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Asia-Pacific Pharma Newsletter

Keeping you up-to-date with the latest developments in the industry

News and analysis by PwC industry specialists for pharmaceutical, biotechnology, medical device, diagnostic and healthcare companies

Issue 4, December 2010

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Editor's Note

The PwC Pharma & Life Sciences specialists are pleased to provide you with the fourth issue of our Asia-Pacific pharmaceutical industry newsletter.

In this issue, we present two special reports. The first introduces a PwC report on the Australian pharmaceutical industry. "Issues and opportunities in a time of change" looks at how the industry is seeing significant and accelerating change, and how companies will need to respond effectively in order to thrive in a radically changing and more intensively regulated market. The main findings of this recent industry survey in Australia are outlined in this newsletter.

Our second special report takes a look at how the Singapore government is making important efforts to attract the life sciences industry. From our previous newsletters, you would be aware of the initiatives the Singapore government is taking to support the Medical Devices industry. Now, it has announced a S$3.7 billion investment in the Biomedical Sciences Research and Development for 2011–2015. Read more about that in our special report.

In the compliance section, we take stock of what has happened since the speech on compliance delivered by the Department of Justice in the US a year ago.

Also, read about the key features of the memorandum of understanding agreed between the Australian government and Medicines Australia in the pricing and reimbursement section.

The Taiwanese government has implemented several policies and regulations to stimulate the development of the pharmaceutical and life sciences industry – and details are provided in the regulatory part of this newsletter.

New transfer pricing regulations have been issued in Australia, Indonesia and Japan and transfer pricing audits have intensified in Thailand. More information on this topic in the tax section.

We hope this newsletter is informative. If you would like to discuss any topic in greater detail, feel free to reach out to your PwC territory contact or the specialists credited in each article.

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Special Report

Issues and opportunities in a time of change for the Australian pharmaceutical industry

In a recent industry survey, we have found that the Australian pharmaceutical industry is seeing significant and accelerating change. Companies will need to respond effectively in order to thrive in a radically changing and more intensively regulated market. Our main findings:

Responding to reforms

Only 10% of respondents reported that they fully understood the implications of wider healthcare reforms on the pharmaceutical industry. Pharmaceutical companies will need to move quickly to improve their understanding of how the reforms will affect their business. Some of the likely changes the industry may have to address include bulk drug purchasing by groups of hospitals, extension of prescribing rights to nurses, and the evolution of multidisciplinary care.

Improving regulatory processes

Respondents were generally positive about the reforms to the regulatory regimes of the Therapeutic Goods Administration (TGA) and Pharmaceutical Benefits Advisory Committee (PBAC). However, respondents suggested that the differing regulatory regimes need to be harmonised, streamlined and made more transparent in order to improve access to drugs for patients.

Understanding price disclosure

Current and planned price disclosure rules will strongly affect the industry's fortunes. Less than 50% of respondents said they had a full understanding of the implications of price disclosure. To improve business certainty, companies will need to develop a better understanding of the reforms and respond decisively.

Meeting the generic challenge

Substitution rates of around 72% were confirmed by the industry. The dramatic increase in generic drug sales following the end of patent protection periods will over the next few years cause further disruption. More companies are expected to enter the generic market or expand their existing generic sales.

Greater compliance and increasing costs

Regulatory compliance is improving. However, in an era of ongoing regulatory reform, compliance costs are expected to rise.

Adapting to the rise of E-health

The rapidly emerging global trend towards E-health will radically change Australian healthcare. Respondents indicated that they still have not fully leveraged the use of E-health opportunities. Companies will need to adapt to advances such as the greater use of mobile technology by therapists and patients, the implementation of electronic medical records, and the advent of electronic prescribing.

Learning to collaborate more

With the growth in personalised medicine, the industry sees collaboration as critical for the future success of pharmaceutical companies. Australian companies, to date, have been slow in fully exploiting collaborative opportunities and would benefit from increased collaboration.

Promoting innovation

Survey respondents indicated that pharmaceutical companies need greater incentives to perform innovative R&D in Australia. The Federal Government will play a key role in creating incentives to risk capital and promoting Australia as a leading centre for R&D.

In the full report, we discuss the above issues and include comparisons with our results from the 2008 survey on the same topic.

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Special Report

Singapore's new plans support R&D in the biomedical sciences sector

The Singapore government has announced a S$3.7 billion investment in Biomedical Sciences (BMS) research and development for the period 2011–2015. This is 12% more than what the Government had put aside from 2006–2010.

At the same time, the Government has also set up the BMS Industry Partnership Office (IPO) to facilitate better integration of research performers across the BMS landscape and to continue to attract major R&D investments by multinational companies. Specifically, BMS IPO is intended to be a one-stop shop for BMS companies that wish to engage multiple Singapore agencies in research collaborations. These Singapore agencies, with their spectrum of capabilities that spans the entire value chain of basic BMS research and translational and clinical research (TCR), include research institutes operating under the aegis of the Agency for Science, Technology and Research (A*STAR), hospitals and universities.

