2051. SHRI A. ELAVARASAN: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the Drugs Controller of India has instructed the Natco, a pharmaceutical company, to stop production of Albupax after it failed to clear toxicity test;

(b) if so, the details thereof; and

(c) the details of drugs not approved by Government, after failing to clear the toxicity test during the last three years?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD): (a) and (b) The Central Drug Laboratory, Kolkata, in its test report has declared the drug Albupax (paclitaxel Albumin bound particle injectable suspension) to be not of standard quality due to the presence of higher level of Endotoxin than acceptable limits. On the basis of the test reports, the Central Drugs Standard Control Organization (CDSCO) suspended the permission to manufacture the said drug by following the laid down procedure and also asked the manufacturer to recall the product from the market.

(c) Approval of any drug for the first time in the country is based on the overall toxicity & efficacy profile of the drug as per requirements of Drugs & Cosmetics Rules. During last three years, Central Drug Standard Control Organization has not approved any drug having unacceptable toxicity and efficacy profile.

#### **Steps to control spread of AIDS**

2052. DR. JANARDHAN WAGHMARE: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether Government is aware of the deadly consequences of Acquired Immune Deficiency Syndrome (AIDS) which is widely prevalent in the country; and

(b) if so, how far Government has been able to control this deadly disease?