Year	No. of sample analysed	Adulterated and misbranded
2011-12	64,593	8,247
2012-13	69,949	10,380
2013-14	72,200	13,571

The implementation and enforcement of the Food Safety and Standards Act, 2006 primarily rests with State/UT Governments. Random samples of food items, including milk, are being drawn by the State Food Safety Officers and sent to the laboratories recognised by the Food Safety and Standards Authority of India (FSSAI) for analysis. In cases, where samples are found to be not conforming to the provisions of the Act and the Rules and Regulations made thereunder, action as provided for under the FSS Act is taken against the offenders.

(c) and (d) The Supreme Court of India, while hearing a Petition (c) No. 159/2012, wherein the petitioner had raised issues regarding rampant adulteration/contamination in milk and milk products in the country, observed/directed that considering the gravity of the situation as well as in larger public interest, it is necessary that Union of India should think of making appropriate amendments in the Food Safety and Standards Act, 2006, so that such type of crimes could be curbed to a large extent. The menace of milk adulteration can be curbed only by strengthening of food safety structures in the country and more effective implementation of the Food Safety and Standards Act.

With a view to make more stringent provisions in the Food Safety and Standards Act, 2006 the Food Safety and Standards (Amendment) Bill, 2014 which was introduced in the Rajya Sabha on 19.02.2014, has been withdrawn.

Non-Prescribing of medicines by CGHS doctors

2643. SHRI RAM KUMAR KASHYAP: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether Government has issued any direction to the CGHS dispensaries not to issue medicines prescribed by doctors of Government hospitals to CGHS beneficiaries, which they have been taking for the last several years especially chronic patients suffering from heart and mental diseases;

(b) whether these patients are being directed by the CGHS doctors to approach again to prescribe only generic medicines mentioned in the schedule of CGHS which create lot of problem for them as they have to purchase those medicines from the market;

(c) if so, the reasons therefor; and

(d) by when these orders are likely to be withdrawn and, if not, the reasons therefor?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI JAGAT PRAKASH NADDA) : (a) Medicines are being issued at CGHS Wellness Centres from the approved CGHS formulary which presently consists of 1447 generic and 622 branded medicines, 254 Life saving medicines (DCGI approved for use in India) and the formularies of ESIC (Employees State Insurance Cooperation) and ECHS (Ex-Servicemen Contributory Health Scheme). Medicines, which are not included in these formularies and not available in dispensaries, when prescribed by Government Doctors are being procured through Local Purchase at the discretion of CMO I/C (Chief Medical Officer In-charge) of the Wellness Centres.

(b) to (d) No such directions have been issued in the CGHS.

Regulatory mechanism for clinical trials

2644. SHRIMATI KANIMOZHI: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether there is any reliable year-wise information regarding the number of people who have participated in clinical drug trials, who have died while participation or have developed serious adverse effects in the last three years and, if so, the details thereof;

(b) whether Government has established any mechanism for compensating the families of victims who have died or have developed serious adverse effects after participating in clinical drug trials, if so, the details thereof; and

(c) whether Government has taken any measures to put in place a mechanism to regulate such trials in the country and if so, the details thereof ?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI JAGAT PRAKASH NADDA): (a) The target sample size for approved clinical trials as available in the Clinical Registry maintained by Indian Council of Medical Research for the year 2011, 2012 and 2013 is 69273, 70879 and 74291, respectively. As per the available information, the number of SAEs of death reported in 2011, 2012 and 2013 is 438, 436 and 590 respectively. The number of SAEs of other than death for the same years is 4035, 2786 and 1122. All Serious Adverse Events (SAEs) including deaths or injury which occur during clinical trials are not attributable the clinical trials as such events will also be related to diseases such as cancer, AIDS, etc.