Today, over 100 global biomedical sciences companies have leveraged Singapore's world-class research and manufacturing capabilities, excellent clinical and scientific infrastructure, competitive tax advantages, connectivity to Asian markets and pro-business environment to carry out strategic business operations, such as cutting-edge research, manufacturing and regional headquarters in Singapore. They include Abbott, GlaxoSmithKline, Merck Sharp & Dohme, Pfizer, Roche, Becton Dickinson, Medtronic and Siemens.

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Compliance

The US Justice Department (DOJ) is little over a year into a major sweep of the pharmaceutical industry for Foreign Corrupt Practices Act (FCPA) violations. (For details of a speech delivered at the Pharmaceutical Regulatory Compliance Congress' annual forum in November 2009 where Lanny Breuer, assistant attorney general and head of the DOJ's Criminal Division, shared the Department's plans to crackdown on Foreign Corrupt Practices Act (FCPA) violations across the pharma and medical device industries, please refer to issue 2 of this newsletter published in March 2010).

Although the investigations have been low profile so far, the effort has the potential to change the way drug and medical device companies do business.

Many big pharma companies have received letters of inquiry from the DOJ and the Securities and Exchange Commission (SEC) about their practices abroad.

There is a huge risk for big pharma and medical device companies who are growing exponentially in Asia and the interactions with healthcare professionals – in many of the Asian countries, they are government officials – are only increasing. Where the obvious risks are in the sales and marketing area while promoting drugs, attention is also going to the clinical trials and the interactions that companies have with the medical profession in this field. Patient safety is a clear motivation for the latter. Regulators fear that the effect of corruption in clinical trials abroad, where research is not as sophisticated or regulated as in the US, could lead to unsafe drugs entering the market.

Given the way of doing business in Asia is substantially different than in the west, companies need to be aware of the commercial practices in Asia and all the creative ways that sales reps come up with to meet their sales targets or CRAs convince doctors to participate in trials and enroll patients. Companies need to put incentive schemes together to drive the right behaviour and realise and accept the initial negative impact it might have on the numbers.

All Asia-Pacific territories, whether mature (Australia, Japan, New Zealand) or still developing (China, India, Philippines, Taiwan, Korea), have pharmaceutical industry associations that all have ethical codes – the basis for self regulation of the marketing of drugs. Most companies have translated these codes in SOPs to govern the way they operate, but difficulties are in implementing this in day-to-day activities.

Many of the large pharma players are actively cooperating with investigators to reduce liability. Companies that have not yet come under investigation should proactively investigate their exposure and self-report any violations that turn up. The DOJ expects pharma and life sciences companies to focus on their compliance efforts. Internal investigations and remedial measures may be costly. But the costs of not doing the responsible thing can be much higher.

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Australia

Improving industry compliance amidst ongoing regulatory change

In recent years, the Australian pharmaceutical industry has moved actively to improve transparency and standards in interactions between healthcare professionals and pharmaceutical companies. Contributing to this trend has been the strengthening of industry codes and the promotion and clear communication of regulatory requirements. As a result the levels of regulatory compliance in the pharmaceutical industry have been increasing recently.

Medicines Australia recently reported, in its 2009–2010 Annual Report, that adherence to its Code of Conduct (Code) had increased with a drop in new complaints from 59 in 2008–2009 to 39 in 2009–2010. Of the new complaints finalised in 2009–2010, 45% were found not to be in breach of the Code. Medicines Australia has also indicated that its members have continued to maintain a high level of compliance with the Code requirements for the provision of high-quality education and appropriate hospitality for health professionals.[1]

In order to improve the transparency of the generics medicines industry, the Generics Medicines Industry Association (GMIA) has also moved to strengthen its own industry code. On 3 November 2010, the Australian Consumer and Competition Commission granted conditional authorisation to the GMIA's Code of Practice for three years.[2] Authorisation provides protection from court action for conduct that might otherwise raise concerns under the competition provisions of the Trade Practices Act 1974.[3]

However, should the GMIA seek authorisation at the end of this time it will be important for the GMIA to demonstrate how the code has been enforced and how effective it has been in regulating the compliance of its members with the code. It is fair to say that pharmacists and generic companies will come under increasing scrutiny under the new code.

Respondents to a recent PwC industry survey indicated that the increasing levels of compliance are the result of greater investment in resources and systems, better training and greater emphasis on the issue from senior executives. Adherence to these principles will be essential to ensuring that industry participants continue to comply with the constantly changing industry standards and regulations.

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[1] Medicines Australia Annual Report 2009 – 2010, p 26.
[2] http://www.accc.gov.au/content/index.phtml/itemId/954565
[3] Trade Practices Act 1974 (Cth).

Mergers & Acquisitions

Japan

Mainly due to conservative nature of the industry, Japanese mid-size pharma companies have not actively participated in M&A. Large pharma companies like Takeda and Astellas, however, have taken to acquiring smaller pharma companies outside Japan to meet their strategic objectives.

