

Asia-Pacific Newsletter

Issue 2 | March 2010



The PricewaterhouseCoopers Pharma & Life Sciences experts are pleased to provide you with the second issue of our Asia-Pacific pharmaceutical industry newsletter.

This issue includes a brief overview of the pharma mergers and acquisitions activity in Asia during 2009. There was a notable increase in M&A activity in the latter part of 2009, gradually coming back to pre-financial crisis levels. Although it is still early in 2010, we are already beginning to see increased appetite in the market.

We like to draw your attention to the speech on Compliance given by the Department of Justice in the US and the fact that multiple investigations are focusing on the business practices in pharmaceutical, medical devices and life sciences companies in Asia and the expectations the US regulator has with respect to compliance with the FCPA.

As in our previous newsletter we also highlight pricing & reimbursement, regulatory and tax news from the different territories.

We hope this newsletter is informative and if you like to discuss any topic in more detail, feel free to reach out to your PwC territory contact or the experts mentioned in the article.

Compliance

US Regulator Warns of Crackdown on Bribery & Corruption in the Pharmaceutical and Medical Device Sectors

In a speech given at the Pharmaceutical Regulatory Compliance Congress' annual forum in November, Lanny Breuer, assistant attorney general and head of the US Department of Justice's Criminal Division, shared the Department's plans to crackdown on Foreign Corrupt Practices Act (FCPA) violations across the pharmaceutical and medical device industries. The Department has recently taken steps to link their FCPA and Health Care Fraud teams in a way that allows them to apply deep industry expertise to the proactive investigation and prosecution of violations.

"Our focus and resolve in the FCPA will not abate, and we will be intensely focused on rooting out foreign bribery in your industry. That will mean investigation and, if warranted, prosecution of corporations to be sure, but also investigation and prosecution of senior executives. Effective deterrence requires no less."¹

Breuer highlighted the risks within the international pharmaceutical and device markets, acknowledging "that nearly every aspect of the approval, manufacture, import, export, pricing, sale and marketing of a drug product in a foreign country will involve a 'foreign official' within the meaning of the FCPA".¹ Breuer went on to say, "The industry must resist short cuts. It must resist the temptation and invitation to pay off foreign officials for the sake of profit. It must act, in a word, lawfully".¹ In many countries where doctors, pharmacists, lab technicians and other health care professionals are considered "foreign officials" under the FCPA, Mr. Breuer's comments point to the significant challenges facing large organizations with extensive international sales forces that need to manage compliance risk despite the local cultural or industry practices. In Asia, where local business practices often contravene the rules of the FCPA, and where there is a pervasive presence of government officials and government-related entities, it is especially important for Pharmaceutical companies to heed Breuer's warning.

While not providing specific or binding guidance to the audience on what constitutes corrupt payments, Breuer stated that corrupt payments "violate the FCPA because they are given to obtain or retain business"¹ and may include "cash, gifts, charitable donations, travel, meals, entertainment, grants, speaking fees, honoraria, and consulting arrangements, to name a few".¹

Breuer acknowledged the potentially substantial costs of internal investigations and remediation, but believes these costs are outweighed by the significant financial and non-financial implications that accompany non-compliance. He emphasised the need for each company to have "a rigorous FCPA compliance policy that is faithfully enforced".¹ He also discussed the potential for favourable treatment of a company that takes a proactive approach to FCPA compliance, voluntarily discloses any violations, and cooperates fully with any Department of Justice inquiries, as has been seen in previous actions taken.

It is clear from his speech that Breuer expects the industry to take compliance with the FCPA seriously, and that those who choose not to will be made to pay the price. This is supported by significant growth within the Department's FCPA enforcement team in recent years, which includes the addition of healthcare industry experts. There is also increased cooperation and coordination between other agencies, such as the FBI and the US Securities and Exchange Commission (SEC), who also have grown their FCPA compliance-focused teams in recent years and who are collectively pursuing over 120 active FCPA cases at the moment.

Many of the recent and ongoing cases are focused on business practices in Asia. The various enforcement agencies recognize the importance of Asia to the Pharmaceutical industry's growth and they understand the temptations, challenges and risks of doing business in this part of the world. Knowing all of this, Pharmaceutical, Medical Device, and other Life Sciences companies with operations in Asia should consider their compliance with the FCPA and move to make improvements as necessary. Mr. Breuer expects nothing less.

