



**India China Pharmaceuticals Conference & Business Meet 20-21 Aug 2018, Hotel Yangtze Renaissance Hotel, Shanghai, China**

**Organiser**

**Pharmaceuticals Export Promotion Council of India(PHARMEXCIL India)**

**Co-Organiser**

**China Chamber of Commerce of Import & Export of Medicines and Health Products(CCCMHPIE)**

**Supported by**

**Ministry of Commerce & Industry, Government of India  
Consulate General of India, Shanghai, China  
Embassy of India, Shanghai, China  
CADC**

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## PHARMECEUTICAL DELEGATION FROM INDIA

Sr.no	Name of the Delegate	Designation	Company Name
1	Mr.Ajit Singh	Chairman	ACG Associated Capsules Pvt. Ltd
2	Mr.Arvind Kumar Chandak	President-China Operations	Aurobindo Pharma Limited
3	Mr.R. Srinivasa Rama Rao	Chief Executive Officer	Bio Pharma Laboratories Pvt. Ltd.
4	Mr. Vivek Kaushal	Sr. General Manager	CBC Corporation(India)Pvt Ltd (Subsidiary of CBC Group Japan)
5	Mr.Sanjay Moolchandani	Director	Cipla Ltd
6	Dr.Satheesh Kumar	Head of Representation	Dr.Reddy's Laboratories Ltd.
7	Mr.Manish Sabharwal	Managing Director	Dr. Sabharwal's Medicals Pvt. Ltd.
8	Mr. Dhruv Sabharwal	Executive Operation	Dr. Sabharwal's Wound Care
9	Mr. V K Singh	President-Operations	Emcure Pharmaceuticals Limited
10	Mr. Bhupendra H Sangani	Managing Director	Galentic Pharma (India) Pvt Ltd
11	Mr.Suresh Pathak	Chief Executive Officer	GLS Pharma Ltd
12	Mr.Ardhendu Ghosh	Chief Representative, China	Hetero Labs Ltd
13	Mr. Sanjaykumar Patel	Director	Infinium Pharmachem Pvt. Ltd.
14	Mr. Gurudutt Shenoy	Vice President – APAC	Accord Healthcare
15	Mr.Paresh Patel	Sr. General Manager (International Business)	Intas Pharmaceuticals Ltd.
16	Mr.Girish Jaiwal	Chief Executive Officer	Kings Global Biotech Limited
17	Mr.Kenny Jiang	China Office Head	Lupin Pharmaceuticals Ltd
18	Mr.Devendra Mehta	Managing Director	Mehta API
19	Mr. Anil Sontakke	Senior Manager, International Marketing	Naprod Life Sciences Pvt. Ltd.
20	Mr.Sunil R Gupta	Partner	Nutrigrace
21	Mr.Praveen Kumar Barur	General Manager – API Sales and Business Development	Natco Pharma Ltd
22	Mr. Aditya Kankan	Director	Protium Pharma (India) LLP
23	Mr.Amrit Arora	Director	Rescuers Life Sceinces Ltd
24	Mr.Vikas Singhal	Director	Rumit Lifecare
25	Mr. Kalpesh Shah	Vice President	S Kant HEALTHCARE Limited
26	Mr.Mohan Rao Manam	Vice President - Business Development & Regulatory Affairs	Suven Lifesciences Ltd
27	Mr. Ashok Shetty	General Manager	VHB Medisciences Limited

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**India-China Pharmaceuticals Conference & Business Meet**  
20-21, August, Hotel Yangtze Renaissance Hotel, Shanghai, China

时间 Time	主题 Topics	嘉宾 Speaker
8:30- 9:00	企业报到 Registration	
9:00- 9:10	印方开幕致辞 Opening Remarks from India	Mr Anil Kumar Rai, 印度驻上海领事馆总领事 Consul General Consulate General of India in Shanghai
9:10- 9:20	中方开幕致辞 Opening Remarks from China	罗晓梅女士 商务部亚洲司副司长 Madam Luo Xiaomei Deputy Director General, Department of Asian Affairs Ministry of Commerce of the China
9:20- 9:50	药品审评审批改革进展情况 Updates on Approval Regulations for Pharmaceutical Product in China	温宝书 药品审评中心处长 Weng Baoshu, Division Director CDE
9:50- 10:20	中印医药产业发展现状及合作路 径 The Landscape of Chinese Pharmaceutical Industry and Opportunities for China-India Cooperation for the Sector	孟冬平女士 中国医药保健品进出口商会副会长 Madam Meng Dongping,