At least 28 companies among the 43 member companies of Japan Generic Medicines Association were established more than 60 years ago. Most of them have neither acquired their competitors nor been acquired by other companies throughout their relatively long histories – underscoring their very limited experience in M&A.

However, this may be changing in the next couple of years. The generics market is growing in Japan, albeit not as quickly as expected. Besides, as a matter of course, Japanese companies are not exempted from patent expiries of products with large sales. Under these circumstances, some brand drug manufacturers have already expressed interest in the Biosimilar business. They can leverage their skills and infrastructure in the brand drug business to develop and promote Biosimilar while conventional generic manufactures do not have sufficient resources to embark on Biosimilar business. On the other hand, generic manufacturers know how they operate their business with minimum cost, which may be an advantage over brand drug manufacturers.

Brand drug manufactures and generic manufacturers can complement each other in order to establish a viable business model in the Japanese pharma market. The question now is who will show the courage to be the forerunner in this conservative world.

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Regulatory

China

Chinese Pharmacopoeia updated, with focus on international competitiveness

The ninth edition of the Chinese Pharmacopoeia (2010 edition) has been officially released by the State Food and Drug Administration (SFDA), effective as of 1 October 2010. The new edition is composed of three volumes (Chinese medicine, chemical drugs and biological products) and is the most comprehensive version to-date. It has over 4,600 entries in total, 1,300 new entries and has covered most items in the national essential drug list and the national reimbursement drug list.

Chinese Pharmacopoeia sets the country's legal standards for drug development, manufacturing, distribution, administration and management. The 2010 new edition has raised standards on drug safety and quality control and aims to improve the international competitiveness of drugs made in China. Furthermore, the new version also gives additional emphasis on drug quality and safety testing applying modern analytical technologies.

Source: SFDA; Wicon Pharma China; FiercePharma Manufacturing

2009 Annual Report on Drug Registration Approval released by SFDA

The 2009 Annual Report on Drug Registration Approval has been released recently by the State Food and Drug Administration (SFDA). The report shows that in 2009 a total of 6,428 drug registration applications were accepted, with about 80% from domestic applicants and 20% from overseas applicants. The SFDA approved 792 registration applications for new drugs, changing dosage forms, generic drugs and imported drugs in accordance with the new Provisions for Drug Registration. Among them, 69% were chemical drugs, 12% were traditional Chinese medicines and 4.8% were biological products. In addition, the number of multi-centre global trial applications and approvals increased significantly in China, with 132 such cases approved by the SFDA in 2009.

Source: SFDA; Wicon Pharma China

Threshold for criminal charges against drug counterfeiting to be lowered

An amendment that aims to increase charges against the manufacturing and sales of counterfeit drugs was included in the draft amendment to China's Criminal Law which was submitted for review by National People's Congress Standing Committee in August 2010.

Based on the current law, manufacturing and sales of counterfeit drugs is not considered a crime unless consumer health is seriously harmed. The new amendment proposes that any kind of drug counterfeiting should be defined as crime, regardless of the degree of health issues it causes. The amendment demonstrates how the Chinese government is firming up its stance in its fight against counterfeit medicine and strengthening regulation on drug safety to better protect public health.

Source: Wicon Pharma China; people.com.cn

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India

India's Central Drug Standard Control Organization releases drafts of medical device regulatory applications

In India, the Central Drugs Standard Control Organization (CDSCO) is in charge of the Drug and Cosmetics Act (DCA) under which at least 14 categories of medical devices are listed as drugs. The medical devices considered as drugs and the "notified medical devices" are currently regulated under the DCA.

India continues to signal that new medical device regulations are on the horizon. On 4 August 2010, the CDSCO published on their website, a draft of two different medical device-related documents: the "Guidance Document on Common Submission Format for Registration of Medical Devices in India" (that gives general instructions on how to apply for medical device registration), and the "Requirements for Conducting Clinical Trial(s) of Medical Devices in India." (that similarly provides basic instructions on how to apply for clinical trials for medical devices).

Source: Pacific Bridge medical: http://www.pacificbridgemedical.com/newsletter/article.php?id=491

Indian Cabinet approves draft trade pact with Japan

The Indian government has approved a draft of India's free trade agreement with Japan, which is likely to be signed during Prime Minister Manmohan Singh's visit to Tokyo. The comprehensive Economic Partnership Agreement (EPA) will cover about 90% of the bilateral trade between India and Japan, most importantly paving the way for Indian pharmaceuticals to gain access to the highly regulated Japanese market. Along with an expanded venue for India's growing generic pharma industry, thousands of other products ranging from steel and apparel to machinery will be traded between the countries, either without duty or at substantially reduced tariffs.

Source: The Indian Express: http://www.indianexpress.com/news/cabinet-approves-draft-of-trade-pact-with-japan/696794/

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Taiwan

The Taiwan government has proposed and implemented several policies and regulations to stimulate the development of pharma and life science industry in 2010.

