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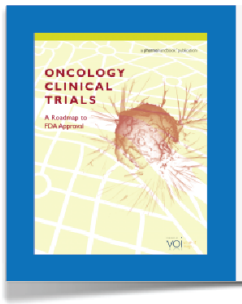

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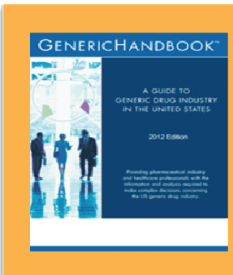

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A Guide to the International Pharmaceutical Industry

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Contents

NOTES

Overview

The content of **pharma***handbook*® consists of research on published sources and original analysis and interpretation. For the portion from secondary sources, publicly available information from governments, international organizations, academic research, trade associations, press reports and corporate websites was used. In all cases except matters of "general knowledge" (e.g. the overall structure of a healthcare system), the source is credited.

Wherever possible, we have relied on authoritative sources and preferred the most authoritative source when several were available. In some cases, however, it was necessary to fill in gaps by using bits and pieces of information from multiple sources to assemble the most accurate representation possible. In these cases, VOI Consulting, Inc. is listed as the source and, if several assumptions were used, the methodology by which we arrived at the figures is included as well. Aside from these instances, the original analysis and interpretation consists of evaluation of market trends, political environments and forecasts of likely outcomes.

Calculation of GDP and National Healthcare Spending

GDP figures have been calculated in two ways. The first, Purchasing Power Parity, takes relative living standards and domestic price levels into consideration and provides GDP in "international dollars" which reflect buying power relative to the United States. A problem arises with this method when trying to compare actual pharmaceutical consumption against PPP-calculated figures. Therefore, we have also included GDP figures based on average exchange rates. In most cases, a person interested in doing business in a foreign country would find the exchange rate values more useful.

Market Calculations

Unless otherwise noted, the total size of the pharmaceutical market in each country represents the ex-manufacturer value of drug sales in retail, hospital and other channels. Information available via IMS press releases was used for most developed markets. In other cases, industry associations, government publications and other sources were used. While we have made all efforts to ensure uniformity in this data, the need to rely on different sources inevitably creates some difficulties in cross-market comparisons. For example, some sources include OTC products, others used retail market value, in other cases, the methodology was not transparent. These cases require analysis and interpretation. We estimate that the results of this process are accurate to within 5-10%.

Time Considerations

pharma*handbook*® contains the most current information available as of its publication date. However, readers should be aware that changes can occur quickly and may want to contact us or check additional sources on matters of substantial importance.

Monetary Figures, Exchange Rates & Growth Calculations

As a rule, monetary figures in the publication are reported in both local currency and in U.S. dollars. This serves two purposes:

U.S. dollar figures provide a measure of value that is widely understood on an international basis and allow for of comparison of relative value across different markets.

Local currency figures provide a measure of organic dynamics in the market. In other words, because of fluctuations in currency values, the use of U.S. dollars (or any external currency) can lead to a distorted picture of market activity.

For example, if a country's pharmaceutical sales increased by 5% in local currency terms but the currency appreciated 10% in value against the U.S. dollar, then the U.S.-dollar denominated growth rate would be 15.5%. Use of local currency helps avoid this distortion and these are the figures that should be used to judge changes in actual demand.

When U.S. dollar figures are cited for periods in the past, they are based on the average annual exchange rate during the relevant year. When dollar figures are cited in forecasts for future periods, they are based on the last full calendar year in which exchange rate data is available (in this case 2012). As a result of the use of a constant exchange rate for future periods, the discrepancy between growth in local and U.S. currency does not apply to forecasts.

In addition to the U.S., the Australian, Canadian, New Zealand and Taiwanese currencies are also dollars. A dollar sign by itself indicates the U.S. dollar whereas A$, C$, etc. indicate figures in the local currency. Unless the figure is preceded by A$, C$, etc. it should be read as a U.S. dollar.

Finally, note that several countries have revalued their currencies in recent years. These countries and revaluation dates are Romania (July 2005), Turkey (January 2005), and Venezuela (January 2008). Implications of the revalued currencies are discussed in the relevant country chapters.

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TAIWAN 2013

Taiwan

Figure 1 - Population and Economic Statistics						TAIWAN
Category	Measurement	2009	2010	2011	2012F	2013F
Population	Population (000)	23,223	23,227	23,231	23,235	23,239
	Rank (All Countries)	51	51	51	51	51
GDP	Current (US$ Mil)	400,206	377,450	466,800	NA	NA
	Rank (All Countries)	NA	NA	NA	NA	NA
	PPP (US$ Mil)	770,300	852,800	887,300	NA	NA
	Rank (All Countries)	NA	NA	NA	NA	NA
Per Capita GDP	Current (US$ Mil)	17,233	16,250	20,094	NA	NA
	Rank (All Countries)	0	0	0	NA	NA
	Purchasing Power Parity	33,170	36,716	38,195	NA	NA
	Rank (All Countries)	0	0	0	NA	NA
Exchange Rate	Local to US$ (Yearly Avg)	0.03030	0.03030	0.03390	0.0336	NA

Figure 1 - Population and Economic Statistics

Figure 2 – General Healthcare Statistics			TAIWAN
Measurement	Figure	Source	Year
Total Healthcare Spending (US$ Mil)	24,534	Calculated	2010
Per Capita Health Spending (US$ Mil)	1,056	Calculated	2010
Total Healthcare Spending (PPP)	55,432	Calculated	2010
Health Spending as Percent GDP (Exchange Rate)	6.50%	DOH	2010
Public Sources as Percent Total Health Spending	62.45%	DOH	2010
Private Sources as Percent Total Health Spending	37.55%	DOH	2010
External Sources as Percent Total Health Spending	0.00%	DOH	2010
Social Security Spending as Percent Total Health Spending	52.00%	DOH	2010
Out-of-Pocket Spending as Percent Total Health Spending	36.43%	DOH	2010
Percent Population Fully Insured	99.40%	DOH	2010
Percent Population Publicly Insured	99.40%	DOH	2010
Number of Pharmacies	5,150	DOH	2012
Number of Physicians	40,002	DOH	2011
Number of Hospitals	477	DOH	2012
Number of Acute Care Hospital Beds	128,932	DOH	2012

Figure 2 – General Healthcare Statistics

Taiwan

Healthcare System

Taiwan spent approximately 6.5% of GDP on health services in 2010[1] whereas the average for developed countries is 9.5%.[2] A major reason for this is that administration costs are extremely low at only 2.2% of total health expenditures.[3] Heavy reliance on information technology, including smart cards that allow for disease monitoring, fraud detection and a reduced level of avoidable complications, is cited as a major contributor to the system's efficiency.[4]

Universal healthcare was launched in March 1995 with the creation of the National Health Insurance (NHI). Prior to implementation, 59% of the population had health insurance. The system enrolled 92% of Taiwanese within the first nine months and, as of September 2010, 99.4% of the population was covered.[5] (Although enrollment is compulsory, a portion of the rural and expatriate communities have not signed up). NHI funding is primarily derived from levies on gross income, the rate of which has been raised from 4.25% at inception to 4.55% in 2002 and 5.17% in 2010.[6]

A "second generation" NHI funding system (2G NHI) is scheduled to come into effect in the near-term. Its primary difference is that while first generation contributions were based entirely on monthly salary income, the second generation will expand this to include earnings from interest, dividends, part-time jobs, rentals, and bonuses all of which will be subject to a taxation and a 2% supplementary premium will be levied on employers.[7] As an offsetting measure, the premium on salary income was expected to fall from 5.17% to 4.91%, however, current expectations are that the rate will be set at 5.00%.[8] It should be noted that the system was originally intended to take effect in mid-2012 but was delayed until the start of 2013; although the government has announced firm plans to follow this schedule, there appear to be numerous outstanding issues that require resolution.

