

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

RAJYA SABHA
UNSTARRED QUESTION NO. 1822
TO BE ANSWERED ON 06th MARCH, 2020

PHARMA INDUSTRY IN INDIA AMID US-CHINA TRADE WAR

1822. SHRIMATI VIJILA SATHYANANTH:

Will the Minister of **COMMERCE & INDUSTRY** be pleased to state:

- (a) whether it is a fact that the ongoing U.S. and China trade war is an opportunity for the Pharma industry in India;
- (b) whether it is also a fact that larger companies were looking at India for more product source and services;
- (c) whether it is also a fact that a lot of companies have approvals stalled because of warning letters from the USFDA; and
- (d) whether it is also a fact that this has caused new product introduction and growth?

ANSWER

THE MINISTER OF COMMERCE AND INDUSTRY
(SHRI PIYUSH GOYAL)

(a) & (b): The Indian Pharma industry has been growing consistently over the last few years. The pharma exports during 2018-19 were USD 19.13 billion, with a growth of 10.72% over the previous year. During April 2019 - January 2020, the pharma exports were at USD 17.32 billion, registering a growth of 11.53% over the corresponding period of the previous year.

The pharma industry is always on the lookout for opportunities to add new products and new markets, including in USA and China, which are subject to regulatory approvals and market authorisations from the regulatory authorities of the respective countries.

Indian pharma offers the best of quality and skilled manpower at the most affordable prices. Contract manufacturing in India is one of the areas where there is an opportunity for the Indian Pharma industry.

(c) & (d): As per information available in the public domain, the audits by USFDA take place on a regular basis as per criteria set by USFDA global office. The authorities conduct audit and provide inspection reports and based on that report, in case of any non-conformities, warning letters may be issued asking the manufacturers to comply with the non-conformities stated in the letter. In such cases, the stalling of approval process is temporary until the manufacturers are able to comply with the requirements of the importing country.

The approval and introduction of new products is an on-going process and pharma exports from India have been growing at more than 10% annually since last two years.
