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The Status Quo of the Biotech Industry in Taiwan

(I) Supply & Demand of the Biotech Industry

(1) Current Status of Taiwan's Biotech Industry

Taiwan's biotech industry includes three (3) major sectors: new emerging biotech, pharmaceuticals and medical devices. The status of Taiwan's biotech industry is shown in Table 2. In 2006, the total annual revenue for these industries was approximately \$5.5 billion, which came mostly from the new emerging biotech sector with 268 companies, each with a revenue of about \$4.9 million. The business scope covered genomics, drugs, diagnostics, agricultural biotech, environmental biotech, protein drugs, contract research organizations, biochips and bioinformatics. In 2006, the domestic pharmaceutical industry generated around US\$2 billion in revenues, with 368 companies, and each with an average of \$5.5 million in revenue. Among those companies, there are currently 154 local pharmaceutical and 71 traditional Chinese herbal medicine companies, all of which are fully compliant with cGMP and GMP, respectively. According to the data provided by the Bureau of National Health Insurance, the total domestic pharmaceutical market is around US\$3.70 billion.

Table 2. Biotech Industry in Taiwan

Industry	2002		2003		2004		2005		2006	
	Revenue	Export value	Revenue	Export value	Revenue	Export value	Revenue	Export value	Revenue	Export value
New emerging Biotechnology	7.4	2.4	8.7	3.3	9.7	4.4	12.4	4.9	14	5.6
Pharmaceutical	15.9	0.6	18.1	1.3	17.2	1.1	20.1	3.7	21.2	4.4
Medical devices	9.4	6.5	11.9	8.5	15.0	10.6	19	8.7	22.4	9.4

Unit: US\$ billion

Source: Biotechnology and Pharmaceutical Industries Program Office, MOEA, 2007

Taiwan's new emerging biotech industry covers seven areas, including biomedicine, agricultural biotech, diagnostics, environmental biotech, functional foods, and CROs. The biomedical sector is the largest, taking up 28% of the entire biotech industry. The functional food sector represents 21%, while agricultural biotech and CROs account for 14%. The other areas are diagnostics and environmental biotech.

The supply and demand of Taiwan's new emerging biotech and pharmaceutical industry (2005/2006) is shown in Tables 3 and 4, respectively.

Table 3. The Supply and Demand of Taiwan's New Emerging Biotech Industry

Unit: NT\$ million

Year	Revenue (A)	Export value (B)	Import value (C)	Domestic market (D=A-B+C)	Market growth rate (E)	Export ratio (F=B/A)	Import Ratio (G=C/D)	Domestic Supply Ratio (1-G)
2005	386	153	161	394	100.0%	39.6%	40.9%	59.1%
2006	434	176	187	445	112.9%	40.6%	42.0%	58.0%

Source: Biotechnology and Pharmaceutical Industries Program Office, MOEA (2007)

Taiwan's pharmaceutical industry is classified into three areas – pharmaceutical preparations (55.8%), pharmaceutical fine chemicals (35.8%), and Chinese herbal medicines (8.4%). The output value of the pharmaceutical preparation sector is the highest. In 2006, Taiwan's pharmaceutical industry generated \$2.03 billion, with 368 companies and about 12,224 people in this sector. It reached \$4.2 million in export value and 1.61 million in import value.

Table 4. The Supply and Demand of Taiwan's Pharmaceutical Industry

Unit: NT\$ million

Year	Revenue (A)	Export value (B)	Import value (C)	Domestic market (D=A-B+C)	Market growth rate (E)	Export ratio (F=B/A)	Import Ratio (G=C/D)	Domestic Supply Ratio (1-G)
2005	624	115	577	1,086	100.0%	18.4%	53.1%	46.9%
2006	660	137	698	1,221	112.4%	20.8%	57.2%	42.8%

Source: Pharmaceutical Industry Technology Development Center (2007)

The medical devices industry returned \$2.14 billion, coming from 500 companies, with an average revenue of \$4.2 million each. The size of the biotech industry workforce is about 37,114, of which 8,570 are in the new emerging biotech industry, 12,224 in the pharmaceutical industry, and 16,350 in the medical device industry. Over US\$3.5 billion worth of investments have been funneled into the biotech industry since 2001, with an investment amount exceeding US\$720 million in 2006.