NHI offers comprehensive coverage, including Western and traditional Chinese Medicine, dental care, pharmaceuticals and home nurse care. Outpatient services are subject to copayments ranging from US$ 1.70 for visits to clinics to US$ 12 for visits to academic health centers. The poor, veterans, rural residents, children

1 "2010 National Health Expenditures Abstract." Department of Health Jan 17 2012
2 Using OECD membership as a proxy for developed countries.
3 "2010 National Health Expenditures Abstract." Department of Health Jan 17 2012
4 "Checking up on Taiwan healthcare: Market challenges and opportunities." PwC Newsletter Jun 2012
5 "Taiwan Market Overview." IMS Taiwan 2012
6 Sources: Lessons From Taiwan's Universal National Health Insurance: A Conversation With Taiwan's Health Minister Ching-Chuan Yeh." Health Affairs Jul-Aug 2009; "Foundation criticizes health care reform." The China Post Sep 13 2012
7 "Government Delays New Health Insurance Programme in Taiwan." IHS Global Insight Daily Analysis Apr 4 2012
8 "Foundation criticizes health care reform." The China Post Sep 13 2012

under three and sufferers of some chronic diseases are exempt from copayments. Hospital visits are subject to coinsurance contributions ranging from 10% to 30% depending on the length of stay, up to US$ 1,050 per stay or US$ 1,750 cumulative during a calendar year.[9] (See Payment & Reimbursement section for drug copayment policies). Widespread availability, high quality and low out-of-pocket costs result in high approval ratings among beneficiaries: satisfaction levels have approached 90% in recent years.[10]

Figure 3 below shows sources and flows for healthcare in 2010. Note that these figures reflect the amounts spent on personal healthcare services; administration costs, public health expenditures and the like are not included. As indicated, government, businesses, and households contributed roughly similar amounts into the NHI fund but the largest single amount (42% of personal healthcare total) was paid by households on an out-of-pocket basis in the form of copayments and non-covered expenses.

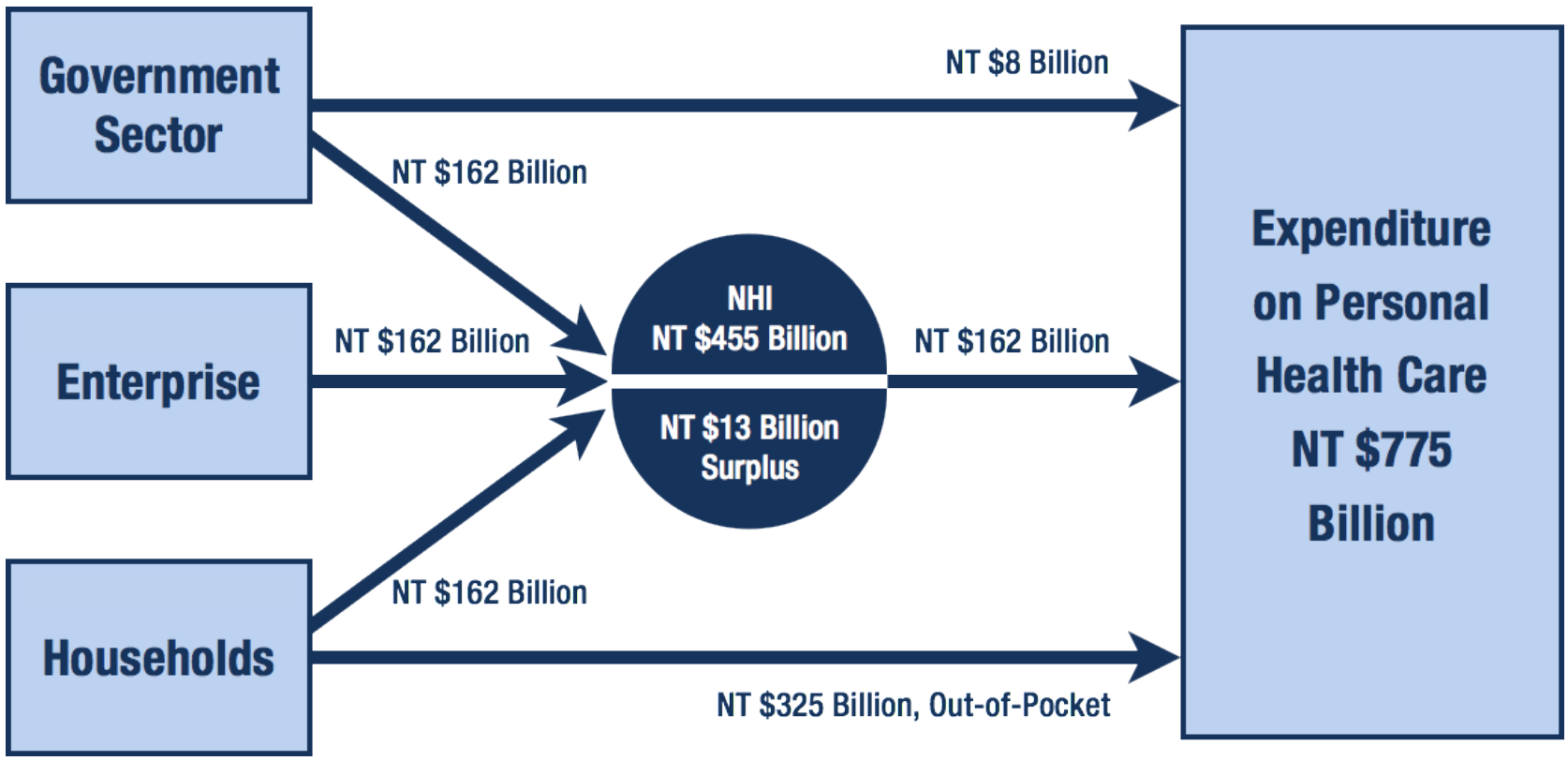

Figure 3 - Funding Flows for Personal Healthcare 2010[11]

In Taiwan, as in most of East Asia, hospitals play a major role in the delivery of outpatient as well as inpatient care. Per Figure 4, hospital outpatient care accounted for 22.6% of total 2010 health spending whereas all types of clinics accounted for a slightly higher, 23.1%. However, the clinic figure also includes dental care and Traditional Chinese Medicine (TCM); looking only at western medicine clinics in comparison to hospital-based outpatient services shows that the delivery of ambulatory allopathic medicine is roughly twice as likely to take place in a hospital rather than clinic environment.

9 "Medical Services: Copayments." Bureau of National Health Insurance 2012
10 "2010 National Health Expenditures Abstract." Department of Health Jan 17 2012
11 "2010 National Health Expenditures Abstract." Department of Health Jan 17 2012

Figure 4 – Health Spending by Destination 2010			TAIWAN
Sector	NT$ Bil	US$ Bil	% of Total
General Administration	20	0.63	2.20%
Public Health	37	1.17	4.20%
Hospitals	373	11.82	41.90%
Outpatient	201	6.37	22.60%
Inpatient	172	5.45	19.30%
Clinics	206	6.53	23.10%
Western Med	108	3.42	12.10%
Dental Med	78	2.47	8.80%
Chinese Med	20	0.63	2.20%
Specialty Institution	59	1.87	6.60%
Other	196	6.21	22.00%
Total	891	28.24	100.00%

Figure 4 – Health Spending by Destination 2010[12]

NHI beneficiaries have freedom of choice in selecting healthcare providers.[13] Figure 5 shows the mix of health institutions in Taiwan. As indicated, the hospital sector includes a small number of high volume academic centers as well as a substantially larger number of intermediate size metropolitan hospitals and smaller community hospitals. In addition to Western medicine facilities, there are a significant number of TCM clinics and hospitals. Note that 84% of all hospitals and 98% of outpatient clinics are privately owned.[14] At the start of 2010, 92.1% of all health institutions in the country had contracts with the NHI.[15]