		<b>Vice President CCCMHPIE</b>
<b>10:20 - 10:40</b>	<b>PHARMEXCIL简介及印中医药合作介绍</b>  <b>The Introduction of PHARMEXCIL and China-India Pharmaceutical Cooperation</b>	<b>Ravi Udaya Bhaskar, 印度药品出口促进会会长</b>  <b>Mr. Ravi Udaya Bhaskar, President, PHARMEXCIL</b>
<b>10:40 - 11:00</b>	<b>茶歇</b>  <b>Tea Break</b>	
<b>11:00 - 11:45</b>	<b>中印双方企业代表发言</b>  <b>Presentation by Company Representative from China and India</b>	<b>国药国际、上海沪源、印方企业</b>  <b>China Sinopharm International Corporation China Chinopharma Ltd. Dr.Satheesh,Dr.Reddy's Laboratories Ltd</b>
<b>11:45 - 11:55</b>	<b>签署合作谅解备忘录</b>  <b>Signing of MoU</b>	<b>孟冬平女士, 中国医药保健品进出口商会副会长</b>  <b>Mr. Ravi Udaya Bhaskar, PHARMEXCIL会长</b>
<b>11:55 - 12:00</b>	<b>总结及合影</b>  <b>Wrap up and Group Photo</b>	<b>孟冬平女士, 中国医药保健品进出口商会副会长</b>  <b>Mr. Ravi Udaya Bhaskar, PHARMEXCIL会长</b>
<b>12:00 - 13:00</b>	<b>午餐及自由交流</b>  <b>Lunch and Open Discussion.</b>	
<b>13:00 - 18:00</b>	<b>企业对接会</b>  <b>Business Match Making</b>	

## PHARMACEUTICAL SEMINAR : DELIBERATIONS & PRESENTATIONS

Pharmexcil in association with CCCMHPIE organised India-China Pharmaceutical Conference & Business Meet during 20-21st August 2018 at Hotel Renaissance, Shanghai, China. The event is organised with support of Ministry of Commerce & Industry, Government of India, Embassy of India at Beijing and is hosted by Consulate General of India, Shanghai.

**His Excellency Mr. Anil Kumar Rai, Consul General** offered his opening remarks from India and welcomed the Guests from China and India. Speaking at the opening of the event, he reflected upon



the role and responsibility of India and China in achieving the sustainable development on Ensuring healthy lives well-being for all at all ages. While appreciating the Indian pharma companies for manufacturing affordable quality medicines of international standards, he mentioned that the Chinese policy makers and drug regulators recognised that unless greater market access is given to foreign companies and the obsolete, unwarranted as well as artificial barriers are removed, achieving affordable healthcare will not be feasible.

Given the policy imperative to ensure affordable drugs to all, China is set to emerge as the fastest growing pharmaceutical markets in the world and India's advantage in the sector makes it a natural choice for cooperation. We hope that reforms in drug registration process in China will pave for removing the hurdles for Indian pharma companies. China and India being on the largest economic partners are especially looking forward to cooperate in this sectors and create a win-win situation. He informed that this conference and Business Meet is first of its kind in the area of Pharmaceuticals with the presence of 27 Indian Pharma companies with participation from more than 200 Chinese Pharmaceutical companies.

While appreciating the efforts of Pharmexcil in doing this mega event, it is requested that this momentum should be continued for strengthening India -China trade cooperation.

**Madam Luo Xiamei, Deputy Director General, Department of Aisan Affairs, Ministry of Commerce of the China** offered opening remarks from China mentioned that following PM Modi and Xi Jinping's bilateral meeting there is a growth in bilateral relations. The



Chinese investment in India is increasing and the scope for cooperation between the two countries are enormous. Premier Li Keqiang has spoken that opening up of China will only further increase. This meeting will act as a platform for cooperation between pharma sector of the two countries. She mentioned that the new regulations will meet the demands of the public to make medicines affordable. The opening up of pharma sector in China will be in line with the national strategy to develop the industry, be innovative, be internationally competitive including internationalisation of the registration and approval

procedures with online application and approval system. The procedures for clinical trials will be simplified and China will follow the ICH guidelines. There will be larger team of experts to evaluate and assist in the approval procedure. She highlighted the need to have improved communication between the manufacturer and regulator to avoid unnecessary delays because of incomplete applications.