(II) Gap in Industry Supply Chain, Investment Niche and Prospective Foreign Investors

Taiwan's biotech industry supply chain is showing a gradual shift from research to manufacturing; however, it is still considered weak compared to others. Most of the biotech companies are small- to- medium sized in capital and are in the technology/product development stage, producing healthy foods and generic drugs, not high-profit protein drugs. Taiwan's bioindustry needs to develop strategic alliances with international biotech companies as well as obtain the support of foreign investors in order to boost its research capabilities and improve its facilities. By combining the expertise and experience of foreign biopharmaceutical companies with Taiwan's R&D

ability, it will increase the opportunities as well as success of Taiwan's domestic enterprises.

Table 4. Taiwan's biotech industry supply chain

Basic research	Application	New drug development	Pre-clinical trials	Clinical trials I,II	Clinical trials III,IV	Manufacture	Sales
Upstream	Middlestream				Downstream		
Academic	Non-profit R&D organization	New drug development company	CRO BA/BE	Clinical trail center - CRO		Manufacturer	Sales
Academia Sinica NTU NYMU NCKU CGU NTHU NCTU NCHU	NHRI DCB ITRI PITDC ATI FIRDI ARES	UBI-asia. Medigen. Vitagenomics. TaiGen Biotechnology. Glyconex. Mycenax. AbGenomics. Panion & BF Biotech. SunTen. CytoPharm. Microbio. Taiwan Liposome. Hedonist. ScinoPharm. Synmosa Biopharma. TTY Biopharm	DCB. PPC. VCRO. MDS. Genovate. Mithra. TTMC. QPS. Genesis Biotech. Level Biotechnology.	NTNU. Veterans General Hospital. NCKU. Taipei Municipal Wan-Fang Hospital Glyconex. ScinoPharm. UBI-asia. PPC. QPS. PAREXEL		DCB UBI-asia. Glyconex. YSP Sinphar Taiwan Biotech Co. TTY CCSB Genovate STANDARD GENTLE Pharmaceutical Co. TaFong Pharmaceutical Co.	TAH-AN Chemical & Pharmaceutical Co. CCSB Chin Teng Pharmacy Industrial CO. Hedonist. Orient Europharma Co. YSP Sinphar Taiwan Biotech Co. Genovate. Medigen. TTY

Source: Biotechnology and Pharmaceutical Industries Program Office, MOEA (2008)

Most biomedical drugs are still in the research or clinical trial period. However, through technical transfer and cooperation, there are currently licensed products sold in the American and European markets. Taiwan's main research and development power is focused on non-profit R&D organizations, particularly the Academia Sinica, Development Center for Biotechnology (DCB), Industrial Technology Research Institute, National Health Research Institutes, and Animal Technology Institute Taiwan, which are active in biomedical research.

Most pharmaceutical preparations companies produce generic drugs. Main products include cardiovascular drugs, gastrointestinal drugs, diabetes drugs, antibiotics, ibuprofen, nutritional supplements, suspension, external medicines and eyewashes, injections. Domestic pharmaceutical companies manufacture generic drugs with the expiration dates of patents, and paid them with low prices. In contrast, even if the patent is expired, when foreign companies manufacture generic drugs, they can still gain higher profits because of high-level competitive research. The Industrial Development Bureau (IDB) assigned the Medical and Pharmaceutical Industry Technology and Development Center to promote and organize pharmaceutical industry export strategic alignment to assist domestic companies, which includes US, PIC/S and Japan alignments. By connecting the island's pharmaceutical companies with union's manufacturers and agencies, the industry could gain more opportunities to export products to the global markets.

Taiwan's Chinese herbal medicine mainly focuses on the domestic market and it is steadily increasing in export value. In 2006, the annual revenue for Chinese herbal medicines in Taiwan was approximately \$1.74 million, and the island's demand was approximately \$3.43 million. From 2001 to 2005, Taiwan's government promoted "The 5-year Industrial Technology Development Program for Chinese Herbal Medicine Industry", which aimed to reduce and solve the problems of developing Chinese medicines, such as R&D, herbal resources and quality control, legislation, clinical trial environment, and investment. In 2005, drafts for the botanical drug product IND and NDA applications were announced. The Committee on Chinese Medicine and Pharmacy also set 13 Chinese Medicine Clinical Trial Centers that published Taiwan's Chinese Medicine Pharmacopoeia, enforced GMP in traditional Chinese medicine factories, established Chinese medical centers and examination standards for the purpose of making great improvements in the environment, intellectual patent protection, clinical trials,

quality control, research environment and professionals. Without any doubt, these results enable domestic companies to devote more efforts into the research and development of Chinese herbal medicines. Up until 2005, there were 5 cases that already obtained permission in foreign countries and 26 cases that already applied for clinical trials. For instance, NatureWise Biotech & Medicals Corp. is a successful company that developed the new drug, “LipoCol Forte”.

