saving medicines free of cost to the patients getting treatment under the Public Health Centres (PHCs);

(b) if so, the details thereof and the amount allocated for this purpose during the Twelfth Five Year Plan, year-wise and State/Union Territory-wise; and

(c) the steps taken/being taken by Government for proper monitoring of the amount and for availability of quality medicines free of cost in these public health centres/hospitals for this purpose?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD): (a) and (b) Public Health being a State subject, under the National Health Mission (NHM), financial support is provided to the States/UTs to strengthen their health care system including for providing free essential drugs in public health facilities including Primary Health Centres. From the current year, substantial funding is available to States to implement the NHM Free Drugs Service Initiative subject to stipulated conditions within the State's resource envelope of NHM.

(c) States/UTs have been requested to put in place a robust procurement and IT enabled logistic systems, quality assurance mechanism, facility-wise Essential Drug List (EDL) and Standard Treatment Guidelines and provision for prescription audits. Funds for strengthening these systems are also are being provided to States/ UTs under the NHM. Functioning of the drug procurement and distribution system is being monitored and wherever, gaps are noticed, the States are asked to address those gaps.

Blacklisting of Indian drugs in foreign countries

2557. SHRI SANJAY RAUT: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether Government's attention have been drawn towards the recent decision of US drug regulator USFDA, and U.K.'s drug regulator regarding blacklisting and issuing of warnings against some Indian drug manufacturers involved in manufacturing of generic drugs and other products; and

(b) if so, what is Government's response and reaction thereto?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD): (a) and (b) Yes. USFDA has taken action against an Indian drugs manufacturer for alleged violation of US laws.

These manufacturing units are inspected by Indian regulatory authorities as per the provisions of Indian laws.

Monitoring of spurious drugs in the country

2558. DR. NAJMA A. HEPTULLA: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether Government has evolved any mechanism to monitor and check manufacturing and marketing of spurious, sub-standard and expired drugs in the country;

(b) if so, the details thereof and, if not, the reasons therefor;

(c) the number of cases of manufacturing and marketing of spurious, sub-standard and expired drugs reported/detected during the last three years and the current year; and

(d) the action taken against the erring persons/drug manufacturers during each of the last three years and the current year, State/UT-wise?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD): (a) and (b) The Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945 made thereunder have adequate provisions to monitor and check manufacturing and marketing of spurious, sub-standard and expired drugs in the country. The provisions relating to manufacture and sale of drugs are regulated by the State Drugs Control Authorities appointed by the State Governments which monitor the quality of drugs manufactured and marketed in the country through the system of licensing, inspection and drawing of samples for testing. The Drugs and Cosmetics Act provides stringent penalties for manufacture of spurious and adulterated drugs to make it a deterrent for the anti-social elements who indulge in manufacture of spurious drugs. Besides, the Government has taken the following measures to check the problem of Spurious / Sub-standard Drugs.

1. The Drugs and Cosmetics Act, 1940 was amended under Drugs and Cosmetics (Amendment) Act, 2008. Stringent penalties for manufacture of spurious and adulterated drugs have been provided. Certain offences have also been made cognizable and non-bailable.

2. The States / UTs were requested to set up special Courts for trial of offences under the Drugs and Cosmetics Act for speedy disposal. So far,