¹ Source: <http://www.justice.gov/criminal/pr/speeches/2009/11/11-12-09breuer-pharmaspeech.pdf>

M&A

There was an impressive amount of pharma industry M&A activity in the Asian market during 2009. Key drivers fuelling this M&A activity include:

- blockbuster drugs coming off patent and increasing competition from generics
- desire to expedite and expand new drug pipelines
- growing interest in vaccines as a potential growth engine
- industry consolidation and specialization
- growth opportunities in emerging markets and global expansion

The largest M&A deal in the year ended 31 December 2009 was Dainippon Sumitomo Pharma of Japan's approximately US\$ 2.6 billion acquisition of Sepracor. This deal represents Japan's 3rd largest outbound, cross-border deal in the pharma sector¹ and provides Dainippon Sumitomo Pharma with a strong U.S. sales and marketing channel for its new schizophrenia drug, Lurasidone, which is currently undergoing clinical trials.

Beckman Coulter's purchase of the diagnostic division of Olympus Corporation for approximately US\$ 790 million provides Beckman Coulter with a more significant presence in Europe and Asia. The acquired division of Olympus manufactures clinical chemistry systems and provides Beckman Coulter with a high quality product for large medical centers.²

Aside from the Beckman Coulter-Olympus deal, other significant M&A deals concluded between U.S. and Japanese pharma companies were: Hisamitsu Pharma's acquisition of Noven Pharmaceuticals for approximately US\$ 428 million, Taisho Pharma acquisition of Bristol-Myers Squibb's Asia Pacific OTC assets for approximately US\$ 310 million and Sekisui Chemical's acquisition of American Diagnostica for approximately US\$ 51 million.

There were also two significant M&A deals involving Indian pharmaceutical companies: Sanofi Pasteur acquired 80% of Shantha Biotechnics for approximately US\$ 781 million and Hospira acquired Orchid Chemicals & Pharmaceuticals' Injectables Pharmaceuticals business for approximately US\$ 400 million.

The implementation of new medical reform policies in China seem to drive M&As between local companies. Finally, Novartis' acquisition of an 85% stake in Zhejiang Tianyuan Bio-Pharma for approximately US\$ 125 million seems to accentuate growing interest in tapping into the global vaccines market.

The following table provides information on some of the M&A deals in Asia during 2009.

¹ Source: MarketWatch, "Dainippon Confirms Plan to Buy Sepracor for \$2.6 Billion", September 3, 2009, www.marketwatch.com

² Source: The Orange County Register, "Beckman Coulter to Pay \$800 Million for Olympus Division", September 6, 2009, www.ocregister.com

Select Asia Pharma Deals 2009

Date	Acquirer	Country	Target	Country	Transaction Value
Mar-09	Sekisui Chemical Co., Ltd.	Japan	American Diagnostica, Inc.	US	US\$ 51 Mil.
Mar-09	Cephalon International Holdings, Inc.	US	Arana Therapeutics Ltd.	Australia	US\$ 200.76 Mil.
Mar-09	Beckman Coulter Inc.	US	Olympus Diagnostics	Japan	US\$ 790 Mil.
Mar-09	PT Kimia Farma	Indonesia	PT Indofarma	Indonesia	undisclosed
May-09	Sciele Pharma, Inc. / Shionogi & Co., Ltd.	US, Japan	Victory Pharma, Inc.	US	US\$ 150 Mil.
Jun-09	Sanofi-Aventis Ltd.	France	Shenzhen Neptunus	China	US\$ 34 Mil.
Jun-09	Codinus Co., Ltd.	Korea	Han Seo Pharmaceutical Co., Ltd.	Korea	US\$ 12 Mil.
Jul-09	Hisamitsu Pharma Co., Inc.	Japan	Noven Pharmaceuticals Inc.	US	US\$ 428 Mil.
Jul-09	A1 Co., Ltd.	Korea	NHS Co.	Korea	US\$ 29.8 Mil.
Jul-09	Matrix laboratories Ltd.	India	Astrix Labor Laboratories Ltd.	Indian	
Jul-09	Sanofi Pasteur SA	France	SHanH	Indian	US\$ 780 Mil.
Jul-09	Allergan Inc,	US	Samil Eyecare (Samil Pharmaceutical Co.)	Korea	US\$ 16.7 Mil.
Jul-09	Yunnan Medical&Pharmaceutical Industry Co., Ltd	China	Yunnan Phytopharmaceutical Co.,Ltd	China	US\$ 17.6 Mil.
Jul-09	Abbott Laboratories	U.S	Wockhardt Co., Ltd.	India	US\$ 130 Mil.
Jul-09	Sanofi Pasteur Inc.	France	Shantha Biotechnics Ltd.	India	US\$ 783 Mil.
Jul-09	Shanghai Anping Medical Treatment Technology Co., Ltd	China	Shanghai Lun Kan Medical Investment Management Ltd.	China	US\$ 6.8 Mil.
Aug-10	Roche Holding AG	Switzerland	Singapore Lonza's Biologics Plant	Singapore	US\$ 290 Mil.
Aug-10	Hisamitsu Pharmaceutical Co., Inc.	Japan	Noven Pharmaceuticals Inc.	US	US\$ 16.7 Mil.
Aug-09	China Pharmaceutical Group Ltd.	China	Sihuan Pharmaceutical Holdings Group Ltd.	China	US\$ 315 Mil.
Sep-09	Dainippon Sumitomo Pharma Co., Ltd.	Japan	Sepracor Inc.	US	US\$ 2.6 Bil.
Sep-09	Taisho Pharma Co., Ltd.	Japan	Bristol-Myers Squibb Ltd.	US	US\$ 310 Mil.
Sep-09	Pfizer Animal Health Inc.	U.S	Vetnax Animal Health Ltd.	India	US\$ 48.8 Mil.
Sep-09	Vetoquinol SA	France	Animal Health Division of Wockhardt Ltd.	India	US\$ 30 Mil.
Sep-09	Rhodia SA	France	Rhodia Thai Industries Ltd.	Thailand	
Sep-09	Biocon	India	IDL Specialty Chemicals	India	undisclosed
Sep-09	China Animal Healthcare Ltd.	China	Beijing Jianxiang Hemu Biological Technology Ltd.	China	US\$ 30.7 Mil.
Sep-09	PerkinElmer Inc	U.S	SYM-BIO Lifescience	China	US\$ 64 Mil.
Sep-09	PT Kalbe Farma Tbk	Indonesia	PT Enseval Putera Megatrading Tbk	Indonesia	US\$ 61.2 Mil.
Sep-09	Century Medical Inc	Japan	Showa Ika Kohgyo	Japan	NA
Oct-09	Inviragen, Inc.	US	Sing Vax Pte Ltd.	Singapore	NA
Oct-09	Guangzhou Kozern Pharmaceutical	China	Guangzhou LifeTech Pharmaceuticals	China	US\$ 22 Mil.
Oct-09	Guangzhou Kozern Pharmaceutical	China	Guangzhou LifeTech Pharmaceuticals	China	US\$ 22 Mil.

