CPhI china

18 19 20 June 2019

Shanghai New International Expo Centre(SNIEC), Shanghai, China

India Pavilion

INDEX

PHARMEXCIL PARTICIPATION IN CPhI CHINA 2019

EVENT AT GLANCE:

The 19th CPhI China organized by Informa Markets and CCCMHPIE, co-organized by Sinoexpo Informa markets, China during 18th-20th June 2019 at the Shanghai New International Expo Center (SNIEC) concurrently with other exhibitions such as ICSE China 2019, P-MEC China 2019, Innopack China 2019, NEX China 2019 and LABWORLD China 2019.

The exhibition area this year exceeded 20,000 square meters for the first time, with more than 3,200 domestic and foreign exhibitors and over 70,000 visitors from 120 countries and regions to join the great event of pharmaceutical industry for 3 days.

CPhI China 2019, a three day exhibition has provided an opportunity to meet key industry stakeholders, manufacturers, suppliers and innovators at one place.

Exhibitor & Visitors Participation:

- No. of Exhibitors: 3,200 Exhibitors
- No. of Visitors: 70,000 Pharma industry professional Visitors from 120 countries
- Country Pavilions: India, South Korea, Turkey, Poland, Russia etc.
- Top Ten Exhibitors by Countries: China, Japan, India, South Korea, Taiwan, Italy, USA, Germany, Switzerland, United Kingdom

Pharmexcil organised "India pavilion'' at CPhI China sixth time with participation from the following Indian Pharma companies.

1. R.L.FINE CHEM PVT. LTD
2. MURLI KRISHNA EXPORTS PVT LTD
3. UMANG PHARMATECH PVT LTD
4. SUPARNA CHEMICALS LTD
5. METROCHEM API PVT LTD
6. SURYA REMEDIES PVT LTD
7. PHARMEXCIL
8. RAPTIM RESEARCH PVT LTD
9. RINI LIFE SCIENCE PVT LTD
10. SHREEJI PHARMA INTERNATIONAL
11. LASONS INDIA PVT LTD
12. LEE PHARMA LTD
13. SIFLON DRUGS
14. SWATI SPENTOSE PVT LTD
15. ACTIVZ LIFESCIENCES (I) PVT. LTD
16. SHRI VINAYAK CHEMEX (I) PVT. LTD
17. RUMIT LIFECARE
18. NOSCH LABS PVT LTD
19. NATCO PHARMA LTD

INAUGURATION OF INDIA PAVILION

India Pavilion at CPhI China was inaugurated by Mr.Anil Kumar Rai, Consul General, Consulate General of India in Shanghai on 18th June 2019. Mr.DVS Reddy,-Member COA, Mr.Satish Wagh, Chairman-Chemexcil, Mr.Sudhir Vaid, MD-Concord Biotech and other industry leaders were present. The Consul General interacted with the member companies in India pavilion and learnt about theirs issues to export drugs to china. The delegates south the cooperation of the CGI office for easy market access into china.

Pharmexcil Catalogue:

We have printed 200 copies of the brochures/Pharmexcil catalogue containing information about Indian Pharma industry and its Accreditations, details of the participants and their products details and distributed to the visitors and local pharma associations.

MEETINGS:

- The delegation from Pharmexcil comprising of Mr.Murali Krishna, Joint Director and Ms.Ch.Lakshmi Prasanna, Sr. Regulatory Affairs Officer had meeting with Ms.Guo Xiaodan, Secretary of Sub-Chamber, Department of Pharmaceuticals, China Chamber of Commerce for Import & Export of Medicines & Health Products (CCCMHPIE). It is learnt that Asian Chamber of Ministry of Commerce, China is proposing to hold the "India –China Pharma Week" focusing the collaboration between the Pharmaceuticals regulators of two nations in the month of August at Beijing.

