

China APIs export & import trends

Active pharmaceutical ingredients (API) make up a key sector of the Chinese pharmaceutical industry and play an important role in the world's pharmaceutical industry, with rapid expansion in market volume and an ever increasing influence on the global pharmaceutical industry. The development of the Chinese APIs industry is being achieved under Chinese policies and economic environment, and in the broader context of strong pharmaceutical industry developments and technology advances currently underway in China, and the development of the Chinese and global medical market. The Chinese APIs industry has its own characteristics as regards products, producers and countries trade is performed with.

CHINESE API IMPORTS AND EXPORTS

APIs make up an important part of China's imports and exports in the medical sector. The API exports value takes more than half of all medical goods. In recent years, the annual average rate of increase of the export volume and turnover amount was up by 19 percent and 17 percent respectively. In 2004, China exported 1,506 kiloton of APIs, worth \$4.1 billion. In the first half of 2005, the export volume has already risen to 858 kiloton, turnover being around \$2.95 billion. In 2005, we estimate the export volume of Chinese APIs will reach 1,600 kiloton, with turnover close to \$6 billion.

China is one of the countries with the largest API production and sales, and it also makes up one of the largest areas for API demand. In 2004, API imports accounted for 734.6 kilotons and \$2 billion. In the first half of 2005, API imports already reached 360.4 kilotons and \$1.12 billion. This historical change shows import volume of pharmaceutical raw materials begins to drop after 2003, but value rises steadily. In the past five years, the increase rate has been 27 percent. This demonstrates the increasing demand of China for API with high added