**Mr. Weng Baoshu, Division Director, Center for Drug Evaluation, CFDA** made a presentation on approval regulations for pharmaceutical product in China. He said CFDA is under tremendous pressure for granting the product registration approvals. With the changes in the regulatory regime of China, we are benchmarking global standards and in the process of transformation, we will of course have difficulties and challenges.

In order to solve the problem of backlog of drug registration applications and improve the quality and efficacy of drug evaluation and approval, CFDA has issued No. 230 document in 2015, Notice on Several Policies on Drug Registration evaluation and Approval in which ten reform tasks are defined.

Notice of several policies on drug registration evaluation and approval in 2015 no. 230, identifying 10 reform tasks.

- ❑ **Promote the standards for evaluation and approval of drugs**
- ❑ **Promote quality conformity evaluation of generic drugs**
- ❑ **Accelerate the evaluation and approval of innovative drugs**
- ❑ **Implement the main responsibilities of the applicant**
- ❑ **Timely release drug registration application information**
- ❑ **Improve drug clinical trial approval**
- ❑ **Simplify drug approval procedures and improve the drug re-registration system**
- ❑ **Improve the quality control system for evaluation**
- ❑ **Comprehensively disclose drug evaluation and approval information**

Centering on the determined five objectives and nine tasks, carry out “3-base & 7-system” construction. Through communication and exchange in key stages for the R&D of innovative drugs, jointly research and settle problems in R&D process and problems uncovered in the technical guidance; In recent two years, about 500 times of communication meetings were convened to provide support and services for the R&D and evaluation of innovative drugs and clinical drugs urgently needed.

A number of 423 registration applications in 25 batches have been accumulatively released with priority for evaluation. 99 registrations have been approved for market launching through priority for evaluation (involving 50 varieties in total), including antitumor drug Afatinib tablet, rare disease drug Rucotinib tablet and medicine for children Levetiracetam concentrated solution for injection, thus providing effective guarantee for meeting the demand of clinical medicine and promoting public health.

SFDA and NHC joint announcement (No. 23) :

- For drugs and medical devices launched overseas for the treatment of critical or rare diseases, if there is no species difference, overseas data may be used for import application.
- Clinical variety applied should be inspected according to needs (independently or entrusted)
- Cancel the re-registration archives verification procedure.
- Implement life-long number system for import registration certificate.



**Madam Meng Dongping, Vice President, CCCMHPIE** presented an overview of the landscape of Chinese Pharmaceutical Industry and opportunities for China-India Pharmaceutical Cooperation. During the presentation, She addressed the following issues raised by India side and emphasized that we are deeply committed to the trade cooperation in the area of Pharmaceuticals between China and India.

- 1) **Zero tariffs on imported anti-cancer drugs and encourage the import of innovative drugs:** From 1<sup>st</sup> May 2018, the import tariffs on drugs including anti-cancer drugs, alkaloid drugs with anti-cancer effects, and TCM have been reduced to zero. Imported innovative drugs, especially urgently needed anti-cancer drugs will be timely reimbursed in the health insurance system. Accelerate the importation and listing of innovative drugs. Clinical trial applications will be changed from approval to expiration acquiescence. A maximum of 6 years of data protection period for innovative chemical drugs is adopted
- 2) **Cancel port testing of imported chemical drugs:** In April this year, CFDA/NMPA issued the "Notice on related matters regarding customs testing of imported Chemicals drugs"(No. 12 of 2018), cancel the port testing of imported chemical drugs, strengthen post-supervision and inspection. After the implementation of relevant policies, imported chemical drugs can be directly distributed to medical institutions and retail pharmacies after customs clearance, which can shorten the time to enter the Chinese market by 2-3 months and reduce the cost of overseas drugs entering the Chinese market.  
Source <http://cnda.cfda.gov.cn/WS04/CL2050/227852.html>
- 3) **Technical Guidelines for Accepting Overseas Clinical Trial Data” issued: On July10<sup>th</sup>,** CFDA/NMPA issued the Technical Guidelines for Accepting Overseas Clinical Trial Data” (No.52, 2018). For BE data of generic drugs completed abroad, if the quality is good, and authenticity, completeness, accuracy and traceability requirements are met, such data can also be used for registration in China.  
<http://cnda.cfda.gov.cn/WS04/CL2050/325800.html>
- 4) **Notice on related issues of optimizing review and approval of drug application:** On May 23, 2018, this announcement was open for public opinions. It will optimize the approval process and improve the quality and efficiency of re-registration of imported drugs. Two majors changes: First, simplify the process of re-registration of imported drugs and improve efficiency; second, implement a new numbering model to help manage and trace the source.  
<http://cnda.cfda.gov.cn/WS04/CL2050/228140.html>
- 5) **Opinions on Priority Review and Approval to Encourage Drug Innovation:** This opinion was issued on December 28, 2017 with the purpose to enhance drug registration management, speed up development and marketing of clinically valuable new drugs, clinically urgently needed generic drugs, and solve the contradictions in drug registration. At present, the number of drug registration is thus reduced from 252,000 in 2015 to less than 4,000.