Figure 5 - Taiwan's Health Infrastructure 2012		TAIWAN
Type	Number of Institutions	
Academic Medical Centers	22	
Metropolitan Hospitals	83	
Local Community Hospitals	372	
Chinese Med. Hospitals	13	
Western Med. Clinics	9,929	
Chinese Med. Clinics	3,159	
Pharmacies	5,156	

Figure 5 - Taiwan's Health Infrastructure 2012[16]

On average, hospital stays lasted 10.3 days and there were 15.2 outpatient visits per person in 2010. In both cases, these figures increased over the past ten years, which is contrary to the developed world trend. Aside from an aging population (the percentage of people over 65 is expected to increase from 10.7% in 2010 to 22.5% in 2028), other factors contributing to overutilization include cultural reasons, a lack of a primary care gate-keeping system, and poorly-aligned financial incentives.[17]

At the end of 2011, there were approximately 250,000 medical professionals working in Taiwan. This included

12 "2010 National Health Expenditures Abstract." Department of Health Jan 17 2012
13 "Inexpensive Medicine or Invisible Problems?" Taiwan Today May 1 2012
14 "Statistics Hospital and Clinic statistics 2011 Hospitals and Clinics: Table 1 Number of Hospitals and Clinics by Ownership, 1997-2011." Department of Health Aug 16 2012
15 "National Health Insurance in Taiwan: 2011 Annual Report." Bureau of National Health Insurance 2012
16 "National Health Insurance in Taiwan: 2011 Annual Report." Bureau of National Health Insurance 2012
17 "Checking up on Taiwan healthcare: Market challenges and opportunities." PwC Newsletter Jun 2012

roughly 40,000 physicians and 5,600 licensed practitioners of Chinese medicine.[18]

A diagnosis related group (DRG) payment system for hospital reimbursement has been under consideration for several years. After multiple delays and adaptation to local health needs, "Tw-DRG" reimbursement was implemented for 164 DRGs in January 2010. The system is being phased in over five years and will eventually cover 1,029 classifications.[19]

At present, however, the majority of hospital and essentially all non-hospital services are paid on a fee-for-service basis. Fees are set at a low level, thereby requiring high patient volumes in order to cover expenses. Also, as will be discussed in later sections, low fees combined with the profits earned through the sale of prescription drugs create a number of problems in the pharmaceutical market.

Taiwan

Pharmaceutical Market

Figure 6A - Pharmaceutical Market Snapshot					TAIWAN
Year	Amount in US$ (Mil)	US$-Based Growth Rate	Amount in Local Currency (Mil)	Local Currency Growth Rate	Source
2004	3,224	NA	107,853	NA	VOI / IMS / BMI
2005	3,389	5.10%	109,040	1.10%	VOI / IMS / BMI
2006	3,467	2.30%	112,856	3.50%	VOI / IMS / BMI
2007	3,487	0.60%	114,662	1.60%	VOI / IMS / BMI
2008	3,762	7.90%	118,661	3.50%	VOI / IMS / BMI
2009	3,836	2.00%	126,616	6.70%	VOI / IMS / BMI
2010	4,116	7.30%	129,831	2.50%	VOI / IMS / BMI
2011	4,614	12.10%	136,100	4.80%	VOI / IMS / BMI
2012F	4,687	1.60%	139,503	2.50%	VOI
2013F	4,898	4.50%	145,780	4.50%	VOI

Figure 6A - Pharmaceutical Market Snapshot

Sales figures are at Ex-Manufacturer Prices and include both Ethical and OTC sales. 2012 Exchange rates based on Jan-Jun data; 2013 uses 2012 exchange rates

18 Statistics Hospital and Clinic statistics 2011 I Hospitals and Clinics: Table 88 Number of Registered Medical Personnel in Hospitals, Clinics and Other Medical Care Institutions, by Locality, 2011." Department of Health Aug 16 2012

19 "National Health Insurance in Taiwan: 2011 Annual Report." Bureau of National Health Insurance 2012

Figure 6B - Pharmaceutical Market Snapshot		TAIWAN
Pharma Market Profile	**Data**	**Source**
2011 Per Capita Consumption US$	198.60	Calculated
2011 Pharma as % GDP	0.99%	Calculated
2010 Pharma as % Healthcare Total (Ex-Mfr)	16.80%	Calculated
As % 2011 Global Total Pharma	0.50%	Calculated / IMS
Public Payment as % Total Sales	77%	VOI / OECD
Private Payment as % Total Sales	23%	VOI / OECD
Pharmacies as % of Total Sales	14%	IMS
Clinics as % of Total Sales	8%	IMS
Hospital as % of Total Sales	78%	IMS
Branded as % Total Volume (Rx Only)	57.00%	See Text
Branded as % Total Sales Value (Rx Only)	70.50%	VOI / BMI
Generics as % Total Volume (Rx Only)	43.00%	See Text
Generics as % Total Sales Value (Rx Only)	29.50%	VOI / BMI

Figure 6B - Pharmaceutical Market Snapshot

Figures above based on values at average annual exchange rates.

Taiwan

Market Profile and Structure

Taiwan's pharmaceutical market features several structural characteristics that create a misaligned incentive structure for health providers that, in turn, lead to overprescribing and high costs. First, hospitals are the dominant delivery channel for all forms of health services, including pharmaceuticals and ambulatory care. Second, physicians or the institutions where they are employed commonly dispense the products they prescribe. Finally, healthcare providers are able to negotiate prices with drug manufacturers. These acquisition prices are significantly below the amounts that dispensaries receive in reimbursements from BNHI. This is particularly true of hospitals, which are able to use their dominant market presence to extract favorable terms from drug companies. Current reports suggest that average margins on drug sales are 25 to 40% with larger hospitals earning higher margins.[20] Although Article 49 of the National Health Insurance Law requires that reimbursement reflect actual transaction costs, the gap between acquisition costs and reimbursement rates (sometimes called the "black hole" in Taiwan) continues to provide a significant source of revenue for providers.[21] At present, the government appears to have largely abandoned the effort to separate prescribing and dispensing functions. [22]

The above factors create a situation where physicians and healthcare institutions have both the incentive and ability to over-prescribe prescription drugs. In fact, empirical research has shown that in Taiwanese clinics where the prescribing-based profit motive was removed the total value of outpatient prescriptions fell by 30% without observable adverse impact on patient health.[23]

As a means of reducing the gap between acquisition costs and reimbursement rates, BNHI periodically enacts price cuts known as "Price Volume Surveys" (PVS), the most recent of which occurred in December 2011. PVS procedures are discussed in more detail under the Pricing section but, in brief, the aim is to claw back a portion of the gap between acquisition costs and NHI reimbursement levels. As is also discussed in more detail under the Pricing

20 "Inexpensive Medicine or Invisible Problems?" Taiwan Today May 1 2012

21 "Getting out of the black hole." American Chamber of Commerce in Taiwan Sep 2012

22 "Special 301 Submission." PhRMA Feb 20 2011

23 "Prescribing Institutions: Explaining the Evolution of Physician Dispensing." Asia Health Policy Program working paper #24, Walter H. Shorenstein Asia-Pacific Research Center, Stanford University Oct 28 2011

section, pharmaceutical manufacturers are supporting a proposal that would replace the Price Volume Surveys with a Drug Expenditure Target (DET) as it is believed that the latter will provide greater predictably for the market.[24]

At 78% of total, hospitals are the dominant channel for pharmaceutical sales; retail pharmacies hold the next largest share with 14% while clinics make up the remainder at 8%.[25] To comply with previous SPD reforms while also retaining the income associated with dispensing, most outpatient clinics created "gateway" pharmacies which are owned by and located next to the clinic. Roughly 80% of prescriptions filled by pharmacies come from these gateway facilities.[26]

Multinational companies capture the majority of sales value (77%) but local companies have the highest share by volume (approximately two-thirds).[27]

Taiwan

Market Performance and Forecasts

Taiwan is the 26th largest pharmaceutical market in the world.[28] At consumer prices, medicines consistently account for an average of 25% of total health spending, substantially higher than the OECD average of 16%.[29]

At ex-manufacturer levels, the Taiwanese pharmaceutical market totaled US$ 4.61 billion in 2011, which translates to US$ 199 per person.[30] Relative to 2010, this represents 4.8% growth in local currency and 12.1% growth in U.S. dollars.