International cooperation

a. Taiwan and China

The Taiwan government is looking to expand the potential market for the biotechnology and pharmaceutical industry. After the signing of Economic Cooperation Framework Agreement (ECFA) early this year, the governments of Taiwan and China have agreed to hold further discussions regarding the opportunities to achieve a win-win situation for cooperation on both sides of the strait. The next round of Chiang-Chen Talks to be held in December, the highest level of communication between Taiwan and China, is expected to focus on cooperation on medical and health matters. The topics may cover the collaborative efforts on new drug R&D, simplification of clinical tests and the import process of medical equipment, business cooperation of Chinese herbs and health supplements. Taiwan anticipates to establish a mutually agreeable clinical or product standard to accelerate the process of introducing medical related products in the Greater Chinese market.

b. Taiwan and Australia

Following past years' efforts, Taiwan and Australia have finally entered into the "Memorandum of Understanding Concerning Cooperation in the Regulation of Therapeutic Goods" this April. The aim of signing this memorandum is to continue to develop cooperation on the regulations of drug administration between Taiwan and Australia, so as to facilitate the development of the domestic biotechnology industry and then the expansion of the domestic biotechnology industry in the global market.

The key scope of the memorandum is to facilitate the exchange of information and documents relating to drug administration and explore the potential for collaborative activities. The related information and documents include policies, practices, standards, manufacturing quality, laboratory testing, pre-market assessments, post-market surveillance, market compliance and requirements for the regulation of drugs, while the collaborative activities cover the exchange of personnel, observing inspections and the planning of joint workshops, training, conferences and related meetings. In the long run, industries would benefit from the harmonisation of legal systems and the sharing of information between both parties.

Acceleration of drug application process

The Taiwan Food and Drug Administration (TFDA) of the Department of Health (DOH) made an advance announcement in May about the "amended draft of the Provisions Governing the Registration and Market Approval of Drugs", which amends a total of 40 Articles as a result of public feedback from experts, scholars, pharmaceutical manufacturers, and other stakeholders. Without impeding the quality, safety and therapeutic effect of drugs, most of the amendments are about simplification of application procedures and loosening of regulations for drug registration and market approval. Regulations loosened are mainly applicable to new drugs, radioactive drugs, allergenic drugs and drugs for export, in order to accelerate the process to sell new drugs in the market and promote the export of domestically manufactured drugs.

TFDA has also simplified the drug review procedures for imported generic drugs and exempted those drugs from the preliminary review for registration and market approval processes since this April. Imported generic drugs will be reviewed under the same conditions as domestically made generic drugs, which may substantially speed up the application submitted by foreign pharmaceutical manufacturers.

Newly announced "Statute of Human Biobank Management (Statute)"

Immediately after the Statute enacted this early year, the Human Biobank Information Security Regulation has been made effective in August. The latter aims to strengthen the safety of biobanks database and ensure that participants' rights and privacy are protected. Due to a lack of rules, divergent disputes abounded about the establishment and adoption of biobanks for the collection of human biological specimens. For example, an academic researcher or a physician collected biospecimens from native Taiwanese. Although they claimed that the collections were for research only, human rights groups condemned the collection as an invasion of human rights. As a result, the Taiwan government recognised the need for biobanks to be regulated. The Statute and its related regulation were created to achieve the goal of protecting the nation's privacy and promoting the development of medical science in more effective ways.

According to the Statute, only government, medical, academic, and research institutes are competent to establish biobank databases. In terms of the collecting of organisms, the participants should be informed of the relevant matters by reasonable means, and the collecting of organisms may be conducted only after obtaining the written consent of participants. The related information, including the organisms and its derivatives are limited to the purposes of biological and medical research. The regulation, which is to complement the Statute with regard to the protection of biobanks security, will provide more complete guidance for biobanks owners to comply with, as far as information security is concerned. For example, according to the regulation, concerning the personnel management, the security assessment is required and the database management personnel and researchers may not serve concurrently. In addition, the authorisation protocol of access to the biobanks should be established and all log files should be preserved for a certain period. Moreover, the biobank owners should establish annual security auditing programmes and the project auditing will be conducted as and when necessary.

To sum up, the Taiwan government has demonstrated a determination to promote the pharma and life sciences industry and has committed to injecting more resources and introducing a supportive regulatory environment for the industry. It is a welcome move that indicates Taiwan is progressing towards building a more conducive environment for the pharma and life sciences industry as a whole.

The article was prepared by referring to the sources of the websites of Department of Health, Executive Yuan and Science & Technology Law Center of Ministry of Economic Affairs, R.O.C. (Taiwan).

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Pricing & Reimbursement

Australia

Current position in relation to proposed amendments

The House of Representatives in Australia has now debated, voted and passed the National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010. The Bill will not become law, however, until passed by the Senate who are debating the Bill for a second time.

