As per direction of Hon'ble Supreme court dated 21.10.2013, it has been decided that for all clinical trials, in addition to the requirement of obtaining written informed consent, audio-visual recording of the informed consent process of each trial subject, including the procedure of providing information to the subject and his/her undertaking on such consent, is also required to be done while adhering to the principle of confidentiality. This is applicable to the new subjects to be enrolled in all clinical trials including Global Clinical Trials. As per the directions of the Hon'ble Supreme Court, the applications for conducting clinical trials are also being appraised through a three-tier mechanism--the New Drug Advisory Committees in CDSCO, a Technical Committee of experts, chaired by the Director General Health Services, and the Apex Committee, chaired by the Secretary,. Health and Family Welfare.

The table below depicts the number of clinical trial applications received in CDSCO:

Year	No. of applications Received
2011	306
2012	480
2013	207

Administrative control of NPPA

2109. SHRI D.P. TRIPATHI : Will the MINISTER Of HEALTH AND FAMILY WELFARE be pleased to state :

(a) whether it is a fact that there are many medicines on which manufacturers earn huge profits;

(b) if so, the details thereof;

(c) whether Government is planning to shift the National Pharmaceutical Pricing Authority (NPPA) to the Union Health Ministry; and

(d) if so, the reasons therefor?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD) : (a) and (b) The Department of Pharmaceuticals in the Ministry of Chemicals and Fertilizers has notified the Drugs (Prices Control) Order, 2013 (DPCO, 2013) on 15th May, 2013 in supersession of DPCO, 1995. There is a change in the methodology of pricing of drugs, moving from 'cost based pricing' to 'market based pricing'. There are 348 medicines (652 formulations) with specified dosage and strength in the National list of Essential Medicines, 2011 (NLEM) which have been included in the first schedule of DPCO, 2013 and brought under price control. Out of total NLEM drugs, National Pharmaceutical Pricing Authority (NPPA) has already notified the ceiling process in respect of 404 formulations up to January, 2014 under the provision of the said order.

In respect of drugs not covered under the Drugs (Prices Control) Order, 2013 *i.e.* non-scheduled drugs, manufactures fix the prices themselves without seeking the approval of Government. However, DPCO, 2013 provides for monitoring the maximum retail price (MRP) of these non-scheduled formulations that no manufacturer can increase the MRP of a non-scheduled medicine more than 10% of MRP during preceding 12 months. The Government has not studied the cost of scheduled medicines under DPCO, 2013.

(c) No.

(d) Does not arise.

Detection of eradicated diseases

2110. SHRI K.N. BALAGOPAL : Will the MINISTER OF HEALTH AND FAMILY WELFARE be pleased to state :

(a) whether Government have identified some clinical cases in which eradicated diseases have been reported;

(b) if so, the details thereof; and

(c) what are the steps taken to address this issue?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD) : (a) and (b) Small pox and Guinea worm are the two diseases declared