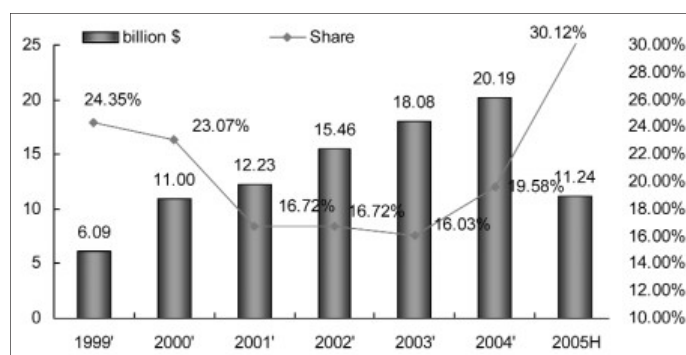


Figure 1. Developments of China API export value, 1999-2005H

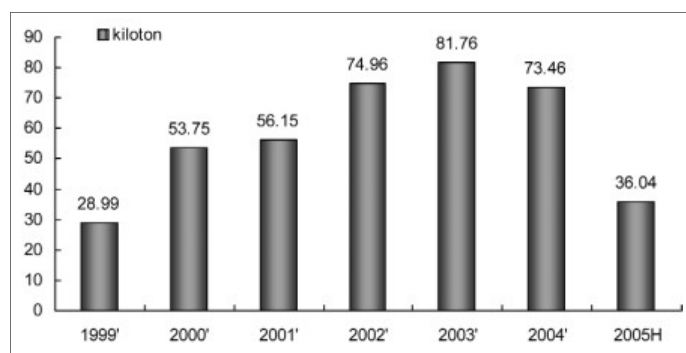


Figure 2. Developments of China APIs export volume, 1999-2005H

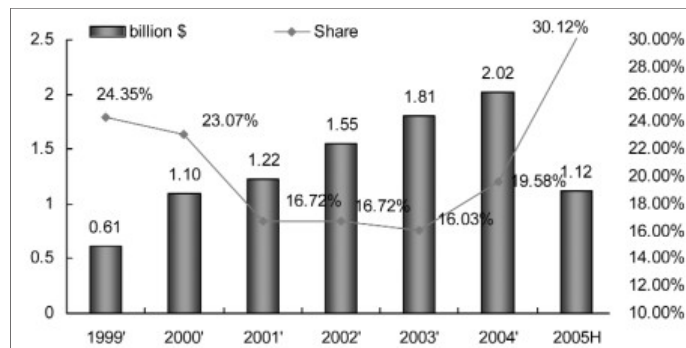


Figure 3. China API import value trends, 1999-2005

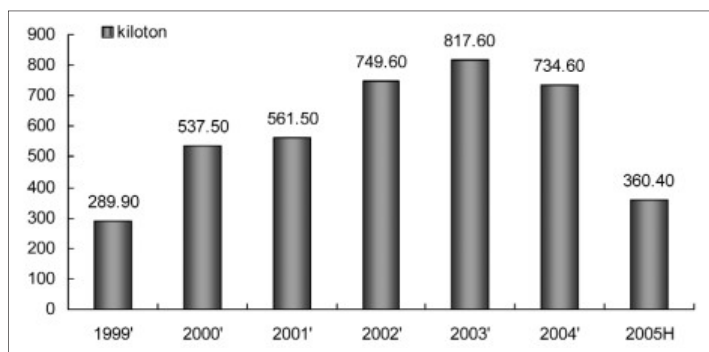


Figure 4. China's API Import volume trends, 1999-2005

value, and that low added value products could be achieved in domestic market of china. The RMB exchange rate promotion will stimulate import demand. Estimates for the second half of 2005 foresee that import volumes will increase compared to the past. Whole year estimates therefore see import amounts growing by 30 percent, with \$2.6 billion in turnover.

Chinese bulk drugs import and the exportation ratio in quantity, Imp: Exp=1:2.4; in amount Imp: Exp=1:2.6.

THE CHINESE BULK DRUGS EXPORT PRODUCT

The Chinese bulk drug productions can be divided into three big groups: chemistry bulk drugs, biochemistry bulk drugs and natural extracts. Products and by-products making up the exports are over 2,000 kinds, most of them being primary product exportation, including antibiotics, vitamins, amino acids, organic acids, alkaloids and so on, and being exported as the category of chemical

products, feed additives or food addition agents. Therefore the main characteristic of export products is low value, large quantity. In 2005, the Q1 and Q2 exports of classified bulk drugs have seen antibiotics, vitamins, organic acids and amino acids as the first four kinds of commodities, accounting for 49.71 percent of total exports. These four API groups include superior Chinese export

order	class	Share in sum
1	antibiotic	18.49%
2	vitamin	14.36%
3	organic acid	8.94%
4	amino acids	7.93%
5	Natural Extracts	4.71%
6	organ extract	4.66%
7	sulfamido	3.93%
8	antipyretic analgesic	3.73%
9	aminoderivative	3.47%
10	hormones	3.28%
11	Erzymes	2.14%
12	quinolones	1.74%
13	alkaloid	1.03%
14	cyclic alcohols	0.85%
15	barbiturates	0.46%
16	blood products	0.20%
17	acyclic alcohols	0.13%
18	insulin	0.10%
19	vaccines	0.05%
20	others	19.81%

Table 1. Export classes of China APIs, 1-6/2005
Table 2. The top 10 China APIs for export value, 1-6/2005

products, like citric acid, Vitamin C, penicillin, paracetamol and Amino acid mixture or intermediate. The Chinese bulk drugs export products constitute the basic chemical industry product.

CHINESE BULK DRUGS EXPORTATION ENTERPRISE

There are over one thousand API producers in china including

pharmaceutical and chemical plants, most of which

also produce official drugs, whereas a number of companies only produce some kinds of bulk drugs. Export organizations include the production enterprise and the trading company. Most

of the enterprises sell their products both in the domestic market and overseas, whereas a few only for export markets. In the first half of 2005, the 3 leading enterprises in exportation volume were Northeast General Pharmaceutical Factory, Anhui BBKA Biochemical Co., and Ltd, Zhejiang Medicine Co.Ltd.

In recent years, there have been a number of Chinese private, small and medium-sized enterprises developing very rapidly. Such companies specialize in producing a few of large volume and low value primary intermediate and feed additive, such as Penicillin, Vitamin, Organic acid and so on. Low costs and higher energy availability have led to these companies becoming strong competitors on the international market. Differently than enterprises producing primary intermediates, some companies are developing drug substances for human treatment. They are working to achieve registration of their products in the European and American markets and cooperating with multinational companies for contract processing.