At the time of writing, the Bill incorporates an agreement reached between the Australian government and Medicines Australia, the peak pharmaceutical originator association that was enshrined in a memorandum of understanding ("MOU") dated 6 May 2010 and announced in the Federal Budget in Australia on 11 May 2010.

The MOU aims to provide for a more efficient pharmaceutical benefit scheme ("PBS") by enhancing certainty for the industry and by implementing regulatory reforms and delivering almost A$1.9 billion in savings to the PBS over five years.

The key features of the MOU are:

- A four-year agreement during which originator drugs on Formulary 1 ("F1") will not be subject to different price settings and therapeutic groups.
- The government will receive price cuts on Formulary 2 (generic and off-patent drugs) ("F2") and an accelerated and expanded price disclosure programme.
- The Government will achieve bankable savings of A$1.9 billion over the five-year forward estimate period.

The A$1.9 billion in savings is to be achieved through the following policy measures requiring legislative amendments:

- From 1 February 2011, the price reduction in when a medicine moving from F1 to F2 following the first generic introduced, increases from 12.5% to 16%.
- From 1 February 2011, a 2% price reduction to all medicines listed on F2A as at 11 October 2010 will be applied.
- From 1 February 2011, a 5% price reduction to all medicines listed on F2T as at 11 October 2010 will be applied.
- From 1 December 2010, a strengthened price disclosure regime will apply to all medicines listed on F2 with a guaranteed 23% weighted average price reduction for the first round of price disclosure, concluding in April 2012.

As the Minister for Health and Ageing, Minister Roxon noted in the second reading speech:

"Price disclosure allows market forces to play a part in PBS pricing. Competition between pharmaceutical companies to gain market share for their products can result in significant discounting to pharmacies. The actual price of a brand of medicine may be much less than the Government's PBS subsidy price…plus disclosure ensures that over time, Government prices reflect more closely actual market prices. This is a fairer deal for taxpayers."

These changes will require companies to disclose to the government the actual net ex-manufacturer's price at which all PBS funded medicines on the F2 formulary are sold. This will mean that there will be an increase in the number of brands required to disclose from currently approximately 220 to nearly 2000 brands when price disclosure becomes mandatory. The originators, through Medicines Australia, are supporting the Bill (although a number of its members will suffer price cuts) in order to attain a four-year period of pricing stability as part of the MOU. Whereas the Generics Medicines Industry Association ("GMIA") has vigorously challenged the Bill on the basis that further price cuts are unnecessary as the earlier PBS reforms initiated under the previous Howard Government in 2007, by the then Minister for Health, Tony Abbott, will achieve much greater savings than the government initially envisaged of A$3 billion.

In PwC's independent assessment undertaken for the government that was tabled in Parliament in February this year, it was estimated that total savings under the 2007 PBS Reforms would likely be between A$4.2 billion and A$6.6 billion over the 10-year period to 2017/18.

The Senate inquiry now has to weigh up the competing interests in determining whether to support all or parts of the Bill while promoting an efficient and sustainable PBS.

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Japan

The Ministry of Health, Labour and Welfare (MHLW) announced in 2007 an "Action program to promote the use of generic drugs" and set a 30% (volume) as a target penetration rate of generic drugs by 2012. Both generic drug manufacturers and the MHLW have taken action to promote the use of generic drugs in Japan in cooperation with medical service providers.

Generic drug manufacturers have worked on a stable supply of their products, provision of information on product quality, and preparation of an interview form. The MHLW has prepared a leaflet and a pamphlet for improving health consumers' awareness of generic drugs and these materials have been handed out to patients at pharmacies. The MHLW has also supported prefectural governments in setting up committees and/or working groups to promote the use of generic drugs.

In addition to these initiatives, the MHLW implemented the following changes in the healthcare insurance system:

- Pharmacies that dispense high volumes of generic drugs will receive higher dispensing fees.
- Pharmacists can dispense a generic product whose strength is different from the drug on the prescription or a generic product of a different dosage form from the drug on the prescription, at their discretion under pre-defined conditions.
- Medical institutes that aggressively use generic drugs will enjoy additional benefits in medical service fees.

Notwithstanding this, further actions are deemed necessary to meet the target since the current penetration remains relatively low at around 20.2%. It is proposed to reduce the price of some branded drugs that have been on the NHI pricelist for a long period of time, as this is one of the reasons it is argued that there has been low penetration of generics. As a result of this reduction, the price of some branded drugs will be reduced to a rate comparable to its generic equivalent. This price reduction is a trade-off to allow the NHI price of most other innovative drugs to remain higher for a longer period of time. It is seen that the price cuts themselves should be considered favourable from the perspective of optimising drug expenditure while allowing generic drugs to penetrate the local market.

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China

New drug pricing guidance has been drafted by China's National Development and Reform Commission (NDRC). The new "Measures for the Administration of Drug Price (Draft)" was released by NDRC in June 2010 and feedback from pharmaceutical companies and industry associations have been collected.