Date	Acquirer	Country	Target	Country	Transaction Value
Oct-09	Lonza Group Ltd	Switzerland	Simbiosys Biowares India Ltd	India	undisclosed
Oct-09	Gadelius K.K.	Switzerland	Cathex Co., Ltd.	Japan	US\$ 11 Mil.
Oct-09	Merck Specialties	Germany	Bangalore Genei	India	US\$ 9 Mil.
Oct-09	Kyowa Medical Holdings Co., Ltd.	Japan	Kuribara Medical Instruments Co., Ltd.	Japan	US\$ 15.4 Mil.
Oct-09	Toho Pharmaceutical Co., Ltd.	Japan	OMWELL Inc.	Japan	US\$ 150 Mil.
Oct-09	SK Chemicals Co., Ltd	Korea	CTC Bio Inc	Korea	US\$ 9 Mil.
Oct-09	CHA Bio&Diotech	Korea	Hanson Biotech Co., Ltd.	Korea	US\$ 20 Mil.
Oct-09	CellBank Co.	Japan	BCS	Japan	undisclosed
Oct-09	Lifeline Industries Inc.	India	Erica Pvt., Ltd.	India	US\$ 29 Mil.
Oct-09	Li Chunhua	China	China Animal Healthcare Ltd	China	US\$ 18 Mil.
Oct-09	HAL Holdings	China	Neth Antilles	China	US\$ 21 Mil.
Oct-09	Shanghai Pharmaceutical Co., Ltd.	China	3 Subsidiaries of SI Pharmaceuticals Group Ltd.	China	US\$ 293 Mil.
Oct-09	Shanghai Pharmaceutical Co., Ltd.	China	Shanghai Industrial Pharmaceutical Investment Co., Ltd.	China	US\$ 1,057 Mil.
Oct-09	Shanghai Pharmaceutical Co., Ltd.	China	Pharmaceutical business subsidiaries of Shanghai Pharmaceutical (Group) Co., Ltd.	China	US\$ 792 Mil.
Oct-09	Shanghai Pharmaceutical Co., Ltd.	China	Shanghai Zhongxi Pharmaceutical Co., Ltd.	China	US\$ 294.1 Mil.
Nov-09	Pharmaceutical Product Development, Inc.	U.S	Chinese CRO of Bio Duro	China	US\$ 77 Mil.
Nov-09	Pharmaceutical Product Development, Inc.	U.S	Excel PharmaStudies, Inc.	China	NA
Nov-09	Shanghai Fosun Pharmaceuticals	China	Chindex International Inc	China	US\$ 22 Mil.
Nov-09	Investor Group	Hong Kong	Everpride Biopharmaceutical	Hong Kong	US\$ 3 Mil.
Nov-09	CordLife Ltd.	Australia	China Stem Sell	China	US\$ 10 Mil.
Nov-09	Hangzhou Jinbang Trading	China	Hangzhou Tianmushan Pharma	China	US\$ 7 Mil.
Nov-09	Ascendium Group Ltd	BVI	China MedStar Ltd	China	US\$ 34 Mil.
Nov-09	Novartis AG	Switzerland	Zhejiang Tianyuan Bio-Pharmaceutical Co., Ltd.	China	US\$ 125 Mil.
Nov-09	Alfresa Holdings Co.	Japan	Alfresa Nikkensangyo Co., Ltd.	Japan	US\$ 18 Mil.
Nov-09	Korea Schnell Pharma Co., Ltd.	Korea	Aprogen, Inc.	Korea	US\$ 2.2 Mil.
Nov-09	Koastron Co., Ltd.	Korea	Chungei Pharma Co., Ltd.	Korea	US\$ 4 Mil.
Nov-09	GNCO Co., Ltd.	Korea	Sumagen Co.,Ltd	Korea	US\$ 7 Mil.
Nov-09	Dong-A Membership group Co., Ltd.	Korea	Korea Bone Bank Co., Ltd.	Korea	US\$ 74 Mil.
Nov-09	Taisho Pharma Co., Ltd.	Japan	Bristol-Myers Squibb Indonesia	Indonesia	US\$ 310 Mil.
Dec-09	Hospira, Inc.	US	Orchid Chemicals & Pharmaceuticals Ltd.	India	US\$ 400 Mil.
Dec-09	Chen Fa Shu	China	Yunnan Baiyao Group Co., Ltd.	China	US\$ 323 Mil.
Dec-09	Function well Ltd	Taiwan	Champ Tech Optical Foshan Corp	China	US\$ 231 Mil.

