Government of India
Ministry of Chemicals & Fertilizers
Department of Pharmaceuticals

LOK SABHA

UNSTARRED QUESTION No.768

TO BE ANSWERED ON THE 1ST MARCH, 2016

EU Ban on Indian Generic Medicines

768. Shri Y.V. Subba Reddy

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state :

(a) the reasons why EU has banned 700 and odd Indian generic pharma medicines exported by Indian pharma companies;
(b) whether the Ministry briefed the Ministry of Commerce to raise this issue with the EU during India-EU, FTA negotiations;
(c) whether the above drugs are newly being exported to the EU or are these were earlier in circulation in the EU;
(d) the reply of the Ministry to one of the allegations of the European Union regarding manipulation of clinical trials of above drugs; and
(e) the action plan of the Ministry to resolve this issue with EU?

ANSWER

MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI HANSRAJ GANGARAM AHIR)

a) European Medicines Agency (EMA) recommended for the suspension of about 700 pharmaceutical forms and strength of medicines for which authorization in the European Union (EU) was primarily based on clinical studies conducted at GVK Biosciences at Hyderabad, as inspection at GVK Biosciences conducted by French Medicines Agency (ANSM) revealed data manipulations of electrocardiograms (ECGs) during the conduct of some studies of generic medicines.
b) After the instruction of EU for withdrawal of these 700 products, the Government had at that time temporarily deferred resumption of the talks on Free Trade Agreement with EU.
c) Pharmexcil has informed that, since the drugs were approved for several companies including Indian and overseas companies, the exact position is not available.
d) & (e) Currently India and EU are constructively engaged to sort out regulatory issues between the two countries and expand and strengthen technical co-operation on Good Manufacturing practices.

-x-x-