(d) the estimated amount of the funds required for this purpose for the next three years;

(e) the details of plan for the purchase and continuous supply of medicines and the mechanism for the distribution of medicines; and

(f) the steps taken by Government to ensure that these benefits reach the targeted beneficiaries?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD): (a) to (f) With a view to providing affordable health care to the people by reducing their out of pocket expenses on medicines, the Central Government has envisaged to start an initiative for the free supply of essential medicines in public health facilities in the country during the Twelfth Five Year Plan. It would be a Centrally Sponsored Scheme funded by the Central Government with contributions from the States. This initiative will promote rational use of medicines. The initiative is based on the Tamil Nadu model where medicines are procured in bulk by the Tamil Nadu Medical Services Corporation (TNMSC), in generic name, directly from the manufacturers and supplied free of cost through an IT enabled supply chain management system to the public. States would be encouraged to set up TNMSC like institutions or use any existing institution with sufficient autonomy for bulk procurement of essential drugs in generic names directly from the manufacturers. The drugs are envisaged to be supplied by the district ware houses through an IT enabled supply chain management system. A sum of Rs. 16000 crore has been approved for the scheme for the Twelfth Plan period.

As regards the information to be received from the States and UTs, so far Assam, Dadra & Nagar Haveli, Goa, Gujarat, Haryana, Kerala, Nagaland, Odisha, Puducherry, Tamil Nadu, Tripura, West Bengal, Andaman and Nicobar Islands, Andhra Pradesh, Himachal Pradesh, Mizoram, Sikkim, Chandigarh, Chhattisgarh, Rajasthan, Daman and Diu and Delhi have furnished the requisite information.

Compliance mechanism for obtaining consent in clinical trials

*418. SHRI N.K. SINGH: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether Government has any compliance mechanism for ensuring that the informed consent of the subjects of clinical trials in India is obtained;

(b) if so, the details thereof;

(c) if not, the reasons therefor;

(d) whether any penalty is imposed for the failure in obtaining the informed consent of the subjects of clinical trials;

(e) if so, the details thereof; and

(f) if not, the reasons therefor?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD): (a) to (f) The requirements and guidelines for undertaking clinical trials are specified in Schedule Y to Drugs and Cosmetic Rules, 1945, which *inter alia* provide that in all trials a freely given informed written consent is required to be obtained from each study participant. The investigator must provide information about the study verbally as well as using a Patient Information Sheet, in a language that is non-technical and understandable by the study subject. The subject's consent must be obtained in writing using an 'Informed Consent Form'. The Drugs and Cosmetics Rules have recently been amended by Gazette Notification G.S.R. 53(E) dated 30.1.2013 to include statements describing that in the event of injury of the trial subject, he/she shall be provided free medical management as long as required and in the event of clinical trial related injury or death, the Sponsor or his representative shall provide financial compensation for the injury or death. The Format of Informed Consent Form for clinical trial subjects has been amended to capture the information relating to address, qualification, occupation, annual income of the subject and name & address of his nominee (for the purpose of compensation in case of trial related death). It has also been made mandatory for the Investigator to hand over a copy of the patient information sheet and duly filled Informed Consent Form to the subject or his/her attendant.

In case of any deficiency on the part of the persons conducting clinical trials in obtaining proper consents, the amended rules provide that the Licensing Authority *i.e.* Drugs Controller General (India) [DCG(I)] may, after giving an opportunity to showcause, pass orders as under after due investigation:

(i) Issue warning letter giving details of deficiency found during the inspection, which might affect the right or well being of the clinical trial subject or the validity of the study conducted at that site.

(ii) Reject or discontinue the study;

(ii) Suspend or cancel the clinical trial permission;

(iv) Debar the investigator(s), sponsor including their employees, subsidiaries and branches, their agents, contractors and subcontractors to conduct any clinical trial in future.

Contingency plans for insulating the country from high oil prices

*419. DR. KANWAR DEEP SINGH: Will the Minister of PETROLEUM AND NATURAL GAS be pleased to state:

(a) whether the Government has any contingency plans in mind in order to insulate the country from high oil prices in case geo-political tensions involving Iran start having an immediate impact on global crude oil prices;

(b) if so, the details thereof; and

(c) if not, the reasons therefor?

THE MINISTER OF STATE IN THE MINISTRY OF PETROLEUM AND NATURAL GAS (SHRIMATI PANABAKA LAKSHMI): (a) to (c) The quantum of crude oil imported by Indian refineries from various sources is decided by them on the basis of technical and commercial considerations. In order to reduce its dependence on any particular region of the world, India has been trying to diversify its sources of crude oil imports. Currently, India is importing crude oil from more than 30 countries spread across different continents. An immediate impact on global crude oil prices due to reduction in supplies from a particular region/country is minimized by release of additional crude oil production from the spare capacities available in other producing regions/countries.

Environmental clearance to sea port at Vizhnijam

*420. SHRI D. BANDYOPADHYAY: Will the Minister of ENVIRONMENT AND FORESTS be pleased to state:

(a) whether Government has given clearance to the construction of a sea port at Vizhnijam in Kerala, which according to some environmentalists, is likely to cause an ecological disaster; and