Pricing & Reimbursement

Australia

A new report on healthcare expenditure in Australia (Health Expenditures Australia 2007-08) reports that expenditure on health in Australia has increased from US\$10.8 billion in 1981-82 to US\$103.6 billion in 2007-2008. At the same time Australia's Gross Domestic Product (GDP) increased from US\$172.3 billion to US\$1,132 billion, so health expenditure as a proportion of GDP has gone from 6.3% in 1981-82 to 9.1% of GDP in 2007-08.

Of the total spend in 2007-08, 95% (US\$98 billion) was recurrent expenditures on health goods and services with the remaining 5% on capital expenditure, whilst expenditure on medications was estimated at US\$13.7 billion (14%) of the total recurrent health spending.

With this backdrop there have been a number of important announcements in the last two months of 2009 which we will see changes to PBS savings and pricing and reimbursement.

First, the Australian Government announced the creation of three new therapeutic groups (TGP's) as part of its 2009 Mid Year Economic and Fiscal Outlook.

The three new TGP's cover:

- two anti-depressants – venlafaxine and desvenlafaxine
- oral bisphosphonates for osteoporosis, and
- oral bisphosphonates for Paget disease of the bone.

These new TGP's will be subject to reference pricing within each therapeutic group from 1 April 2010.

Secondly, the Department of Health and Ageing (DoHA) has issued a clarification on the implications of generic medicines listings on mandatory price reductions in the F2 formulary. Where a new brand of a product is listed in respect of a product in F2T which has previously attracted phased mandatory price reductions, the remainder of the 25% price reduction will be fully applied at the next price point change (i.e. 1 April, 1 August and 1 December) following listing.

Lastly, "cost recovery" has now commenced from 1 January 2010 such that the cost of new submissions to list on the Pharmaceutical Benefits Scheme (PBS) will cost US\$119,500.00 for major and US\$12,500.00 for minor submissions. There will be no refunds for rejected submissions and re-submissions will be charged as new submissions.

China

The healthcare reforms in China are taking shape and in the last quarter of 2009 multiple policies and guidance have been issued.

On 17 August 2009, China's Ministry of Health (MoH) released the "National Essential Drug List" (NEDL) and on 30 November 2009, the Ministry of Human Resources and Social Security (MoHRSS) released the new "National Drug Reimbursement List" (NDRL) under the Basic Medical Insurance (BMI), Occupational Injuries Insurance (OII) and Maternity Insurance (MI) Programs.

The release of the NEDL and the NDRL are expected to mainly benefit Traditional Chinese Medicine enterprises and generic drug manufacturers, who feature their drugs on the lists rather than innovative drug-oriented producers. MNCs may need to make a choice in their business strategy in China to either continue to focus on the more affluent coastal regions and tier 1 and tier 2 cities or to broaden their product portfolio with low cost drugs and build up capacity to tap into the huge, fast growing volume-based market in the rural areas.