Reimbursement cuts that came into effect in December 2011 are likely to slow the local currency growth rate to 2.5% in 2012, leading to sales of NT$ 139.5 billion (or US$ 4.69 billion at first-half 2012 exchange rates). There is some uncertainty regarding timing and scope of DET implementation and whether the government will abandon the PVS price cuts if DET is fully adopted. We assume that DET will be adopted and no additional PVS rounds will be implemented at least through the end of 2013. We also assume that the process of awarding premium prices for innovative drugs will accelerate slightly from its current very moderate pace, thereby resulting in slightly higher average prices for new medicines. With these factors in mind, we are forecasting a 4.5% growth rate in 2013.

Taiwan

Regulatory

Note that an administrative arm of the central government known as the "Executive Yuan" handles most domestic government responsibilities. Taiwan's key regulatory agencies, all of which are part of the Executive Yuan, are:

Department of Health (DOH): Responsible for management and oversight of all aspects of the country's healthcare system.

Taiwan Food and Drug Administration (TFDA): On January 1, 2010, this agency assumed unified authority for food and drug safety in Taiwan. It replaced the Bureau of Pharmaceutical Affairs (BOPA) as the country's primary drug regulatory body. This change is discussed in more detail later in this section.

Center for Drug Evaluation (CDE): A government-funded but semi-independent center with advisory power to review and facilitate drug approvals for BOPA. CDE was founded by DOH in July 1998 with the mission of upgrading the

24 "Taiwan White Paper: 2012." American Chamber of Commerce in Taipei Jun 5 2012

25 "Role of Generics in the Taiwanese Health Care System, Regulations and Market Competition Issues." Workshop on Taiwan-Germany Generic Related Legal Issues, June 3, 2011 and "Taiwan market overview." IMS Health 2012

26 "Prescribing Institutions: Explaining the Evolution of Physician Dispensing." Asia Health Policy Program working paper #24, Walter H. Shorenstein Asia-Pacific Research Center, Stanford University Oct 28 2011

27 "Role of Generics in the Taiwanese Health Care System, Regulations and Market Competition Issues." Workshop on Taiwan-Germany Generic Related Legal Issues, June 3, 2011 and "Taiwan market overview." IMS Health 2012

28 "Taiwan market overview." IMS Health 2012

29 BNHI and OECD data

30 VOI Consulting, Inc. based on ITIS data

efficiency of the drug approval process. In practice, it exercises the greatest degree of control in approval decisions. CDE also plays the lead role in clinical trial approval, determining ethnic bridging study requirements, reviewing drug master files, review of generic drug applications (e.g. bioequivalency and bioavailability studies). In recent years, CDE added pharmacoeconomic reviews for national formulary purposes to its list of activities.[31] These responsibilities are discussed in later sections.

Integrated Medicinal Products Review Office (iMPRO): A team comprised of TFDA and CDE personnel who review applications for drugs and clinical trials of investigational agents.

Bureau of National Health Insurance (BNHI): Manages the National Health Insurance system; collects and distributes revenues; through the reimbursement schedule, serves as the country's drug price-control authority.

Drug Benefit Committee (DBC): Division within BNHI that manages the national formulary.

Taiwan Intellectual Property Office (TIPO): Responsible for patents and other intellectual property issues.

An English language copy of the Pharmaceutical Affairs Law that governs Taiwan's drug industry may be found at:

www.doh.gov.tw/.../200507_Pharmaceutical%20Affairs%20Act.pdf

Taiwan

TFDA

The Taiwan Food and Drug Administration (TFDA) became the unified authority for food and drug safety on January 1, 2010. This was done through a merger of the Bureau of Pharmaceutical Affairs (the previous drug regulator) along with the Bureaus of Food Safety, Food and Drug Analysis, and Controlled Drugs. The new regulatory agency was designed to closely follow the structure of the U.S. FDA. To a significant degree, the change was undertaken to bring the country's production standards and regulations in line with those in other countries in the region, including China, Japan and South Korea. This is considered an important step in the process of creating an export market for Taiwan's growing biotechnology sector.[32]

As noted above, the Center for Drug Evaluation (CDE) is a semi-independent agency that plays a prominent role in decisions regarding Taiwan's pharmaceutical sector. Attempts to bring CDE directly under TFDA authority were abandoned because of difficulties attracting sufficiently experienced reviewers at government salaries. As a result, CDE continues to operate as an independent advisory board.[33]

Taiwan

Approval Procedures

Applications are made to one of the four sections within the TFDA that are concerned with drug reviews: biological products, genetic products, new drugs, or bioequivalence/bioavailability (note that the last of these also handles IND reviews).[34] Although TFDA has statutory authority on drug approvals, most of the actual review work has traditionally been handled by CDE.

To improve the efficiency of reviews, TFDA and CDE established the Integrated Medicinal Products Review Office (iMPRO). iMPRO is not a separate office, but rather a joint team of TFDA and CDE personnel who are responsible for the evaluation of the investigational new drug clinical trials, as well as applications for new drugs, new indications for existing drugs, generic drug applications, bridging study evaluations, and drug master file applications. Operating procedures call for the combined team to review applications and hold review meetings to discuss cases. Applications

31 CDE website (www.cde.org.tw) ; accessed Sep 2012
32 "Food and Drug Administration to be launched in early 2010." China Post Oct 14 2009
33 "Interview with Jaw-Jou Kang, Director General, Taiwan FDA." Pharma-in-Focus 2012
34 "Late Clinical Development in Asia." CDE Presentation at DIA 2011

are submitted to advisory committees when there are significant concerns over efficacy or safety. TFDA officials make the final decision and inform the applicants.[35]

Until recently, the drug approval process was dramatically delayed by a requirement that a manufacturer produce Certificates of Pharmaceutical Product (CPP) from two separate countries with world class regulatory systems.[36] After several years of discussion, these policies were relaxed such that the CPPs may be waived provided that the drug application contains data that meets requirements for ethnic participation in clinical trials (see following discussion).[37]

TFDA requires that foreign and domestic manufacturing sites be inspected every two years. This can be done either through an in-person visit or through a desk review according to the risk priority.[38]

Taiwan

Bridging Study Policies

Policies on ethnic bridging studies were outlined in the Double Twelve Announcement of December 2000 and came into effect in January 2001. When required, bridging studies must have a minimum of 40 patients. However, sponsors are encouraged to apply for a bridging study evaluation (BSE) as part of the development process to determine whether existing data will be sufficient for approval purposes. Provided that ethnic considerations are addressed during the clinical development phase, these rules do not require additional bridging studies.[39]

Data from trials conducted in neighboring Asian nations may also be used to avoid the need for bridging studies.[40] In late 2010, Taiwanese and Chinese officials signed a specific agreement along these lines: provided that trial sites are in compliance with each party's regulations, data from each country will be recognized by regulatory authorities in the other.[41]

Taiwan

Pricing

Manufacturers have nominal pricing freedom, but this applies only to products that are not subsidized. In practice, commercial success requires admission to the Pharmaceutical Benefits Scheme (PBS) wherein prices are set according to a BNHI formula (discussed below). There are approximately 16,000 products on the PBS currently.[42]