First, according to the new guidance, government authorities will set prices or issue guidance prices for all drugs on the national reimbursement drug list. Based on product category and degree of innovation, various standards are listed which set limits on the expense rate and profit margin that will be considered by government for pricing. The differences between ex-manufacturer and retail prices are also restricted.

Secondly, the new policy phases out separate pricing for originator drugs, which will reduce the pricing benefits received by multinational pharmaceutical companies. There is also a proposal to cut drug prices before patents expire. To this end, government authorities will adjust the guidance prices of patented drugs every three years with at least a 6% reduction in price, and further price reductions should be at least 15% after patent expiration.

Thirdly, the new measures include price regulation that intends to favour first time generic drugs. According to the Draft, for the first five years after a first time generic is listed, government guidance prices for the first three generic drugs will be based on the originator's government guidance price with each follow-on drug receiving a 10% price reduction. If the originator is not listed in the Chinese market, government guidance price for the first time generic drug will be determined based on cost.

The final drug pricing guidance is expected to be released by the end of this year after taking into account the opinions from multiple perspectives. The enforcement of the new guidance may intensify the downward pressure on drug prices in China and hit profit margins of drug makers and drug distributors. Companies with stronger flexibility in cost adjustment will be better suited to withstand the negative impact on profit.

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Taiwan

2G NHI reforms may alter drug price gaps

The Taiwan government has put forward legislative plans to reform its National Health Insurance (NHI) system, due to mounting financial losses and to introduce a second-generation programme. A final version of the 2G NHI bill is expected to be released before the end of 2010 and will primarily focus on reforming the calculation of premiums. Other changes are also anticipated to include measures to curb the drug price gap ("black hole"), which is a major bone of contention among pharmaceutical manufacturers in Taiwan.

The gap refers to the difference between the amount hospitals or clinics actually pay for drugs after discount and the much higher figure used by the NHI regulator, the Bureau of National Health Insurance (BNHI), to reimburse them. Taiwanese legislation stipulates that drugs should be reimbursed at actual transaction costs but this is not enforced, with the result that the price gap continues, as each downward reimbursement price adjustment just sets off another round of demands for discounts.

The return on investment for pharmaceutical companies in Taiwan has been steadily declining in recent years due to the government's policy of conducting periodic Price Volume Surveys (PVS), followed by substantial cuts in reimbursement prices. In the six rounds of price cuts carried out over the past decade (a seventh is now under planning), the magnitude of the price cuts has grown from NT$500 million (US$15.9 million) in 2000 to NT$20 billion (US$635 million) in 2009. As a result, Taiwan now has the lowest overall drug prices in any major market; on average the price of original drugs is only 28% that of the US.

Facing unprofitable price levels, manufacturers are frequently deterred from launching new and innovative drugs in Taiwan. In response, the International Research-based Pharmaceutical Manufacturers Association (IRPMA) in Taipei and its local counterparts have appealed to the government to reform the pricing and reimbursement system to ensure sound long-term incentives are introduced for innovative drugs. They have recommended that the government adopt an annual Drug Expenditure Target (DET) and negotiate expenditure growth rate, which would become the basis for any price adjustments in place of the compulsory PVS.

For the government, the advantages would be improved medical care for the population, better control over healthcare costs, and the ability to incentivise drugmakers to invest in Taiwan in support of its efforts to develop a domestic biotechnology industry. For pharmaceutical companies, use of the DET system in place of the PVS and their substantial price cuts would bring more stability to their business environment.

Taiwan's government has welcomed the industry's initiative and said it will consider the DET suggestion as part of planned regulatory changes to handle the drug price gap issue. However, it remains to be seen what measures will eventually be included in the final version of the 2G NHI bill.

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India

The Indian pharma market is tightly price-controlled. The National Pharmaceutical Pricing Authority (NPPA) controls drug prices through the Drug Price Control Order (DPCO), by prescribing a price ceiling for drugs containing any of the 74 chemicals that are under price control.

Recently, in one of the sharpest price cuts over the past few years, India's drug price regulator has reduced the prices of eight medicines sold by leading Indian pharma companies such as Cipla, Sun Pharma and Unichem by up to 85%. Categories of medication whose prices have been cut are vitamin capsules, antibiotics (Ciprofloxacin), blood pressure medication (Spironolactone and Torsemide) and anti-burn ointments.

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Australia

Interaction of thin capitalisation and transfer pricing

A long-awaited Taxation Ruling which sets out how the thin capitalisation provisions interact with the transfer pricing provisions was issued on 27 October 2010. TR 2010/7 formalises and expands on the views that the Australian Taxation Office (ATO) put forward in an earlier draft ruling. Key focus issues:

- The transfer pricing provisions apply independently of Australia's thin capitalisation provisions in determining the allowable deduction for a taxpayer's related party debt. The transfer pricing provisions are to be applied first to determine an arm's length interest rate. The arm's length rate is then applied to the actual amount of the loan.