The long-anticipated reform policy, "Opinions on Reforming Drug Pricing and Medical Service Pricing Mechanisms" was jointly released by three government agencies, the Ministry of Health (MOH), National Development and Reform Commission (NDRC), and Ministry of Human Resource and Social Security (MOHRSS) on 23 November 2009. The five focus areas of the reform policy are as follows:

Pricing & Reimbursement

China

1. Improve drug pricing administration

The government is going to tighten the price regulation of basic medical insurance (BMI) reimbursable drug products and products covered by the state-funded immunisation. Prices for other drugs and medical services will be determined by the market, but the government will continue to introduce guidance prices for these products.

2. Rationalise drug prices

The government will not only set the upper limit for expensive drugs (as was done previously), but also control the lower limit of prices in order to prevent detrimental price competition in hospital drug purchase tenders (to ensure that manufacturers continue the production of these items). Existing prices for products of individual manufacturers will be adjusted in the case they have substantial price differences (with generics) in order to narrow the price gaps. However, differentiated pricing policies will be adopted for drugs which have significantly different quality standards and are covered under relevant government encouragement and supporting policies. In addition, the central government will gradually centralize the price-setting of drug products.

3. Encourage new drug innovation

The new policy will provide relatively higher sales margins and price stability over a relatively longer time period to truly innovative drug products (on the basis of therapeutic efficacy improvements). This will protect pharmaceutical companies and encourage them to develop innovative new drug. The government also plans to gradually introduce pharmaco-economics in the price-setting of substitutable drugs and innovative drug. Reasonable differential ratios will be maintained for different types of drugs.

4. Control drug distribution margins

Under the new policy, the government will begin to regulate profit margins in drug distribution and encourage consolidation of the sector. While the distribution margins of drugs will be gradually reduced, ceilings will be set for distribution margins and differentiated margins will be adopted for high-priced and low-priced drugs. The margins for high-priced drugs will be lower and those for low-priced drugs will be higher. These measures are encouraging consolidation in the pharmaceutical distribution sector in order to achieve economies of scale, reduce costs and to lower distribution expenditures.

5. Reform the policy for drug sales margins of medical institutions

In order to meet the requirement of “separating medical institutions from drug sales”, the compensation mechanisms for medical institutions will be reformed. During the transition period of reform, the drug sales margins of medical institutions must not exceed 15% and it will be reduced gradually. High-priced and low-priced drugs will have different margins. When necessary, maximum margins can be set on high-priced drugs. The reduced revenues of public hospitals from drug sales will be compensated by raising the price of medical services (such as diagnosis, treatment, nursing, and surgery) and introducing the “pharmacy service fee”.

Pricing & Reimbursement

Japan

The Japanese healthcare system covers all the residents of Japan, and under this system prices of pharmaceutical products (NHI price: National Health Insurance price) and fees for medical care services are set by the government of Japan. These prices and fees are reconsidered and revised every 2 years, and the latest revision is effective from fiscal year 2010 (from April 2010 to March 2011). For pharmaceutical products, prices have been reduced by 5.8% on an average, on the other hand fees for medical services have gone up by 1.55%.

Japan has been faced with the challenges of an ageing population and financial difficulties. This has given rise to a concern around the sustainability of the universal healthcare system of Japan, and therefore the Ministry of Health, Labour and Welfare of Japan is taking steps to control the growth in healthcare expenses. One such action has been the reduction in the NHI prices at each revision date.

The market in Japan has also been suffering from drug lags (of the top 100 pharmaceutical products (by sales) in the world, are yet to be launched in Japan). Long and complicated trials and reviews for approvals have been the main reasons for these drug lags. In addition pharmaceutical companies in Japan have also been asking for incentives to encourage development of new products in Japan.

The background of these claims by pharmaceutical companies in Japan is the unique characteristics of the Japanese market and its change. Drugs take longer time to reach their sales peak and even the realized peak tends to be smaller than other developed countries. However, due to historically low penetration of generic products, pharmaceutical companies enjoy longer product life, which encourages pharmaceutical companies to invest on their R&D. This has been the principal characteristic of the Japanese

market, but this is changing. As mentioned, the Japanese healthcare system is expected to face financial difficulties in the future, and therefore the government of Japan is trying to encourage the use of generic products into the market in order to reduce the expenditure on medicines. This would effectively make the product life of innovator drugs shorter; and hence there is a strong argument for the government to support the industry. Stakeholders in the Japanese market need to provide incentives to develop products in Japan. Consequently, the drug pricing system was based on the U.S. system. The adoption of this newly modified system means that until the patent expires (up to 15 years) the government will not lower the price of a new product, and once the patent expires, the price will be lowered drastically.