At only 28% of their comparable U.S. values, prices of original drugs are among the lowest in the world.[43] In a number of cases, multinational pharmaceutical companies have withdrawn their products from the market because prices were either below production cost or because offering the drug in Taiwan would result in lower prices in markets that include the country in their international reference sets.[44]

Taiwan

Patented Products

The BNHI's New Drug Pricing Committee (NDPC) determines reimbursement prices of single-source (i.e. patented) products. In the past, the reimbursement process for innovative drugs has been slowed by the fact that the BNHI would not accept applications unless they were accompanied by an approved marketing license; in other words, reimbursement reviews could not begin until the regulatory process was complete. TFDA has offered to issue interim

35 http://www.cde.org.tw/English/Pages/Drugs.aspx; accessed Sep 2012
36 "Special 301 Submission." PhRMA Feb 2011
37 "Major Reforms of the Review for Registration and Market Approval of Drugs in Taiwan." Pharmaceutical Society of Taiwan Jun 21 2012
38 "Taiwan White Paper: 2012." American Chamber of Commerce in Taipei Jun 5 2012
39 "Bridging Diversity: Extrapolating Foreign Data to a New Region." Pharmaceutical Medicine 2010
40 "Bridging Diversity: Extrapolating Foreign Data to a New Region." Pharmaceutical Medicine 2010
41 "New agreement between Taiwan and China promotes drug development." Pacific Bridge Medical Newsletter Jan 11 2011
42 "National Health Insurance in Taiwan: 2011 Annual Report." Bureau of National Health Insurance 2012
43 "Taiwan White Paper: 2012." American Chamber of Commerce in Taipei Jun 5 2012
44 "Drug price cut impacts on patients' access to drugs?" Business Weekly Oct 7 2009

approval letters that would allow the BNHI to begin the reimbursement review but BNHI has not acted on this offer to date.[45] As a result of this, the combined regulatory and reimbursement process takes an average of three to four years.[46]

The NDPC uses a reference system to fix a reimbursement ceiling based on the product's median price in 10 countries (Australia, Belgium, Canada, France, Germany, Japan, Sweden, Switzerland, U.K. and U.S., referred to collectively as the "A10"). In practice, the frequent after-market price reductions (discussed below) result in drug prices that are amongst the lowest in the developed world.[47]

Taiwan

Health Technology Assessments (HTA) & Innovation Categories

Since 2008, sponsors have been required to apply for a health technology assessment when seeking to obtain reimbursement for new chemical entities, new indications, or new dosage forms. Applications are made to the BNHI's Drug Benefit Committee (DBC) but the Center for Drug Evaluation (CDE) handles the actual review; the CDE component usually takes 42 days. CDE recommendations are then reviewed by two members of the DBC who make a final report at the DBC meeting where decisions are made. There is an appeals process that may be pursued in the event of a negative decision.[48] For more on the application process and criteria used, see:

http://www2.cde.org.tw/HTA/Pages/Reimbursement%20review%20process.aspx

One outcome of the HTA review is new drugs are categorized based on their perceived level of innovation. As outlined in BNHI's March 2010 publication, "Operation Standards for New Drug Pricing and Reimbursement," the categories are as follows:[49]

Category 1: Breakthrough innovative product, substantial improvement over existing options. Pricing equivalent to A10 with an additional 10% premium available when efficacy or safety trials are conducted domestically.

Category 2A: Moderate improvement over existing options. Prices are set at the lowest A10 level; the 10% premium for locally conducted clinical or pharmacoeconomic research is available.

Category 2B: Similar to existing options. Prices are set at the lowest A10 level; the 10% premium for locally conducted clinical or pharmacoeconomic research is not available.

No drugs were deemed sufficiently innovative to receive Category 1 pricing in 2010 but three were granted this status in 2011. The new system appears to be having some beneficial impact on new drug prices; in the year ending March 2012, the average reimbursement level for innovative drugs receiving first-time listing on the PBS was 50.65% of the A10 median as opposed to 47.81% in the preceding 12 months.[50]

Taiwan

Multi-Source Products

Multisource products have traditionally been reimbursed as a percentage of the original drug's rate. However, Resolution 4 of the 2008 National Medicine Policy Conference called for products with the same API and the same quality to receive the same price as the original drug in order to encourage the generics and create incentives for early entry. In short, under the "same product, same price" approach, reimbursement rates are based on the average price of all products with the same active ingredient. Adjustments, which can be up to 100% of the original's price, are made based on factors such as the existence of approved Drug Master Files (DMFs), PIC/S compliance, or approval by

45 "Taiwan White Paper: 2012." American Chamber of Commerce in Taipei Jun 5 2012
46 "Foreign Trade Barriers: Taiwan." Market Access and Compliance, U.S. Department of Commerce 2012
47 "Inexpensive Medicine or Invisible Problems?" Taiwan Today May 1 2012
48 "Decision making in health technology assessment: Taiwan experience." CDE, Division of HTA Presentation, ISPOR Conference Taipei 2012
49 "Current practice of using ICER threshold in Asia: Taiwan." Center for Pharmaceutical Care Development, Taiwan Pharmacist Association Presentation 2010
50 "Taiwan White Paper: 2012." American Chamber of Commerce in Taipei Jun 5 2012

a leading global regulatory agency.[51]

Taiwan

Price Volume Surveys

Since 2000, periodic Price Volume Surveys (PVSs) have served as the primary cost-containment mechanism for reimbursed drugs. The PVS are designed to claw back a portion of the difference between reimbursement levels and acquisition costs. To perform the surveys, the government requires all NHI participating institutions (92% of the country's total health infrastructure[52]) to report drug purchase data. This information is used to calculate a weighted average market price (WAMP) for products with the same presentation; the WAMP is then marked up by an "r-zone" (i.e. a margin above the WAMP designed as reasonable compensation for prescribers) to arrive at the reimbursement rate.[53]

Despite protests from the pharmaceutical industry and upcoming revisions to the pricing system (discussed below), the most recent PVS occurred in December 2011. Although not as large as the 2009 round, which resulted in US$ 663 million of price cuts, the 2011 PVS was still a major blow to drug makers as 6,800 products were subject to a total reduction of US$ 497 million.[54]

Taiwan

Impact of 2G NHI on Drug Pricing

As previously noted, Taiwan is implementing a series of reforms known as second generation NHI (2GNHI). Funding mechanisms will see the biggest changes but there are also initiatives that will affect drug pricing. These reforms, discussed below, are expected to provide a more stable pricing system and eliminate the need for future rounds of PVS (although no guarantees have been made by the government in this regard).[55]

Taiwan

Drug Expenditure Target (DET)

The Drug Expenditure Target (DET) system, government and industry will work together to establish an annual drug spending objective which will be based on previous activity along with a reasonable growth rate. If actual expenditures exceed the DET, they will be paid back by industry through a variety of mechanisms including price cuts imposed in the following year.[56]

Although discussions regarding the DET have been underway since 2008, the government went ahead with the seventh PVS in late 2011. The DET is currently expected to take effect in January 2013.[57]

Taiwan

Actual Transaction Pricing (ATP)

Under ATP, drugs losing patent protection will be exposed to price reductions leading, over a five-year period, to a reimbursement level that is equivalent to acquisition price.[58] At present, there are a number of unresolved issues as to the timing and mechanics of this process.[59]

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51 "2011-12 Position Paper." European Chamber of Commerce in Taipei Oct 2011 and "Role of Generics in the Taiwanese Health Care System, Regulations and Market Competition Issues." Workshop on Taiwan-Germany Generic Related Legal Issues, June 3, 2011

52 "National Health Insurance in Taiwan: 2011 Annual Report." Bureau of National Health Insurance 2012

53 "Impact of drug price adjustments on utilization of and expenditures on angiotensin-converting enzyme inhibitors and angiotensin receptor blockers in Taiwan." BMC Public Health 2012

54 "2010 National Health Expenditures Abstract." Department of Health Jan 17 2012

55 "Taiwan White Paper: 2012." American Chamber of Commerce in Taipei Jun 5 2012

56 "Objectives of the Reform of Drug Expenditure Management under the 2G NHI System: Quality, Reasonableness and Efficiency." IRPMA website; accessed Sep 2012

57 "Taiwan White Paper: 2012." American Chamber of Commerce in Taipei Jun 5 2012

58 "Framing Taiwan's health insurance reforms." IMS Health Newsletter 2011

59 "Taiwan White Paper: 2012." American Chamber of Commerce in Taipei Jun 5 2012

Taiwan

Payment

BNHI operates a positive list formulary. Since 1996, the Bureau's Drug Benefit Committee (DBC) has been responsible for managing the formulary. The DBC decides whether a drug should be listed, its reimbursement price and whether it should be subject to restrictions on coverage. Once listed, products may be prescribed at any NHI-contracted healthcare facility in Taiwan.