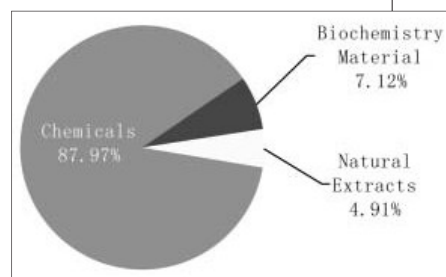


Figure 5. Export structure of China API

ordar	product	Ton	Mil. USD	Share in sum
1	Citric acid	222,066	166.53	5.65%
2	Vitamin C	39,824	149.57	5.07%
3	Vitamin E	13,529	77.66	2.63%
4	penicillinG	6,144	70.85	2.40%
5	Tetracycline	6,096	67.18	2.28%
6	Methionine	324	59.12	2.01%
7	Paracetamol	18,015	58.56	1.99%
8	Heparin	44	32.59	1.11%
9	erythromycin thiocyanate	505	27.43	0.93%
10	Vitamin B ₆	1,616	25.04	0.85%

Table 2. The top 10 China APIs for export value, 1-6/2005



Order	Company	Major Products
1	Northeast General Pharmaceutical Factory	Vitamins
2	Anhui BBKA Biochemical Co.,Ltd	Citric acid
3	Zhejiang Medicine Co.,Ltd	Vitamins
4	Shandong XINHUA Pharm Co.,Ltd	Alkaloid, antipyretic analgesic
5	Zhejiang NHU Company Ltd.	Vitamins
6	Weisheng Pharmaceutical(Shijiazhuang) Co.,Ltd	Vitamin C
7	Pfizer Inc	process materials supplied by clients
8	Jiangsu Jiangshan Pharmaceutical Co.,Ltd	Vitamin C
9	HeBei Welcome Pharmaceutical Co.,Ltd	Vitamin C
10	Henan Hua Xing Medicines Factory	penicillinG

Table 3. 10 China APIs companies with leading export value, 1-6/2005

EXPORT DESTINATION DISTRIBUTION OF CHINESE API

The Chinese bulk drugs are sold all around the world. European Union, US, India and Japan are the biggest trade partners and together they make up 60 percent of China's export markets. China exports bulk drugs such as Vitamins, Amino acid and Sweet taste agent to

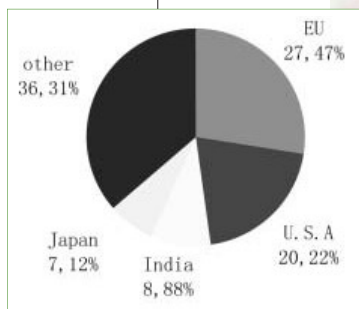


Figure 6. Global distribution of China API export

Order	Country	Share in sum	Major Products
1	U.S.A.	20.22%	Vitamins, amino acids, sweetening agent
2	India	8.88%	Antibiotic, hormones
3	Germany	8.43%	Vitamins, Antibiotic
4	Japan	7.12%	Enzymes, amino acids, activated carbon
5	Netherlands	5.15%	Vitamins, amino acids, Antibiotic
6	Korea	4.15%	Antibiotic, sulfamido, Natural Extracts
7	Belgium	3.61%	amino acids, Vitamins, organic acid
8	Spain	3.19%	Antibiotic, Vitamins, amino acids,
9	Italy	3.07%	Antibiotic, hormones, citric acid
10	U.K.	2.32%	Vitamins, amino acids

Table 4. The top 10 China API export destination, 2005

However, in the past several years, Chinese enterprises irrationally scaled their production, which has destroyed the supply-demand balance, pulled down the product price, and thus impacted on the development of China's API industry. Today, with improved environment protection and energy use, as well as the lower profit

caused by RMB revaluation, the Chinese API industry is experiencing important changes. Some Chinese enterprises are beginning to register their medicinal bulk drugs in developed countries in Europe and America, are improving their product portfolio by adding value to products, applying advanced technology spreading usage in the market, paying attention to patents about to expire, carrying on the contract processing for generic drugs. We expect the Chinese bulk drug industry will further improve its standing in the world market in terms of profits, advanced technology application and generics, without mentioning the already existing advantage of having low cost and large scale production.