This idea originated from the large pharmaceutical companies, in the Japanese market, but this may turn out to be a burden for them. First, though this new system will provide immediate financial benefit to pharmaceutical companies as described above, the government is planning to force companies to pay the amount of money equivalent to the benefits they have obtained from this system if they do not develop a new drug to solve the drug lag problem as indicated by the regulator. This could pose a risk to pharmaceutical companies in Japan. Secondly to secure additional expenditure by this new system, the government decided to further reduce the NHI prices of pharmaceutical products for which the generic products have already been launched. For the Japanese market, as expressed above, long life of products has been one of the most important sources of revenues. To avoid the burden and enjoy the benefit of the new system, pharmaceutical companies will need to contribute to resolve the drug lag problem in Japan, and continue to launch new products.

Pricing & Reimbursement

Korea

Insurance Premiums Increase in 2010

Korea's National Health Insurance Corporation (NHIC) announced insurance premium increases for 2010.

The health insurance contribution rate will increase from 5.08% in 2009 to 5.33% in 2010. Long-term care contribution rates will increase from 4.79% in 2009 to 6.55% in 2010.

The NHIC cited the following factors for the increase in premiums:

- Expansion of health insurance coverage including:
 - decrease in co-payments for cardio and cerebral vascular diseases (10% to 5%), serious burns (20-60% to 5%) and tuberculosis (20-60% to 10%)
 - Increase in insurance benefits for anti-cancer, rare and incurable disease medications, medical equipment for people with disabilities, Magnetic Resonance Imaging (MRI)
 - Increase in support for healthcare costs for pregnancy and child birth.
- Increase in health insurance program medical fees
- Increase in number of beneficiaries of long-term health care from 280,000 in October of 2009 to 340,000 in 2010.
- Extension of long-term care insurance service.

Two Pharma Companies Fined for Rebates

The Korea Food & Drug Administration cited Kolon Pharma and Korea Pharma for providing illegal rebates to doctors and pharmacists. Kolon Pharma was ordered to discontinue sales of 169 products from a period of one month while Korea Pharma was ordered to discontinue sales for 50 products for one month. Both companies are anticipated to opt to pay fines of up to KRW 50 million rather than discontinue sales. There is currently a bill pending in the National Assembly which proposes to increase the maximum fine to KRW 100 million.

Regulatory

India

There is a huge concern about the circulation of counterfeit medicines without authenticated documents in India. There is both concern from consumers and panic by the pharma industry on the allegation of counterfeit drugs produced or circulated in the country.

However, last year in a survey carried out by the Central Drugs Standard Control Organization (CDSCO), prevalence of spurious drugs sold across pharmacy outlets in the country was estimated at 0.046 percent. While an earlier study by World Health Organisation (WHO) undertaken by the International Pharmaceutical Federation, found that 3.1 percent of drugs from India were counterfeit based on packaging and fake contents.

The survey conducted by CDSCO, involved the collection of 24,136 samples of 61 popular brands of oral, solid dosage formulations across nine therapeutic categories (anti-infective, anti-malarial, anti-tuberculosis, steroids, antihistamines, cardiovascular drugs, anti-diabetes, non-steroidal anti-inflammatory drugs and multivitamins) from each zone of CDSCO.

The Indian Government has even firmed up guidelines for its whistle-blower scheme, aimed at rewarding those who alert government agencies about firms and individuals manufacturing and selling counterfeit drugs and cosmetics. However, the country still lacks definition for counterfeit drugs in line with the WHO norms.

Source : CDSCO, Pharmabiz, Mint - The Wall Street Journal

Tax

Australia

Transfer Pricing and Thin Capitalisation

On 16 December 2009, the Australian Taxation Office (ATO) released Draft Taxation Ruling 2009/D6, concerning the interaction between Australia's transfer pricing and thin capitalisation rules, as well as a draft Law Administration Practice Statement, PS LA 3187 (draft), which expresses a practical "rule of thumb" to the effect that taxpayers will be at low risk if they price inter-company funding transactions at the parent company's usual rate of interest.

The key messages from TR 2009/D6 are that the transfer pricing rules can operate to adjust the pricing of inter-company debt (but not the amount of debt), even where a taxpayer's debt levels are within the Thin Capitalisation Safe Harbour of 3:1, and that the ATO will take into account the effects of parental affiliation when determining an arm's length interest rate. The ATO will have regard to an "arm's length amount of debt" when it considers whether the pricing of inter-company debt is arm's length. It is therefore in a taxpayer's best interests to consider the implications of what this means for them. For example, this might mean that it is prudent for a taxpayer to proactively determine what an arm's length amount of debt is for them in their circumstances.