**Mr. Ravi Udaya Bhaskar, Director General, Pharmexcil** welcomed dignitaries from China and India and said this conference is a milestone for strengthening cooperation in the area of pharmaceuticals. We could reach this cooperation levels due to the efforts put in by Ministry of Commerce and focussed deliberations with CFDA, MOFCOM and CCCMHPIE during the last two months.

Towards this direction, we are signing an MoU with Pharmexcil today, which is an leading Pharmaceutical body of Government of India and also setting up Consultation Desk for facilitating trade and addressing queries from time to time between China and India.

We are confident that India and China in the days to come will join hands to complement each other through Joint collaborations than competing each other. Pharmexcil to take this dialogue to the next level invite CFDA officials to offer training programme to the India Pharma industry and this could be done at the earliest possible.



We seek cooperation from China Pharma industry and Government to consider setting up of fermentation technology facility in India under "Make in India".

A Joint Working Group is also proposed for trade cooperation in the area of oncology and antibiotics and the prime objective of the JWG is to ensure supplies of anticancer drugs and antibiotics to meet the China medicinal requirements.

Pharmexcil and CCCMHPIE signed the Memorandum of Understanding (MoU) on this occasion. Mr. Ravi Udaya Bhaskar, Director General from Pharmexcil and Ms. Meng Dongping from CCCMHPIE signed the MoU and it is witnessed by Mr. Anil Kumar Rai, Consul General, Consulate General of India and Madam Luo Xiamei, Deputy Director General, Department of Aisan Affairs, Ministry of Commerce of the China.

## SIGNING OF MOU



Presentations were made by China Sinopharma International Corporation, China Chinopharm Ltd and Dr.Reddy's laboratories, which had highlighted the market strengths, product portfolios and touched upon the regulatory environment. Sought cooperation from CFDA. The representative of Sinopharm emphasized the need for improved communication between the applicants and regulators to ensure safety and better understanding of each other. Dr.Satheesh Reddy from Dr.Reddy's Laboratories emphasized on the challenges faced by foreign companies in Chinese pharma market including the non clarity in acceptance of BE studies done elsewhere, clinical trial requirements of injcetables etc. His word of caution to the Indian companies included the need to pay attention during submission of dossier for registration and while selecting a local partner for cooperation.

## B2B MEETINGS

The event was followed by a B2B of the Chinese companies with the 27 Indian companies, which lasted for more than five hours with both the country participants completing the session with a better understanding of each other's product requirements and regulatory compliances. The event was attended by 27 Indian Pharma companies with participation of 200 delegates inclusive of 128 Chinese Pharmaceutical companies.