  Pharmexcil sought cooperation for our Trade delegation with BSM scheduled in first week of August and also requested to see the possibility of organizing India-China Pharma coinciding our Trade delegation. We have requested to hold India-China Regulatory training program inviting NMPA officials to India this year. Further we have detailed about the International Regulators Meet happening on 19th & 20th September in Hyderabad and sought the cooperation of CCCMPHIE to bring in the NMPA officials for thee meet.

- Sri.Shaymal Misra, Joint Secretary, Ministry of Commerce & industry visited CPhI China and had meetings with some of the major pharmaceuticals companies including Dr.Reddy's Labs, Hetero Drugs, MSN labs, Concord Biotech, Natco Pharma, to understand the concerns of the exporters and had given assurance to the manufacturers that issues will be taken up with Chinese side.

- Dr Mandeep Bhandari, Joint Secretary, Ministry of Health & Family Welfare, Sr.Rajiv Wadhwan, Director (Drugs), MoHFW and Dr.Eshwar Reddy, DCG(I) also visited India pavilion in CPhI china and interacted with member companies.

FEEDBACK FROM MEMBER COMPANIES

Council participated in CPhI China for the sixth consecutive year and organised India Pavilion by taking space of 168 Sq.mtrs with participation of 19 member companies.

The member companies expressed their satisfaction with the arrangements made by Pharmexcil and would like continue their participation in CPhi China 2020 as well.

In terms of the Business enquiries, most of the members have expressed satisfaction and few companies have received the orders.

- Business Enquiries: **450 +**
- Orders received / Approximate Business generated: **200 Crore**

Member companies have requested Pharmexcil to book the space for the year 2020 and we have reserved 224sq.mt space in good location.

ISSUES BEING FACED BY MEMBER EXPORTERS WHILE EXPORTING TO CHINA

- Delay in product registration: National Medical Products Administration (NMPA) is delaying the product registration approvals and it takes about 3 to-5 years for granting the approvals, which in normal cases is 1 year.

- Though NMPA has changed its regulatory framework to align with ICH, these rules are favoring locally manufactured generics.

- As per NMPA regulations, Quality Consistency Evaluation for Generics is required for all the approved molecules. However there is a difference in the treatment given to locally manufactured product and for the imported products. Locally produced Generics, having USFDA approvals gets (I) Priority Review and (ii) Bio Equivalence Waiver. However the same benefits are not extended to the products manufactured outside China.

- China has proposed B.E waiver for drugs approved by US/EU/Japan, however we understood that these regulations are not yet issued.

- NMPA is insisting for Clinical Trail data for Generic injectable imported drugs.

- APIs cannot be imported in China, unless the same is registered with National Medical Products Administration (NMPA). The procedural formalities for obtaining registrations of API theoretically are supposed to take minimum 9 months, but actually take around 3 years. Further, renewal of registration takes a minimum of 1 year which is done once in 5 years.

- When any API is imported in China, National Institutes for Food & Drug Control (NIFDC), through their testing institutes draw samples from every batch. There are around 12 Coastal Drug Testing Institutes attached to Sea/Air Customs. Testing and analysis being product specific, takes around 4 weeks depending on the number of batches and nature of analysis

involved. In general, the cost of testing ranges between USD 2.50 to 3.50 per kg.After testing and analysis, until and unless the positive result comes out against each batch, the product can neither be processed further nor sold in the local market. If any of the batches of the consignment fail to meet the specifications during the registration validity of 5 years, it amounts to cancellation of registration. Such rejected material has compulsorily to be destroyed at the local level.

In China, there is no concept of a marketing license as is the case with most of the countries including India. China does allow contract manufacturing for exports but not for domestic market and as a result investment in plant and machinery is a must in China. This is a big deterrent to Indian companies in doing business in China as it takes a minimum of 6 to 7 years to get returns on the investment

China Healthcare sector-Overview

China has been pushing forward reform and transformation in the healthcare sector. On the government level, the institutional reform on governmental departments launched in 2018 has strengthened the control and management of the health sector by reshuffling and setting up the new Market Supervision Administration, National Medical Products Administration (NMPA), the State Administration for Market Regulation, and the National Health Commission (NHC), and the National healthcare Security Administration.