- The ruling confirms that the transfer pricing methods for determining an arm's length consideration for related party debt arrangements from two earlier tax rulings and outlines a number of important observations on these. For one, it confirms the ATO's view that in setting an interest rate on a related party loan, it must "produce an outcome that makes commercial sense". However, there is no definition of what may constitute a commercially realistic arrangement.

- It is important to take into account 'parental affiliation' in determining the credit standing of the borrower for the purposes of setting an arm's length interest rate.

What does this mean for taxpayers?

It remains important for Australian companies with related party debt to substantiate the rate of interest on related party loans in the context of transfer pricing (especially those with inbound related party debt). Taxpayers should also be aware that they may need to defend both existing debt as well as any new arrangements, given the prospective and retrospective application of the ruling.

In performing a transfer pricing analysis of related party debt arrangements, companies are well advised to consider the impact of parental affiliation on the credit worthiness of the borrower. Also they should seek to demonstrate that the outcomes of the related party debt arrangements make commercial sense and that any legal documentation reflects commercial terms and is enforced in manner expected within third party financing arrangements.

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China

Corporate Income Tax Rules for corporate restructuring

China's Corporate Income Tax ("CIT") rules has been rather vague with relation to the tax treatment on corporate restructuring exercise since it took effect on 1 January 2008. With the release of the detailed tax implementation rules and administrative guidance of corporate restructuring, Caishui [2009] No.59 ("Circular 59") and SAT Public Notice [2010] No.4 ("Public Notice 4"), respectively in April 2009 and July 2010, taxpayers were given clarity and direction in this regard. Meanwhile, along with the new medical reform policies put into effect in China, it is expected a new wave of restructuring transactions between pharma companies, both within the territory of China or cross border, will be emerging in the coming years.

Circular 59 mainly sets out the applicable tax treatments on several types of corporate restructuring while Public Notice 4 provides the detailed guidance on documentation and procedural requirements for each type of restructuring covered under Circular 59. Although there are still quite a few issues left untouched to-date, Circular 59 in conjunction with Public Notice 4 provides a solid basis and platform to address and resolve the tax implications of corporate restructurings. Public Notice 4 has retrospective effect as from 1 January 2010. Furthermore, the guidelines included in this notice may also be applied to corporate restructurings that took place in 2008 and 2009.

As there was an impressive amount of pharma industry M&A deals in the Chinese market in 2008 and 2009, it is advisable for all the involving parties that have undergone corporate restructuring before the release of Public Notice 4 to assess the relevant impact of this circular and take immediate actions depending on their situations. With the clarifications provided by Public Note 4, companies contemplating M&A transactions in the future will have a better chance of a tax neutral treatment if they plan the restructuring carefully. If there are any unclear issues, clarification with the in-charge tax authorities at an early stage is recommended.

Click here to learn more about Public Notice 4 [http://www.pwccn.com/home/eng/chinatax_news_aug2010_15.html]

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Indonesia

New transfer pricing regulation for Indonesia

The Indonesian Directorate General of Taxation (DGT) has published a new transfer pricing regulation for Indonesian taxpayers. The new regulation (PER-43/PJ/2010) represents the first specific guidance to Indonesian taxpayers since transfer pricing documentation became mandatory from 1 January 2008. Significant portions of the regulation are based on OECD Transfer Pricing Guidelines. The effective date of the new regulation is 6 September 2010. The key impacts of PER-43 are summarised below.

Common business practice

An important feature of the compulsory transfer pricing documentation requirement in Indonesia is that a taxpayer's documentation must demonstrate that its transactions with related parties are consistent with the arm's length principle and with ordinary business practice. PER-43 does not elaborate on the common business practice aspect of the documentation requirement; rather, it embeds this within the discussion of the arm's length principle.

PwC's experience is that while the concepts of the arm's length principle and common business practice are related, in practice the Indonesian Tax Office (ITO) usually assesses compliance with these two principles separately in tax audits. The ITO's practical approach is to define common business practice as common practice of players within their industry. Because the regulation does not explicitly elaborate on the common business practice concept, it is uncertain how the ITO would apply this in practice.

Scope of regulation

The regulation applies to transactions between related parties which have an impact on the reporting of income or expenses for corporate tax purposes. This includes sale, transfer, purchase or acquisition of tangible goods and/or intangible goods, payment of rental fees, royalties, or other payments arising from the provision of or use of tangible or intangible property, income received or costs incurred for provision of or utilisation of services, cost allocation and the transfer or acquisition of property in the form of a financial instrument, as well as income or costs from financial instruments.

Implementation of the arm's length principle

PER-43 indicates that the arm's length principle should be implemented by the following steps:

a. Perform a comparability analysis & identify comparables;

b. Determine the most appropriate Transfer Pricing Method;

c. Apply the arm's length principle to the tested transactions based on the result of the comparability analysis and the selected transfer pricing method;

d. Document each step of the process in determining the arm's length price or profit.

