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

RAJYA SABHA
UNSTARRED QUESTION NO. 2353
TO BE ANSWERED ON 12th JULY,2019

MEETING OF DRUG REGULATORS OF INDIA AND CHINA

2353. SHRI SUSHIL KUMAR GUPTA:

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

(a) whether it is a fact that drug regulators of India and China had a meeting recently in Shanghai;
(b) if so, the details of discussions held during this meeting;
(c) has our country demanded a clear roadmap from China to meet our longstanding demand to open up Chinese pharmaceutical market for India exports; and
(d) if so, the steps being taken to increase the share of Indian medicines in Chinese market?

ANSWER

THE MINISTER OF COMMERCE AND INDUSTRY
(SHRI PIYUSH GOYAL)

(a)&(b):Yes Sir, a one-day workshop on regulatory systems in the pharma sector,was jointly organized by National Medical Products Administration (NMPA, erstwhile CFDA) and Central Drugs Standard Control Organisation (CDSCO) for the benefit of pharmaceutical companies on 21st June, 2019 in Shanghai, China. The intensive day-long workshop included detailed deliberations in areas such as regulatory overview of NMPA, registration of imported drugs in China, Indian regulatory system, drug procurement system in China, NMPA overseas inspections and compliance guide, API (Active Pharmaceutical Ingredient) registration process in China and compliance guide. Both sides also decided to work towards greater coordination and cooperation between the two regulators in future.

(c) & (d):India has requested China to open its pharmaceuticals market, especially for affordable and high quality generic drugs from Indian pharma companies. India has also asked China to clear the various regulatory hurdles faced by the Indian pharma companies on priority, including long delays in product approval timelines, lack of clarity in the current registration guidelines, waiver for bio-equivalence (BE) studies and local clinical trials, drug procurement by local governments in China, suomotu approvals for those

Indian pharma companies which have approvals from stringent regulatory authorities like USFDA, EDQM, Japan, 'risk based' batch testing with self-certification etc. The steps taken to enhance and encourage the exports of pharma products, including high standard generics, from India to China are annexed.

*****

Annexure

Steps taken for enhancing and encouraging exports of pharma products, including high standard generics, from India to China

i. Creating awareness among Indian pharma companies on the opportunities in China and guiding them to consider product registrations with CFDA to enable higher exports to China.

ii. Circulation of the Chinese list of exempted 28 tariff items and the list of anti-cancer drug covered under these lines amongst the Indian Pharma industry.

iii. B2B meet organized during 20-22 August 2018 at Shanghai, China which facilitated interaction of Indian Pharma companies with Chinese importers and officials of NMPA.

iv. Creating awareness on the Regulatory requirement in China. Pharmexcil, with the support of Department of Commerce (DoC), organized a training program /workshop on product registration guidelines and dossier filing with the National Medical Products Administration (NMPA, formerly CFDA) for the benefit of our pharma companies on 17th December 2018 at Hyderabad.

v. MoU on cooperation in pharmaceuticals executed between Pharmaceuticals Export Promotion Council of India (Pharmexcil) and China Chamber of Commerce for Import and Export of Medicines and Health Products (CCCMPHIE) in August 2018.

vi. Help Desk set up in Pharmexcil and CCCMPHIE to help companies from both sides in finding the right partners for their business ventures.

vii. Under the India-China Strategic Economic Dialogue (SED) being co-chaired by NITI Aayog from Indian side, a joint working group on pharmaceuticals has been set up by Department of Pharmaceuticals and the first meeting happened on 7th May, 2019 at Beijing wherein the issues impacting market access were raised by the representative of DoC for the consideration of Chinese authorities.

viii. A one-day workshop on regulatory systems in the pharma sector was jointly organized by National Medical Products Administration (NMPA, erstwhile CFDA) and Central Drugs Standard Control Organisation (CDSCO) for the benefit of pharmaceutical companies on 21st June, 2019 in Shanghai, China.

*****