

Rise of the Chinese API Industry

DR. ROB BRYANT

Brychem (UK), 34, The Drive, Orpington, Kent BR6 9AP, United Kingdom
Tel.: +44 1689 600 501. Fax: +44 1689 897 786.
Email: brychem@compuserve.com

The recent scandal over the corrupt administration of Chinese GMP certification is unlikely to greatly slow down the growth of the Chinese pharmaceutical industry and its increasing role as a leading global exporter of APIs and pharmaceutical intermediates.

In this short article, Dr Rob Bryant of Brychem Business Consulting explores the recent changes in the Asian production of APIs, with the emphasis on China's industry.

Over the past ten years, the Chinese pharmaceutical fine chemical (PFC) industry has developed from being overwhelmingly an exporter of intermediates into a major producer of APIs for the global drug industry. With over 450 APIs now registered for export to the USA,

China is rapidly catching up Italy (with around 525 registrations) and will no doubt challenge India (holding over 1,350 US DMFs) within the next few years.

The top fifteen companies by number of US DMFs in the two countries are compared in Table 1 (data approximate; based upon the data published by the US FDA on active registrations). To many within the global PFC industry, the leading Indian company names are very familiar. This is not the case for the much more fragmented Chinese industry, which continues to change and consolidate. For this reason, Brychem and WiCON International have recently published SNAPI, the first validated database of information on the top Chinese API producers. The intention has been to provide a web-

based resource to assist industry participants outside of China to develop a better understanding of the producers,

ABOUT THE AUTHOR

Dr Bryant runs Brychem, a UK-based fine chemical consultancy, specialising in undertaking bespoke techno-economic and marketing studies.

WiCON International is based in the USA and China and reports on the Chinese pharmaceutical industry.

Further details of the database of Chinese producers of pharmaceutical active ingredients are available at www.brychem.com, www.pharmachinaonline.com and www.snapi.eu.

Table 1
Comparison of top US DMF holders in India and China (Aug 2007)

Top 15 Chinese US DMF holders		Top 15 Indian US DMF holders	
Company	DMFs	Company	DMFs
Zhejiang Hisun Pharmaceutical	35	Aurobindo Pharma	107
Chemwerth Inc	14	Dr Reddys Laboratories	105
Zhejiang Huahai Pharmaceutical	14	CIPLA	94
Tai Heng Industry	7	Matrix Laboratories	89
Tianjin Tianyao Pharmaceuticals	7	Ranbaxy Laboratories	80
Qilu Antibiotics Pharmaceutical	6	Cadila Pharmaceuticals	73
Shandong New Time Pharmaceutical	6	Lupin	55
Chongqing Carelife Pharmaceutical	6	Sun Pharmaceutical Industries	55
Zhejiang Jiuzhou Pharmaceutical	5	Orchid Chemicals and Pharmaceuticals	43
Polymed Therapeutics Inc	5	Hetero Drugs	40
Chongqing Daxin Pharmaceutical	5	Wockhardt	36
Chifeng Arker Pharmaceutical Technology	5	Divi's Laboratories	29
Shanghai Sunve Pharmaceutical	5	IPCA Laboratories	29
Zhejiang Supor Pharmaceuticals	5	Glenmark Pharmaceuticals	28
Axitec	5	Neuland Laboratories	25

Source of data: US FDA website

what they make and what qualifications they have as reliable suppliers. Producing this information has been fascinating and has demonstrated the complexity of the Chinese industry and the rapid changes going on there.

Ten years ago, when the author last took a look at Chinese pharmaceutical industry (see <http://www.brychem.co.uk/docs/RJBScip199709.pdf>), APIs being made in China were dominated by antibiotics. Having first wrested production of the majority of the world's fermentation antibiotics from India, Chinese companies have more recently expanded into all therapeutic areas. Today, there is at least one Chinese producer of the vast majority of the world's top-selling APIs, with a good choice of multiple sources for many APIs (see Table 2).

Table 2
Numbers of Chinese companies offering the world's top selling APIs

API	No. producers
Atorvastatin	8
Simvastatin	15
Omeprazole	5
Fluticasone	1
Amlodipine	11
Paracetamol	15
Lansoprazole	9
Ethinylestradiol	9
Olanzapine	7
Hydrochlorothiazide	1
Salmeterol	1
Pravastatin	7
Amoxicillin	23
Paroxetine	11

The quantity of PFCs being made in China is not in doubt. However, many companies still have some way to go in catching up with the best Indian producers in this industry sector. Some of the factors needing attention include:

- ♦ *Quality and reliability.* Chinese GMP is

Table 3
Numbers of API companies in China's leading provinces

Province	Nos.	Province	Nos.
Jiangsu	144	Beijing	22
Zhejiang	102	Chongqing	19
Shandong	56	Sichuan	16
Hebei	51	Tianjin	16
Shanghai	33	Anhui	14
Guangdong	33	Fujian	9
Hubei	24		

Note: Data pertains to 650 companies reviewed in SNAPI to date

variable and the government inspection system is currently being overhauled to improve registration and regular inspections of API facilities. However, where customers undertake their own regular inspections, Chinese companies are able to offer a world-class service.

- ♦ *Environmental issues.* Many Western customers no longer tolerate poor environmental performance in the way that they have done in the past. The Chinese regulatory authorities have begun to take this issue very seriously and many companies located in sensitive areas (such as the Yangtse river basin) have had to spend considerable sums on abatement projects or be closed.
- ♦ *Process patents.* As Chinese companies offer ever newer APIs, the processes being used are more likely to have intellectual property protection in Western markets. The need to develop non-infringing routes is still often ignored and this can result in expensive problems for customers.
- ♦ *Legal issues.* India's laws are similar to those operating in the majority of Western markets, whereas the lack of transparency of the China legal system is a considerable problem
- ♦ *Language and script.* Like Japan, China has maintained a far greater air of mystery than India as a result of the inability of most Westerners to make head

or tail of locally published information. Example: pronunciation of company names is a trivial, but not unimportant, barrier to Western individuals' attempts to get to grips with the country, its people and its industry.

In many other ways, however, India and China offer similar challenges to Western customers. The proliferation of companies and agents make it hard to sort the better companies from those that would best be avoided. The sheer size of the country and the numbers of producers (many of whom are only making formulations, but happily resell their suppliers' APIs) makes travel time-consuming. Although companies are concentrated in several provinces (see Table 3), this is only of limited help when undertaking a series of visits.

Given these problems, both Western and Indian companies should benefit from a straightforward guide to the Chinese API industry. This is what the new online database, SNAPI (Sino-API), now provides. Indian companies, in particular, need to understand the threats and benefits being offered by China, so that they are able to plot a course for their businesses over the next 2-5 years. For without doubt, the Chinese PFC industry will only be ignored by Indian pharmaceutical industry at its peril.