

GOVERNMENT OF INDIA
MINISTRY OF COMMERCE & INDUSTRY
(DEPARTMENT OF COMMERCE)

LOK SABHA
UNSTARRED QUESTION NO. 1759
TO BE ANSWERED ON 21st SEPTEMBER, 2020

US-CHINA TRADE WAR

1759. SHRI PARTHIBAN S.R.:

Will the Minister of **COMMERCE & INDUSTRY** (वाणिज्य एवं उद्योग मंत्री) be pleased to state:

- (a) whether the ongoing US China trade war is an opportunity for the Pharma industry in India;
- (b) if so, whether it is a fact that larger companies were looking at India for more product source and service and if so, the details thereof;
- (c) whether it is also a fact that a lot of companies have their approvals stalled because of warning letters from the US Food and Drug Administration (USFDA) and if so, the details thereof; and
- (d) whether this has caused new product introduction and growth in the country and if so, the details thereof?

ANSWER

वाणिज्य एवं उद्योग मंत्री (श्री पीयूष गोयल)

THE MINISTER OF COMMERCE AND INDUSTRY
(SHRI PIYUSH GOYAL)

(a) to (d): The Indian pharma industry has been constantly striving to add new products and new markets, including in USA and China, subject to regulatory approvals and market authorisations from the respective regulatory authorities of the respective countries.

The USFDA conducts audit of manufacturers on a regular basis as per the criteria set by them. The authorities conducting audit provide inspection reports, based on which, warning letters are issued in case of non-conformities, for the manufacturers to comply with the actions necessitated by the non-conformities. In such cases, the approval process is stalled until the manufacturer is able to comply with the requirements.

The approval and introduction of new products is an on-going process. Pharma exports from India to USA have recorded 15.79% growth rate in 2019-20. Indian pharma companies have secured 31% of the market authorizations granted by USFDA in 2019-20, which shows that Indian companies continue to be able to introduce new products.