CHINA IMPORTS OF BULK DRUGS

There are three kinds of bulk drugs imported by china: first, bulk drugs and intermediates China is importing because domestic demand is not met by Chinese suppliers; second, bulk drugs ordered through joint venture agreements for the production of brand drugs, whose price is different from the general market price; third, a number of products who currently have a price and quality that is superior to domestic products. Among the above-mentioned three kinds of imported bulk drugs, the first covers a variety of products, the second has more value and the third is small both in amount and value. Despite the relative balance of different kinds of imported bulk drugs, Antibiotics and amino acids account for the largest share. Therefore, the industry does have some dependence on advanced antibiotics and purified amino acids.

order	class	Share in sum
1	antibiotic	12.75%
2	amino acids	12.68%
3	aminoderivative	6.96%
4	insulin	5.34%
5	Erzymes	3.85%
6	vitamin	3.33%
7	vaccines	3.16%
8	cyclic alcohols	2.86%
9	acyclic alcohols	2.61%
10	Natural Extracts	2.47%
11	sulfamido	2.39%
12	blood products	1.74%
13	barbiturates	0.97%
14	organic acid	0.84%
15	alkaloid	0.40%
16	organ extract	0.37%
17	hormones	0.28%
18	quinolones	0.25%
19	antipyretic analgesic	0.22%
20	others	36.54%

Table 5. Market of imported APIs, 2005h

Order	Country	Share in sum	Products
1	Japan	17.98%	amino acid,antibiotic, Erzymes
2	U.S.A.	12.77%	Insulin,amino acid, vaccines
3	Korea	10.26%	amino acid,cephalosporinsantibiotic
4	Germany	7.54%	amino acid ,vitamines
5	India	7.49%	Menthol,cephalosporins, Ethambutol
6	France	5.66%	amino acid, insulin, Sorbitol
7	Danmark	4.76%	insulin,enzymes,vitamins
8	Taiwan	4.27%	synthesis side chain
9	Malaysia	2.82%	solvent for drug,adjuvant
10	Belgium	2.81%	vaccines,Methionine

Table 6. The top 10 countries for China imports, 2005h

Order	Country	License	Main Products
1	Japan	115	Microcrystalline cellulose, digestive enzyme, coenzyme q 10
2	Germany	38	Lactose, Microcrystalline cellulose, hydroxyethyl starch
3	India	30	Cephalosporins, ciprofloxacin, dextromethorphan
4	Italy	28	Cephalosporins,nicergoline, antineoplastic
5	U.S.A.	26	Microcrystalline cellulose, clarithromycin, aztreonam
6	Korea	26	Cephalosporins, ovolecithin
7	France	23	Metformin hydrochloride, circulation system
8	Switzerland	18	Diclofenacpotassium, valsartan, sotalolhydrochloride
9	Ireland	14	Fluconazole, idarubicin hydrochloride, doxorubicinhydrochloride
10	U.K.	13	Potassium clavulanate, fluticasone, mupirocin

Table 7. The top 10 countries with SFDA API import license

The countries exporting bulk drugs to China mainly include Japan, US, South Korea, the European Union and India, with the imported products mainly including biochemistry bulk drugs, antibiotics, amino

acids and the medicinal supplementary material with high added value.

IMPORT BULK DRUGS REGISTERED IN CHINA SFDA

By the end of August, 2005, SFDA approved 389 registration applications submitted by 160 companies from 26 countries for bulk drugs and medicinal supplementary material covering 275 kind of generics. Wherein, asahi kasei pharma corporation has the most API import licenses, and the medicinal supplementary material and the cephalosporin have been registered most frequently. Today, the special medicinal

supplementary material has less development in China and some products such as micrite cellulose, lactose still need to be imported.

After China has stepped into WTO, Chinese enterprises have more opportunities to take part in international trade, and the scale of China's API imports has risen accordingly. The import of bulk drugs is no longer restricted to products domestic companies are not able to manufacture. In addition, the increased competitiveness of Chinese

products has opened the Chinese market to the world. In addition, RMB revaluation would stimulate the pharmaceutical industry to import bulk drugs and the imported bulk drugs would help the Chinese API producers to promote their capability and improved product quality.

WU HUIFANG

Orient Health Electronic
Commercial (Beijing) co., Ltd
Fuwaistreet, 7
Xicheng district, Beijing, China