The top five death causes in China are: HIV/AIDS, TB, Viral Hepatitis, Rabies, and Japanese Encephalitis.

China's Booming Pharma Industry supported by enabling policies:

2018 was an important year in China's pharmaceutical Industry. In order to reach a sustainable development in this industry, Chinese government is reforming from all sides including: more drugs in medical reimbursement list, removing customs duties for certain imported drugs, encouraging more innovative drugs, simplifying the drug registration procedure and approval process etc.

The cheese government releases the Technical guidance on Acceptance of Overseas Clinical Trial Data on July 10, 2018, thus conditionally recognize clinical data obtained overseas, either for drugs marked already or through MRCT (multiregional clinical trials). The guideline is believed to be an actual practice to keep abreast of ICHGCP requirements, and speed up the launch of overseas new drugs on China market.

The review and Approval procedures for Urgently Overseas New Drugs on Oct 23, 2018, jointly released by NMPA and NHC, to set up a special channel for the urgently needed overseas drugs already lunched in US, EU, or Japan over the past one decade, on the basis of three criteria.

1. Drugs for treatment of rare diseases
2. Drugs for treatment of serious or life-threatening diseases without any other effective drugs launched in China
3. Drugs for treatment of serious or life-threatening diseases, with significantly better clinical performance.

Reducing Customs duty for Anti-Cancer Drugs:

Starting from May 1st 2018, the Chinese government reduced the customs duties to Zero for all imported anti-cancer drugs.

By October 2018, the total pharmaceutical import had reached 24 billion dollars. Until the end of year, 17 anti-cancer drugs made ways into the medical reimbursement list.

Since March 2019, 4 APIs of anti-cancer and rare disease drugs will be exempt from custom duties. Statics show that the custom duty removal has made the consumer price o 4 anti-cancer drugs (both domestic and imported one) drop in 2018.

Reducing Value-Added Tax for Rare Disease Drugs

On June 2018, five government bodies led by NHC released the five version of care disease catalogue to include 121 rare diseases. Since March 2019, the first batch of 21 rare disease drugs will enjoy tax reduction. These measures aim to ensure access to rare disease drugs to 20 million patients in China.

Centralized procurement of drugs (Similar to GPO practices) iun 11 (4+7) pilot provinces and cities:

A document on centralized procurement of drugs in 11 pilot provinces and cities (also named as the 4+7 centralized procurement policy) was issued on November 15, 2018 to allow Centralized purchases of 31 products in four municipalities of Beijing, Tianjin, Shanghai, Chongqing and four capital cities: Shenyang, Dalian, Xiamen, Guangzhou, Shenzhen, Chengdu and Xi'an. The procurement was believed to account for 3-%-50% of drugs needed in the pilot provinces and cities, and only a few multinationals successfully won the bid. This round of policy changes already and will continue to push for price drop of multinationals. To maintain its market share, price drop seems to be an irreversible trend.

Positive signals on Cross-Border E-commerce Released from State Council Executive Meeting:

On November 2018, the state Council Executive Meeting released the policy on cross-border E-commerce to continue the strong impetus given last year. Imported commodities entering China via Cross-Border E-commerce channel do not need to go through import registration or filing. Instead, they are regulated as items for individual use. In addition to the previous 15 pilot cities, 22 pilot cities will be assed to the pilot list, including Beijing, Shenyang, Nanjing, Wuhan, Xi'an, Xiamen etc. Thus opening up more possibilities for overseas health and nutraceutical products.

China International Performance in the Healthcare Sector

According to the China customs, China's total foreign trade volume in the healthcare sector registered at around 1114.85 billion USD in 2018, among which:

- China's exports volume was 64.42 billion USD, up by 5.96%
- Import volume was 50.43 billion USD, down by 9.75%, partially due to policy changes such as the 4+7 centralized procurement policy and generic drug equivalency review, which jointly created a more competitive market and pushed for price drop in imported drugs.