The draft ruling also confirms the Commissioner's views that tax treaties confer a separate taxing power to the domestic transfer pricing rules (Division 13). However, the ATO concludes that this of no practical consequence because there should not be any

inconsistency between the application of Division 13 and the treaty. We expect differences of opinion on this point. In its PS LA 3187 (draft), the ATO expresses that taxpayers will be at low risk if they price inter-company funding transactions at the parent company's usual rate of interest, and stay within the debt levels allowed by the thin capitalisation safe harbour. This is intended to be an interim measure until the ATO resolves its position on various outstanding issues.

ATO Transfer Pricing Review Activity in 2010

The ATO has commenced its biggest transfer pricing compliance initiative for the large taxpayer market since the late 1990's. 2010 is predicted to herald a surge in transfer pricing activity from tax authorities all over the globe.

The ATO's key focus will include taxpayers with annual revenue greater than A\$250m with low profits or in losses and specifically, those with high risk related party transactions, such as funding and guarantee fee transactions, in addition to business restructuring including Intellectual Property (IP) transactions. The ATO has indicated that this project will continue to run for a period of up to 4 years and it expects that 100 of the 140 questionnaires to be issued, will result in more formal risk assessments of which 30 to 40 will lead to an audit or an Advance Pricing Arrangement (APA).

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Tax

Indonesia

Deductibility of Promotional Expenses – Consistent Rules for All Taxpayers

Promotional expenses – what has changed?

- The Ministry of Finance (MoF) has recently introduced regulation PMK.02/PMK.03/2010 which now provides clearer guidelines for all taxpayers on the deductibility of promotional expenses.
- The new regulation also revokes the old regulation which placed a cap on the deductibility of promotional expenses for taxpayers in the pharmaceutical industry. This new regulation applies retrospectively from 1 January 2009.
- Detailed record keeping and reporting procedures are now required for all taxpayers, which may in fact be detrimental to some taxpayers that cannot adequately support the deduction of promotional expenses.
- Going forward, taxpayers should revisit their information collection processes to ensure they can properly justify the deduction of promotional expenses in accordance with the new requirements.

Good News for the Pharmaceutical Industry

The new regulation also revokes PMK.104/PMK.03/2009, which placed a cap on the deductibility of promotional expenses for taxpayers in the pharmaceutical industry, putting them back on a level playing field with all other taxpayers in respect of such expenses.

Importantly for taxpayers in the pharmaceutical industries that are early balancers, the removal of the cap on deductions for promotional expenses may present an opportunity for them to revise their Article 25 installment amount, for the remainder of their financial year. Given this new regulation applies retrospectively, those early balancers may still be in a position to manage their forthcoming installment payments in such a way as to limit any overpayment of tax for the full year.

Managing installment payments in this manner, to reduce the risk of overpayment, could help avoid the need to seek a refund of any overpaid tax in the future.

Recent Transfer Pricing Developments

The Indonesian Tax Office (ITO) has made several moves in recent months which have increased the level of focus on enforcing compliance with transfer pricing rules. The steps the ITO has taken include:

- Increasing the focus on transfer pricing issues in tax audits and non-audit questionnaires issued to taxpayers.
- Introducing a new related party disclosure form to be filed with corporate income tax returns, which now requires the disclosure of a taxpayer's related party transactions and confirmation of whether transfer pricing documentation is available to test whether those transactions have been conducted at arm's length.
- A regulation for internal tax office use which contains profitability ratio benchmarking for a number of different industries.

Tax

Indonesia

These latest developments in transfer pricing compliance reinforce the ITO's continued focus in this area after introducing mandatory documentation rules in December 2007 and formally adopting the Organisation for Economic Co-operation and Development (OECD) pricing methods as acceptable methods by which to accept or review transfer prices into the Indonesian taxation law. The key development include:

- 1. Increase in TP-focused investigations**
- 2. New corporate income tax return disclosure form**
- 3. Industry-based profitability benchmarking**

What should companies do?

In light of the ITO's current level of focus on transfer pricing, all multinationals with operations in Indonesia should review their readiness to respond to a transfer pricing investigation by the tax office. To be able to complete the new disclosure form and defend any future transfer pricing audit by the ITO, it is critical to prepare robust transfer pricing documentation which applies OECD principles to test whether the company's related party transactions have been done at arm's length.

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Japan

Summary of APA Report

National Tax Agency (NTA) has published "Advance Pricing Agreement (APA) report" for the period from 1 July 2008 to 30 June 2009, which shows the statistical data on the APA requests filed with the Japanese Tax Authority. In accordance with the APA report, 130 out of 174 requests filed for the mutual agreement procedure, were for the APA program, which was the largest number to date. In addition, 91 out of existing APA requests including the carried-forward ones have already been finalized during the administrative year.