As shown Figure 7, patient copayments are calculated as a percent of drug costs up to a maximum out-of-pocket contribution of NT$ 200 (US$ 6.72) for each outpatient visit. A number of groups are exempt from the copayment requirements; these include veterans, members of low-income households, children under three, and patients with serious illnesses.

Figure 7 - Pharmaceutical Copayment Rates 2012 TAIWAN

Actual Cost of Medication (NT$)	Copayment (NT$)	Copayment (US$)
100 and below	0	0.00
101 to 200	20	0.67
201 to 300	40	1.34
301 to 400	60	2.02
401 to 500	80	2.69
501 to 600	100	3.36
601 to 700	120	4.03
701 to 800	140	4.70
801 to 900	160	5.38
901 to 1,000	180	6.05
1,001 and above	200	6.72

Figure 7 - Pharmaceutical Copayment Rates 2012[60]

Although the PBS contains some legacy non-prescription products from previous insurance schemes, OTC products are not generally eligible for subsidies. TCMs are eligible provided they have prescription-only status and are manufactured according to good manufacturing principles (GMP).[61]

Taiwan

Generics

Privately-owned and smaller hospitals are more likely to use generics than larger, publicly-owned hospitals which tend to prefer patented products or branded versions of multi-source drugs.[62] Pharmacists have substitution rights provided that the substituted products are of the "same ingredients, same dosage form and same dosage at an equal or lower price" and unless the prescriber indicates otherwise.[63]

As would be expected, buyers are able to extract more favorable terms from generic suppliers than from manufacturers of single-source drugs; this is evidenced in discount rates which are as high as 50% for generics as opposed to 5 to 10% for original drugs.[64]

60 "Medical Services: Copayments." Bureau of National Health Insurance 2012

61 "Chapter Two Principles on Drug Reimbursement Listing in National Health Insurance." Laws and Regulations Bureau of National Health Insurance website; accessed Sep 2012

62 "An analysis for prescribing patterns of private and public hospitals in Taiwan." Poster Presentation, European Conference on Health Economics 2012

63 Article 40, Regulations for NHI Medical Care and "Role of Generics in the Taiwanese Health Care System, Regulations and Market Competition Issues." Workshop on Taiwan-Germany Generic Related Legal Issues, June 3, 2011

64 "Checking up on Taiwan healthcare: Market challenges and opportunities." PwC Newsletter Jun 2012

Generics hold 29.5% of market sales and approximately 43% of market volume in Taiwan.[65] In a longitudinal study of 32 molecules facing first-time generic competition between 1997 and 2007, researchers found that combined generic share of API volume was only 7% after one year, 30% at 4 years, and peaked at approximately 40% after nearly six years. Further, generic reimbursement rates held steady at between 76 and 83% of brand levels for a period of 80 months after initial entry and then declined slightly to a range of 65 to 76%.[66]

Taiwan

Biosimilars

Taiwan is one of the many countries moving ahead with regulations for generic versions of biologics, or biosimilars. The Department of Health's guidelines on the subject, titled "Review Criteria for Registration and Market Approval of Pharmaceuticals-Registration and Market Approval of Biological Products" were issued on November 21, 2008.

The guidelines are modeled on the E.U. approach and require comparability testing to show similar quality, safety, and efficacy for the biosimilar. The reference product must be marketed in Taiwan and the biosimilar must also share the same form, strength, and route of administration. In comparison to an innovative medicine, biosimilars will have a lower need for clinical and pharmacokinetic data but higher needs for chemistry, manufacturing, and control (CMC) data.[67]

Taiwan

R&D / Clinical Trials

The biopharmaceutical industry has been an official priority for Taiwan's economic development since 1997 and the government has acted on this commitment with substantial support. For example, in June 2007, the legislature approved a biotech investment bill that runs through 2021 and allows for tax exemption of 35% on R&D and related training expenditures as well as other pro-innovation incentives. Taiwan's President has declared research & development essential to economic recovery and pledged to increase the country's R&D budget to 3% of GDP.[68]

In March 2009, the government announced the Diamond Action Plan for Biotech Takeoff with the stated goals of reinforcing the role of industrial R&D in the value chain, establishing a biotechnology venture capital fund, creating a biotechnology incubator center within the National Science Council, and bringing the country's drug regulatory system up to international standards. Although some of these objectives have been met, in part, the program has been charged with inconsistent execution and a continued reliance on U.S. and European regulators.[69]

The production value of Taiwan's biotech industry reached US$ 8.1 billion in 2011, representing a 100% increase since 2002.[70]

Taiwan

Clinical Trials

Taiwan has a fairly long history of clinical research; observers have cited its advanced regulatory system, strong infrastructure, and governmental support as leading attractions.[71] According to Frost & Sullivan, the Taiwanese clinical trial sector was valued at US$ 115 million in 2010 and, with an average annual growth rate of 13%, is expected to reach US$ 210 million in 2015.[72]

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65 VOI Consulting estimates based on data from Business Monitor International (BMI) and IMS; figures reflect 2011 market activity.

66 "National Health Insurance and Generic Competition in the Pharmaceutical Market: Evidence from Taiwan." Department of Economics National Cheng-Kung University Apr 2011

67 "Taiwanese Perspectives on Regulation of Biosimilar medicine." Taiwan FDA Presentation Apr 27 2011

68 "BioSpectrumAsia Top 20 Vol. 2: Asia Life Sciences Industry employs 2.3 mn People." Biospectrum 2009

69 "Key takeaways from BioBusiness Asia Forum." KGI Securities Jul 20 2011

70 "Biotechnology industry gaining ground in Taiwan." Central News Agency Jul 26 2012

71 "New Emerging R&D and Clinical Trial Locations." Business Insights Jan 4 2012

72 "Clinical Trials Market in APAC." Frost & Sullivan Jul 20 2012

Despite these advantages, Taiwan has traditionally been seen as a location for late-stage clinical research, with Phase I capabilities considered underdeveloped. This is confirmed in Figure 8 below which shows that Phase I protocols have consistently represented only 10% of total trials in the country.

Figure 8 - Number of Approved Clinical Trial Protocols and Sites by Phase (2004-2010)								TAIWAN
		2004	2005	2006	2007	2008	2009	2010
Protocols	Phase I	8	14	12	10	11	18	19
	Phase II	22	33	32	46	46	60	49
	Phase III	85	69	86	106	132	95	119
	Phase IV	4	4	3	6	16	14	21
	Total	119	120	133	168	205	187	208
Sites	Phase I	12	26	20	18	14	19	22
	Phase II	57	78	98	158	120	167	158
	Phase III	237	242	300	391	527	407	554
	Phase IV	10	5	4	14	21	19	30
	Total	**316**	**351**	**422**	**581**	**682**	**612**	**764**

Figure 8 - Number of Approved Clinical Trial Protocols and Sites by Phase (2004-2010)[73]

Using a different method, Figure 9 shows the number of industry-sponsored, interventional clinical trials initiated each year in Taiwan as reported by the U.S.-based registry, ClinicalTrials.gov. As indicated, after growing fairly steadily for several years, trial starts took a significant dip in 2011, driven largely by a decline in the number of Phase III studies. Taiwan's rate of participation in industry research has also been fairly stagnant, particularly when compared to South Korea which increased its share of such trials from 3.4% to 5.8% over the same time period. Although it has not been independently confirmed, we speculate that a worsening pricing environment for original drugs is one likely reason for the lack of growth. Figure 9 also confirms the relative lack of Phase I activity in Taiwan.