From the performance over the years, in terms of major trading partners, most of them are still traditional markets of Europe, US and Japan.

Chinas total export volume is of 3.96 billion USD in 2018, with strongest growth in herbal extracts, followed by TCM (Traditional Chinese medicines) finished products and prepared slices. Southeast Asia remains to be the largest exporting destinations for TCM products.

The US, EU and India remained to be the major export markets for APIs originated from China, with slower growth through. The EU, Australia and the US were the top three export destinations for China-made FDFs.
We saw a total export volume of 23.63 billion USD, with steady growth in medical consumable, disposable materials, diagnostics and equipment, rehabilitation devices and dental devices. The industry has kept on diversifying its export market with optimized trade structure, higher quality and efficiency.

An eye-catching sub-sector with strong performance in foreign trade was the health and nutraceutical sector. In 2018, the Chinese health and nutraceutical industry generated some 4.68 billion dollars of foreign trade in total, up by 31.5%, which was another record high. Among which, it exported 1.67 billion dollars worth products, up by 21.8% from 2017. The main exporting destinations were US, Hong Kong, Japan, Indonesia, etc. Such bulk exporting provinces included Jiangsu, Guangdong, Shanghai, Shandong, Zhejiang, among others. Aland, INNOBIO, Sirio were the top three exporters.

The import volume from other countries totaled 3.01 billion dollars, up by 37.7%. The main importing source countries were Australia, US and Germany, and such products were usually imported by companies in Zhejiang, Shanghai, Guangdong, and Beijing, which represented a relatively high consumption capability. E-commerce, particularly cross-border E-commerce successfully brought world renowned brands like Swisse and Blackmores to the China market. Australia is the largest importing source country with 670 million dollars' worth products, followed by US (620 million USD) and Germany (280 million USD).

China's Pharmaceutical Market:

As the global pharmaceutical market demand continues to grow steadily and China forges ahead to advance from a big pharmaceutical company to a pharmaceutical power, China's export value of Pharmaceutical products in 2018 was 36.883billion USD, a year-on year increase of 4.03% maintaining a good growth trend. In specific, the export value of APIs exceeded 30 billion USD for the first time, climbing 3.2% year on year to 30.048billion USD: and the export value of preparations reached a reached high of 4.1 billion USD, up by 18.64% year on year. The steady rising shows unlimited development potentials of China's pharmaceutical market and makes it known to the world the strong pulse of the developments of China's API industry. Meanwhile, China's pharmaceutical industry is entering a new era of quality based and innovation-oriented development with the release of new policies such as conformity evaluation of generic drug, the speeding up of drug review and approval process, and the Marketing Authorization Holder (MAH) system.

India Pharma exports to CHINA P RP by Category $ Million				
Category	2015-16	2016-17	2017-18	2018-19
Bulk Drugs & Drug Intermediates	114.59	103.85	153.98	173.45
Drug Formulations & Biologicals	12.55	17.32	26.23	32.11
Ayush	0.52	0.59	0.58	0.59
Herbal Products	6.43	5.31	9.39	12.50
Surgicals	8.24	12.54	9.77	10.54
Vaccines	3.26	5.83	0.50	0.99
Total	145.58	145.45	200.46	230.19

India Pharma Imports From CHINA P RP by category $ Million				
Category	2015-16	2016-17	2017-18	2018-19
Bulk Drugs & Drug Intermediates	2110.39	1819.67	2055.94	2405.42
Drug Formulations & Biologicals	80.20	63.68	78.10	98.83
Ayush	0.00	0.00	0.01	0.03
Herbal Products	0.96	2.13	0.91	1.04
Surgicals	24.60	25.99	30.06	33.32
Vaccines	34.51	38.96	20.61	17.36
Total	2250.65	1950.43	2185.63	2556.00