The report shows that the APA requests with the TNMM (Transactional Net Margin Method) resulted in 61 agreements which was exceptionally high in comparison with the other transfer pricing methods (e.g. only 5 for the CUP method). From the regional perspective, the top three regions for the agreements were US, Australia and Korea. Historically, the US and Australia were the two major countries party to mutual agreements, but as a current trend, the mutual agreements with Asian countries have been increasing. The number of the counter-part countries for the mutual agreements has also increased from 4 countries in 10 years ago to 18 countries. The average processing period was 23.7 months per a request.

PwC views that the APA procedures have been more efficient and effective to manage the tax risk exposure. As an English version of the APA report is expected to be published by NTA in due course, MNCs investing in Japan should re-visit and evaluate effectiveness of the APA procedures.

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Tax

Korea

Extended Scope of Value-Added Tax Exemption for Medications for Rare Diseases

The Korean VAT Law (VATL) and Special Tax Treatment Control Law (STTCL) were amended on 21 September 2009 to include the import and sale of medication and vaccine to cure influenza. A virus subtype H1N1 (H1N1) under the scope of items exempt from VAT.

Under the above amendment of VATL, the import of medications and vaccines exempt from customs duty per the amended Korean Customs Act (KCA) shall be exempt from import VAT. The output VAT shall also be exempt according to the above amendment of STTCL for the sale of eight additional medications to cure rare diseases, including H1N1.

The amended tax law is unclear, however, as to whether the input VAT credit paid by the taxpayer for the medications and vaccines imported or purchased before the amendment date can be claimed by the taxpayers when those goods are sold with output VAT exemption after the said amendment date. Several pharmaceutical companies are currently in the process of requesting tax rulings for a clear interpretation of this issue.

The amendments to the VATL and STTCL shall be effective for qualified medications supplied on or after 21 September 2009 (until 31 December 2010 for influenza A virus subtype H1N1).

Government to Introduce New Tax Incentives to Encourage Development of New Drugs

During a weekly meeting held in February, Finance Minister Yoon Jeung-Hyun announced that the government would introduce research and development related tax incentives to pharmaceutical companies to encourage the development of new drugs. While citing the high costs and time required to develop new drugs, Minister Yoon expressed optimism that new drug development would make significant contributions to Korea's social and economic growth. Minister Yoon also called on the pharmaceutical industry to improve its sales practices.

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Malaysia

Goods and Services Tax on the Horizon

Concerted moves are being made by the Malaysian Government to implement a Goods and Services Tax (GST) regime in an effort to widen the tax base in Malaysia.

After the initial proposed implementation date of 1 January 2007 was postponed indefinitely, the introduction of GST has now gained momentum with the tabling of the GST Bill in Parliament on 16 December 2009. Indications are for GST to be implemented by mid-2011. The tax would replace the current service tax and sales tax regimes. The proposed GST rate is 4%.

While no specific rules or guidelines have been proposed to govern the pharmaceutical industry at this stage, it has been proposed that the provision of healthcare services by both Government and private hospitals and clinics, will be exempt from GST. The scope of healthcare services would include medical, dental, pharmacy, accommodation, facilities and other related services.

However, the manufacturing, trading, marketing and distribution of pharmaceutical products would likely be considered as taxable.

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Tax

Taiwan

Withholding Tax Exemption For General & Administrative Expenses Allocated to a Taiwan Branch is Now Available for Allocation from Regional Headquarters

Under Article 70 of the Assessment Rules of Profit-Seeking Enterprise Income Tax ("Assessment Rules"), the allocation of head office's general & administrative expenses from a head office to a Taiwan branch will be eligible for tax deduction, without withholding tax implication if certain conditions are met. On 14 September 2009, the Ministry of Finance (MOF) announced the revisions to the Assessment Rules in a tax ruling Tai-Tsai-Shuei No. 09804561280 to extend its applicability for a head office to a regional headquarters. In this context, a Taiwan branch may also claim tax deduction on allocation of regional headquarters' general & administrative expenses without withholding tax implication if the allocation is from a qualified regional headquarters. It is worth noting that the allocation methodologies and required documentation set out in the Assessment Rules.

Thin Capitalisation Rule Passed by the Executive Yuan

On 19 November 2009, the Executive Yuan passed a draft amendment to the Income Tax Act (ITA) which included the thin capitalisation rule. In accordance with the draft amendment, the excess of interest expense on related party loans beyond the prescribed debt-to-equity ratio (to be determined) shall not be tax deductible. The proposed thin capitalisation rule shall generally apply to companies engaged in related party loans other than banks, credit cooperatives, financial holding companies, bills finance companies, insurance companies and securities companies.

In light of the above, pharma companies with related party loans and those considering such financing options should not consider alternative financing strategies in view of the anticipated thin capitalisation rule.

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