Figure 9 - Taiwan Clinical Trial Starts by Phase (Number and Global Share: 2006-2011)								TAIWAN
		2006	2007	2008	2009	2010	2011	CAGR
Trial Starts	Phase I	5	3	5	17	6	14	23%
	Phase II	19	41	40	49	34	34	12%
	Phase III	78	83	98	82	103	75	-1%
	Total	102	127	143	148	143	123	4%
% Global Total	Phase I	0.70%	0.30%	0.30%	0.90%	0.30%	0.80%	2%
	Phase II	1.20%	2.10%	1.80%	2.50%	2.00%	2.00%	10%
	Phase III	4.80%	5.60%	5.60%	6.30%	7.90%	5.80%	4%
	Total	**2.60%**	**2.80%**	**2.50%**	**2.80%**	**3.00%**	**2.60%**	**-1%**

Figure 9 - Taiwan Clinical Trial Starts by Phase (Number and Global Share: 2006-2011)[74]

Taiwan

IND Review Process

All trials involving new molecular entities, new indications, new route of administration and new routes of administration must be approved via an Investigational New Drug (IND) application. In the not too distant past, Taiwan had a "notoriously long" three-tier approval system, which consisted of IRB review and two sequential levels

73 "Late Clinical Development in Asia." CDE Presentation at DIA 2011

74 VOI Consulting analysis of data from ClinicalTrials.gov. Conducted August 2012. Figures based on number of industry-sponsored, interventional clinical trials first reported during the relevant calendar year.

of regulatory review – first by the CDE and then by the Drug Advisory Committee (DAC) with the latter body being responsible for formal recommendations to the Department of Health (DOH).[75]

In February 2007, however, major responsibility for regulatory review was shifted to the Clinical Sciences Division of the CDE. DOH continues to be responsible for issuing final approval for clinical trials. In addition, DAC opinions are informally considered on a regular basis. However, the Committee only becomes formally involved at the request of CDE, a situation that rarely arises. As a result of the streamlined process, the IND review process was substantially improved, with average decision times declining from 54.6 days in 2006, to 40.6 days in 2008 and 34.5 days by early 2011.[76]

In August 2010, Taiwan introduced a fast-track approval system for multinational trials that have already received protocol approval in one of 10 countries (US, UK, France, Japan, Switzerland, Canada, Australia, Belgium, Sweden, or Germany). Under this "clinical trial notification" system, regulatory review is restricted to administrative matters only although TFDA reserves the right to amend the trial at a later stage in the unlikely event that this is necessary. Within the first four months, 17 out of 102 total applications were handled under the CTN system and average review times were 17.5 days as opposed to 34.5 days for standard review.[77]

Trial protocols must also be approved by an Institutional Review Board (IRB) and by the Department of Health before commencing. To improve the applications and reviews for multicenter trials, a joint IRB (JIRB) was established by DOH in 1997, making Taiwan an early adopter of the joint approval approach. According to evidence from Merck, Sharpe & Dohme, the average ethics review time in Taiwan is 76 days.[78]

Taiwan

Manufacturing

In 2011, there were 293 registered Western pharmaceutical companies, of which 25 were involved in the production of biologics for human medical use. There were also 126 manufacturers producing Traditional Chinese Medicines.[79]

Total production value from Taiwanese pharmaceutical companies in 2011 was NT$ 65 billion (US$ 2.2 billion) of which 62% was finished Western drugs, 28% was active pharmaceutical ingredients (API), and the remainder was Traditional Chinese Medicine. As a percent of total industry output, API production doubled between 2006 and 2011; currently, 90% of API sales are generated in overseas markets. In the face of rising competition from ultra low-cost producers in China and India, Taiwanese firms have been focusing on high-end APIs that offer some niche or barrier to entry.[80]

Taiwan's Food and Drug Administration (TFDA) has announced a 2014 target for implementation of the Pharmaceutical Inspection Convention Scheme (PIC/S). Although Taiwan is not a member of PIC/S, the move is expected to increase the viability of the country's export sector.

Taiwan

Patent & Intellectual Property Issues

The Taiwan Intellectual Property Office (TIPO), a division of the Ministry of Economic Affairs, is the relevant patent authority. A specialized patent court has been in operation since mid-2008. It replaced a dual-track system in which infringement cases were heard in civil court but decisions regarding patent validity were handled by administrative authorities. The new system has reportedly reduced the time required for resolution of patent cases by more than

75 "Updates on IND Process and Clinical Trials Status in Taiwan." Drug Information Journal Vol. 43 Iss. 1 2009
76 "An Experimental Model of Regulatory Science in Asia: Center for Drug Evaluation in Taiwan." Drug Information Journal May 2009
77 "Clinical Trial Application and Consultation Systems in East Asia with Expected Improvements in China and Japan from an Industry Point of View." JPMA Presentation Mar 29 2011
78 "Improving New Zealand's environment to support innovation through clinical trials." Merck Sharpe & Dohme Submission Jun 23 2010
79 "Statistics of General Health 2011, Pharmaceutical Affairs: Table 26 Number of Pharmaceutical Firms." Department of Health Sep 5 2012
80 "Pharmaceuticals sector – API prospects intact." KGI Securities Jun 26 2012

half.[81]

Following Taiwan's entry into the World Trade Organization in January 2002, product patent life was extended to 20 years from 15. In cases where the approval process takes more than two years, the patent owner may apply for a patent life extension of two to five years. Applications for extension must be filed within three months of first approval.[82]

Current law contains a "Bolar provision" which allows outside parties to conduct research required to file a generic drug application without infringing an active patent.[83] There is a five-year data exclusivity period but is available only for new drugs (i.e. new indications are not eligible). Further, exclusivity protection applies only for applications that are filed within three years of the drug's first regulatory approval in the world.[84]

In addition to a somewhat problematic data exclusivity regime, there is no formal linkage between the IP and drug regulatory authorities. This means that TFDA can approve imitating versions of products that are still under patent protection. To date there have been 120 instances in which the lack of a linkage mechanism led to approval of patent-infringing products, many of which were subsequently included on the reimbursement lists.[85]

In June 2010, Taiwan and China signed the Cross-Strait Agreement on IP Rights Protection, a mutual recognition pact that calls for priority rights for patents and trademarks issued by one party to be respected by the other. This agreement is expected to expand access of Taiwan-based pharmaceutical manufacturers to China's growing market.[86]

Taiwan

Marketing

Prior approval is required for all pharmaceutical advertising (including OTC). Ads for prescription medicines are restricted to professional media. The innovative industry's self-regulatory marketing code is handled by the International Research-based Pharmaceutical Manufacturers Association (IRPMA). The most recent version of the code, which took effect in 2008, can be found at:

http://www.irpma.org.tw/english/08_cop.htm

Taiwan

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83 "Taiwan White Paper: 2012." American Chamber of Commerce in Taipei Jun 5 2012

84 "Special 301 Report." PhRMA Feb 2012

85 "Taiwan White Paper: 2012." American Chamber of Commerce in Taipei Jun 5 2012

86 "Checking up on Taiwan healthcare: Market challenges and opportunities." PwC Newsletter Jun 2012

VALUE OF INSIGHT

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This Agreement shall remain in effect until terminated. VOI reserves the right to terminate this Agreement and any or all of Your rights hereunder effective immediately if You fail to comply with any term of this Agreement, including, without limitation, by exceeding the scope of the license granted in Section 2 hereof. Upon any such termination, You will destroy the original and all copies of the Content and cease all use of the Content. The termination of this Agreement shall automatically, and without any further action by VOI, terminate and extinguish the license granted herein. You hereby waive any and all challenges to, or claims or defenses regarding VOI's rights in the Content, or VOI's right to terminate this Agreement pursuant to the terms hereof.

