GOVERNMENT OF INDIA MINISTRY OF HEALTH AND FAMILY WELFARE DEPARTMENT OF HEALTH AND FAMILY WELFARE

LOK SABHA UNSTARRED QUESTION NO. 1250 TO BE ANSWERED ON 22ND DECEMBER, 2017

NOC FOR IMPORTING DRUGS/MEDICINES

1250. SHRI K. PARASURAMAN:

Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

(a) whether the Drug Controller General of India issues "No Objection Certificate" for importing medicines, medical consumables, micro nutrients etc.;

(b) if so, whether delay in issuing NOC has come in the way of importing medical consignments in time, if so, the details thereof;

(c) whether the Government proposed to issue NOC in fifteen days time so as to ensure timely import of medical consignments; and

(d) if so, the details thereof?

ANSWER THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI ASHWINI KUMAR CHOUBEY)

(a) & (b): Import of "Drugs" as defined under the Drugs and Cosmetics Act, 1940 and Rules, 1945 thereunder is regulated under the said Act and Rules. For import of drugs, the foreign manufacturing site and the drugs to be imported are required to be registered and import licence is required to be obtained from Central Drugs Standard Control Organisation (CDSCO).

As per Rule 27A of the Drugs and Cosmetics Rules, if an application for Import Registration Certificate is complete in all respects, the licensing authority i.e the Drugs Controller General (India) [DCG (I)] shall, within nine months from the date of receipt of the application, issue such Registration Certificate and in exceptional circumstances and for reasons to be recorded in writing, the Registration Certificate may be issued within such extended period, not exceeding three months as the licensing authority, may deem fit.

Further, as per the guidelines issued by CDSCO for processing of various applications, the timelines for Registration Certificate and import licence have been fixed as 270 days and 45 days respectively.

No report of delay in issuing Import Registration Certificate and Licence has been received by the Licensing Authority.

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(c): No.

(d): Does not arise.