## TO NAME FEW MAJOR CHINESE COMPANIES:

- China Sinopharm International Corporation
- CHINA MEHECO CO., LTD.
- Shanghai Pharmaceuticals Holding Co., Ltd.
- Orient International Holding Shanghai Rongheng International Trading Co., Ltd.,
- High Hope Int'l Group Jiangsu Medicines & Health Products Imp. & Exp. Corp. Ltd.
- Shanghai Fosun Pharmaceutical (Group) Co., Ltd
- Yangtze River Pharmaceutical (Group) Co., Ltd.
- Shanghai Medicines & Health Products I/E CO.,LTD.
- Zhejiang Hisun Pharmaceutical Co., Ltd.
- China Pioneer Pharma Holdings Limited
- Jiangsu Simcere Pharmaceutical Co.,Ltd,
- Zhejiang Huahai Pharmaceutical Co., Ltd.
- China Chinopharma Ltd.
- China Resources Saike Pharma
- Beijing Ehaoyao Pharmacy Chain Co.ltd
- Sunshine Guojian Pharmaceutical (Shanghai) Co., Ltd.
- NanJing Pharmacare Co.,Ltd.
- Intertek Life Bridge (Shanghai) Testing Service Co.,ltd
- FarmaSino Pharmaceuticals (Jiangsu) Co., Ltd
- Kaifeng Pharmaceutical (Group) Co., Ltd.
- NCPC International Corp.
- Apeloia Pharmaceutical Co.,Ltd/Zhejiang Hengdian Apeloia Imp & Exp Co.,Ltd
- YIDA CHINA (HONGKONG) TRADING LIMITED
- Shanghai Neutrump Pharmatech Co.,Ltd
- Shanghai Witofly Chemical Co. ,Ltd
- Guang dong Shanmu Pharmaceutical Company Ltd.
- Hebei Hengtai Pharmaceutical CO.LTD
- Guangzhou Bairui Medicine Co.,LTD
- Hainan Merlottkang Pharmaceuticals Co., Ltd
- Zhejiang Healthcare development company Ltd.
- Ruikang Pharmaceutical Co., Ltd
- Huaxia Shengsheng (Beijing) Pharmaceutical co.ltd
- Lionco Pharmaceutical Group Co., Ltd
- Zhijin Biotech (Shanghai) Co., Ltd
- CASI (Beijing) Pharmaceuticals Co., Ltd.
- Beijing Lunarsun Pharmaceutical Co.,LTD
- Shiyu Capital
- Luoxin Pharm
- Shanghai Cenway International Trading Co.Ltd
- Tianjin GreenPine Pharma Co., Ltd.

- ✓ **About 50 trade enquiries were generated during the Business Meet**
- ✓ **The likely Business generated is to the tune of INR 1.5 crores (approximately)**
- ✓ **The possible Joint Ventures: Intas (Pharma),Natco (Pharma) and Nutra Grace (Nutraceuticals)**

## VISIT TO FOSUN PHARMA & SHANGHAI PHARMACEUTICALS

The Business Delegation from India had meetings with Fosun Pharma and Shanghai Pharmaceuticals on 21st August 2018 and sought cooperation for expanding the product portfolio of India companies.

Mr. Willima Wu, President, Fosun Pharma received the Business Delegation from India and expressed delight for visiting their company. Mr. Deyong Wen, Vice President stated that Fosun Pharma is deeply associated with India and we continue to work with India, as our prime partner for supply of Pharmaceuticals.



Fosun Pharma made a detailed presentation on Product Registration with CFDA which has provided immense benefit to the companies from India side.

Mr. Haoliang Gu, Shanghai Pharma welcomed business delegation from Pharmexcil and shared heartfelt gratitude for visiting the State owned Pharmaceutical company with a great legacy, which is also among top three pharmaceutical distributors in China.



Shanghai Pharma along with management team stated that they are already working with India and we are open for new products from India and it would be a good opportunity for both India and China to work together for a greater market access and trade cooperation in the area of pharmaceuticals.



## **OUTCOME OF INDIA-CHINA PHARMA CONFERENCE & BUSINESS MEET**

- ✓ Pharmexcil created a platform for India pharma industry through the Business Meet to showcase their strengths and explore business opportunities
- ✓ Created a momentum in the Indian Pharma Industry about the business potential of China and medicinal requirements of China
- ✓ Signing of MoU with CCCMHPIE and setting up of Information Desk at India and China for business promotion of Pharmaceuticals and addressing the issues.
- ✓ The event has provided clarity to India side, to an extent on the regulatory procedures and latest developments in the regulatory regime of China NMPA
- ✓ Reach out to CFDA/CDE and expressed willingness to host training programme of CFDA in India and pursuing with CCCMHPIE
- ✓ Fast track registration ensured for essential/needed drugs, especially in the area of oncology and antibiotics.
- ✓ Expressed interest and invited China side for development of Fermentation products in India under "Make in India"
- ✓ Indian pharma industry could meet more than 100 companies and explore the business avenues with China.
- ✓ Likely business generated is to the extent of say INR 1.5 crores and about 50 trade enquiries were also generated
- ✓ About two/three companies from India side expressed their plans to have Joint Ventures
- ✓ Contract manufacturing is another area of interest, which has evolved during the Business meet.
- ✓ Companies from India and China while appreciating the efforts from Pharmexcil, desired to have such Business Meet every year.

Pharmexcil convey its sincere thanks to Department of Commerce, Embassy of India and Consulate Office at China and CCCMHPIE for their support in making this a successful event.

The Delegation from India is led by Mr.Uday Bhaskar, Director General, Pharmexcil and coordinated by Mr.Murali Krishna, Joint Director, Pharmexcil

Note: The presentations made during the Seminar are enclosed as attachments for ready reference