The development of medical devices is an emerging and important strategic industry promoted by the Taiwanese government. Short- mid- and long-term plans focusing on potential medical devices have been mapped out. Short-term plans will focus on clinical trials/bio-equivalence, clinical animal experiments, biotech-related contract manufacturing, bioinformatics, biochips, and drug development. The mid- to long-term plans will focus on gene diagnostics and gene therapy, stem cell technologies, and artificial tissue and organs. It is hoped that the development of these key technologies and products will support the successful expansion of the island's medical device production sector.

As for potential foreign companies, BD (Becton, Dickinson and Company) is a leading global medical technology company that is focused on new product research and development. BD established its Taiwan branch in 1987, providing omnibus research and diagnostic tools for the medical industry. BD has three main subsidiaries, namely BD Medical, BD Diagnostics, and BD Biosciences. It serves healthcare institutions, life science researchers, clinical laboratories, the industry, and the general public.

Baxter International Inc. was founded in 1930, with its Taiwan branch established in 1981. Baxter manufactures and sells more than 120,000 medical products, and provides products and services for home healthcare. After developing the first hemodialysis machine in the 1950s, Baxter became

the leading company in dialysis. Baxter introduces continuous ambulatory peritoneal dialysis (CAPD) as a practical alternative to hemodialysis in 1979. Over thousands of patients now have healthier lives through Baxter's hemodialysis service.

Dada Behring is a global clinical diagnostic company that provides clinical products, health system and health care services, as well as improves patients' quality of life. It provides chemical tests, immunity tests, blood tests, and diagnosis of microbial and infectious diseases.

GE Health is GE's medical group, which comprises GE Healthcare Technology and GE Healthcare Bioscience. It has annual sales of US\$ 14 billion. GE Health is a global leader in medical imaging and information technologies, medical diagnostics, patient monitoring systems, disease research, drug discovery and manufacturing.

ARC Pharmaceuticals Inc. is a Canadian bio-company that focuses on the research and development of novel therapeutic devices as well as medical products for the prevention and treatment of surgical adhesions.

Cochlear, Ltd. was founded in 1982 as a major producer of nucleus products and accessories which convert surrounding sounds into digital signals to stimulate the hearing nerve within the cochlea. After many years of development and improvement, Cochlear, Ltd. has become a world leader in hearing solutions. Over thousands of Taiwanese patients regain their hearing by using Cochlear's products.

(III) Major Suppliers in Taiwan

Taiwan's new emerging biotech industry covers seven areas, which includes biomedicine, agricultural biotech, diagnostics, environmental biotech, functional foods, and CROs. In 2006, the Industrial Development

Bureau (IDB) organized the functional foods industry promotion office, which is responsible for the analysis of potential key techniques and material standards, the establishment of functional food production principles and quality appraisal techniques, and the development of high value-added products which increase the technological standard of the functional food industry. In addition, the Department of Health (DOH) is negotiating to improve the import regulations for traditional Chinese herbal medicines in order to provide benefit to the country's food industry.

CRO has the fastest rate of development in the biotech industry. Through the "Biomedical Technology Island Program", the Taiwanese government has developed a clinical trial research system to encourage the CRO industry to engage in clinical trial research. Domestic biotech companies also joined to build and test Taiwan's clinical trial environment in order to make it more industrialized. The most important CRO and CMO companies include DCB, APEX, MDS Pharma Services-Taiwan, Mithra Bioindustry Co., and Protech Pharmaservice Corporation. DCB's cGMP biopharmaceutical pilot plant facilities, which obtained FDA Type VDMP registration permission, also helped to achieve more opportunities in international CMO.

The major Taiwan biotech companies are listed in Table 5, which are listed according to the size of the registered capital of the company.

Table 5. The Top 10 Biotech Companies in Taiwan

Company	Date Established	Capital (US\$ million)	Business Scope
ScinoPharm Taiwan	1997	170.28	Active pharmaceutical ingredients
China Chemical & Pharmaceutical (P)	1953	90.91	Generic drugs
Yung Shin Pharm.	1965	77.40	Generics, new drug development

Industry (P)			
VitaGenomics	2001	73.92	Genomic drugs
Taigen Biotechnology	2001	54.19	New drug development
Standard Chem. & Pharm. (P)	1967	46.44	Generic drugs
Taiwan Biotech	1962	37.15	Active pharmaceutical ingredients
Cytopharm	2003	32.51	Interferon
Taiwan Flower Biotech	1998	30.96	Flower production
Sinphar Pharmaceutical (P)	1977	30.03	Chinese herbal medicines, Nutraceuticals

Note: “(P)” refers to Public Company.