11. Governing Law; Jurisdiction and Venue

This Agreement shall be governed by and construed under and in accordance with the laws of the State of Florida, applicable to contracts entered into and to be fully performed in that state. All disputes concerning the interpretation, breach, or enforcement of this Agreement shall be brought only in the state and federal courts located in Broward County or Miami-Dade County, Florida. The parties consent to personal jurisdiction and venue in those Courts for such suits. This Agreement will not be governed by the United Nations Convention on Contracts for the International Sale of Goods, the application of which is expressly excluded.

12. Attorneys' Fees

If any suit, arbitration, action at law or in equity is brought to enforce or interpret the provisions of this Agreement, the prevailing party in such action shall be entitled to reimbursement for reasonable attorneys' fees, arbitration fees and/or court costs.

13. Validity

If any part, term or provision of this Agreement is declared and determined by any court or arbitrator of competent jurisdiction to be illegal or invalid, such declaration and determination shall not affect the validity of the remaining parts, terms or provisions.

14. Miscellaneous

This Agreement represents the entire agreement and understanding of the parties hereto with respect to the subject matter contained herein, and supersedes all prior agreements, promises, covenants, arrangements,

communications, representations or warranties, whether oral or written, by any officer, director, contractor, agent, affiliate, employee or representative of either party hereto. The failure of VOI to insist upon strict adherence to any term of this Agreement on any occasion shall not be construed as a waiver of said term and shall not deprive VOI of the right thereafter to insist upon strict adherence to that term or any other term of this Agreement. The headings used herein are for reference only and shall not affect the construction of this Agreement.

YOU EXPRESSLY ACKNOWLEDGE THAT YOU HAVE READ THIS AGREEMENT AND UNDERSTAND THE RIGHTS, OBLIGATIONS, TERMS AND CONDITIONS SET FORTH HEREIN. BY CLICKING THE ACCEPT BUTTON AND/OR CONTINUE TO OBTAIN, USE AND/OR DOWNLOAD THE CONTENT, YOU EXPRESSLY AGREE TO BE BOUND BY THE TERMS AND CONDITIONS OF THIS AGREEMENT. VOI RESERVES ALL RIGHTS NOT EXPRESSLY GRANTED IN THIS AGREEMENT.

USER LICENSE AGREEMENT

Value of Insight Consulting, Inc. (VOI)

Agreement

These VOI License Terms ("Agreement") are a legally binding contract between You (customers) and Value of Insight Consulting, Inc. ("VOI"). Please read all of the terms contained herein prior to obtaining, using, and/or downloading any of the Content provided by VOI. By using or downloading any of the Content, you confirm that you have read, understand and agree to be bound by the terms of this Agreement, and that you have the authority to bind the person or entity specified on your invoice. If You do not agree with the terms and conditions of this Agreement, do not use and/or download any of the Content.

These terms apply to VOI Digital Content, as well as any supplements, updates, Internet-based services, and support services offered by VOI. Using or downloading the Content also operates as Your consent to the transmission of certain computer information during activation, validation and for Internet-based services.

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Any and all licenses granted by VOI are conditioned upon (i) Your compliance with all provisions of this Agreement, and (ii) VOI's receipt of full payment for the Content by You. Any and all licenses granted to You hereunder and Your right to use the Content shall immediately terminate upon Your failure to comply with any provision of this Agreement or to make full payment when due, in which case VOI shall be entitled to pursue all available remedies under the law.

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Delivery of Licensed Content and Fees

Subject to the terms and conditions of this Agreement, licensed Content will be provided to You via electronic transfer and/or download.

Unauthorized Use of Content

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VOI, in its sole discretion, reserves the right to bill You (and You hereby agree to pay) ten (10) times the license fee for any unauthorized use, in addition to any other fees, damages and penalties VOI may be entitled to under this Agreement and applicable law. The foregoing does not limit VOI's rights or remedies in connection with any unauthorized use of the Content or any breach of this Agreement.

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Limited Warranty and Disclaimer

VOI warrants that, to the best of its knowledge: (i) the Content licensed hereunder does not infringe any copyright, trademark, or any other intellectual property right of any third party, (ii) it has sufficient rights to enter into this Agreement and grant You the rights provided herein; and (iii) the Digital Content provided by VOI to You will be free from defects in material and workmanship. In the event of any such material and/or workmanship defects, VOI will provide You with a replacement copy of the Digital Content. This shall be an exclusive remedy.

VOI makes no warranties, nor shall VOI be liable, for any claims related to or arising from Your use of the Content which: (a) has been modified by You, (b) has been combined by You with other products or materials, or (c) VOI has otherwise notified You not to use prior to the effective date of the license for the Content. EXCEPT AS MAY BE OTHERWISE EXPRESSLY STATED IN THIS AGREEMENT AND TO THE EXTENT OF APPLICABLE LAW, VOI MAKES NO OTHER WARRANTY, EXPRESS, IMPLIED OR STATUTORY, REGARDING ANY OF THE CONTENT, OR ANY RIGHTS OR LICENSES UNDER THIS AGREEMENT INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

Limitation of Liability

EXCEPT FOR ANY LIABILITY WHICH CANNOT BY APPLICABLE LAW BE EXCLUDED OR LIMITED, VOI SHALL NOT BE LIABLE TO YOU OR ANY OTHER THIRD PARTY CLAIMING THROUGH YOU FOR INDIRECT, INCIDENTAL, SPECIAL, PUNITIVE, STATUTORY OR CONSEQUENTIAL DAMAGES ARISING OUT OF, OR RELATING TO THIS AGREEMENT AND/OR YOUR USE OR INABILITY TO USE THE CONTENT, WHETHER FRAMED AS A BREACH OF WARRANTY OF MERCHANTABILITY, TITLE, NON-INFRINGEMENT, OR FITNESS FOR A PARTICULAR PURPOSE, IN TORT, CONTRACT, FAILURE OF ESSENTIAL PURPOSE, OR OTHERWISE, EVEN IF VOI HAS BEEN APPRISED OF THE POSSIBILITY OF SUCH DAMAGES. IN NO EVENT SHALL VOI'S TOTAL AGGREGATE LIABILITY TO YOU OR ANY THIRD PARTY CLAIMING THROUGH YOU ARISING FROM THIS AGREEMENT, ITS TERMINATION, AND/OR YOUR USE OF ANY OF THE CONTENT PROVIDED HEREUNDER, EXCEED TEN (10) TIMES THE MONETARY AMOUNT ACTUALLY RECEIVED BY VOI FOR THE USE OF THE APPLICABLE CONTENT. THE FOREGOING LIMITATIONS ARE APPLICABLE NOTWITHSTANDING ANY FAILURE OF ESSENTIAL PURPOSE.

Indemnification

You agree to indemnify and hold harmless VOI and its officers, directors, employees, contractors, subsidiaries, joint ventures, and Content sources against all claims (including, without limitation, claims by third parties), liability, damages (including punitive damages), judgments, settlements, costs and expenses, including reasonable legal fees and expenses, arising out of or related to (i) Your breach of any terms, conditions or restrictions of this Agreement; and (ii) Your use or modification of any of the Content, or combination of any of the Content, with text or other materials.

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