Points of interest

- Guidance on how the comparability factors should be analysed is consistent with OECD Guidelines.
- Where both internal and external comparable data are available, internal comparable data must be used.
- The five OECD pricing methods are endorsed by the DGT and recognised in Indonesian tax law (Comparable Uncontrolled Price, Resale Price; Cost Plus; Profit Split and the Transactional Net Margin Method).
- A strict hierarchy applies for the selection of transfer pricing methods: CUP first, then the 'gross margin' methods (resale price or cost plus) and finally 'net profit' based methods (TNMM or profit split) may be applied
- There is specific guidance for services transactions, royalty transactions and those involving the transfer of IP.
- It does not address the frequently which taxpayers should update their TP documentation (annually is advisable).
- The DGT has the authority to re-determine the amount of related party income and expenses based on the taxpayer's own TP method and documentation or, where the documentation is insufficient, the DGT's own analysis.
- The DGT may make correlative adjustments - though PER-43 does not provide detailed guidance on the process taxpayers must follow to seek such adjustments.
- PER-43 notes that Mutual Agreement Procedures (MAPs) and Advance Pricing Arrangements (APAs) are available to taxpayers. We expect the ITO to issue detailed guidance on the process that taxpayers must follow on the MAPs and APAs.

Click here to learn more about Indonesia's new TP Rules [http://www.pwc.com/id/en/taxflash/assets/TaxFlash_2010-09.pdf]

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Japan

Implications of new Japanese Transfer Pricing (TP) documentation requirements for pharma companies

The 2010 Tax Reform package issued by the Japanese government outlined a number of proposals relating to transfer pricing, one of which was to clarify the scope of documents that may be requested during a transfer pricing examination.

Under Japanese transfer pricing law, the tax authorities have broad powers to recalculate a taxpayer's transfer prices as part of a transfer pricing audit if a taxpayer fails to provide documents "required to be presented or submitted" during the audit. For example, if the taxpayer fails to provide documents that are "necessary to calculate the arm's length price", they have the authority to use so-called "secret comparables" or, as a last resort, apply "taxation by estimation".

Prior to 1 April 2010, Japanese TP legislation did not specify what documents were "required to be presented or submitted" during a TP audit or the range of documents that may be "necessary to calculate the arm's length price". This made it difficult for entities to mitigate the risk of the examiners making an assessment based on "secret comparables" or "taxation by estimation". The new law explains what documents are covered by the phrase "documents required to be presented or submitted" and outlines two categories of documents:

(i) Those providing details of the taxpayer's foreign-related transactions, and

(ii) Those used by the taxpayer for the calculation of arm's length prices.

A detailed list of documents under each category is specified by Ministerial Ordinance.

From one perspective, the new documentation provisions will benefit all Japanese taxpayers, as there is now greater certainty and clarity over what documents are "required to be presented or submitted" during a TP audit. Therefore, as mentioned above, compliance with the new law would appear to provide taxpayers with a way to mitigate the risk of the tax examiners making an assessment based on "secret comparables" or, as a last resort, "taxation by estimation".

The burden of complying with the full list of documentation outlined in the 2010 tax reform is likely to be significant for most taxpayers. First, simply on the face of it, the list of documents and information to be provided is relatively detailed and comprehensive. Given the statute of limitations for transfer pricing in Japan is six years, many corporations may have difficulty preparing or locating the necessary information for transactions that occurred six years ago. A "best practice" takeaway arising out of the new legislation will be for taxpayers to institute a regular (ie annual) process of collating and storing the necessary documentation – particularly in relation to financial data, and any changes to the taxpayer's business or market environment.

One of the stated information requirements is the provision of detailed financial information of the overseas related party, both on a company total basis and specifically in relation to the transactions with Japan (i.e segmented P&L data). For foreign-owned taxpayers in Japan where such information is not used for setting transfer pricing under the particular transfer pricing methodology employed, it is likely to be extremely difficult to obtain the information necessary for compliance. Moreover, even for some Japanese-headquartered taxpayers, it may well be the case that the foreign-related party engages in multiple transactions with related parties. In such circumstances, providing segmented financial data in relation to transactions solely with Japan may well be artificial at best (if some arbitrary allocation of indirect expenses is adopted) or practically impossible at worst.

It is hoped that the tax authorities will take a reasonable and practical approach to the enforcement of the documentation requirements and the exercise of secret comparables or taxation by estimation. For taxpayers in industries that have been heavily audited in the past and/or historically have used secret comparables (such as the pharma industry), the luxury of such expectations may be not available. In these cases, the risks of non-compliance with the new requirements (even if this is inescapable and unavoidable) must be weighed and assessed more carefully. Furthermore, although designed to provide taxpayers with greater clarity, the new legislation may have the unintended consequence of steering more taxpayers to consider the possibility of an advance pricing arrangement for their cross border transactions.

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Taiwan

Reduced corporate income tax of 17% effective from 2010

Aimed to enhance Taiwan's international competitiveness, the corporate income tax rate has been lowered from 25% to 17% effective from fiscal year 2010. The tax cut also reflects the government's commitment to assist small and medium enterprises and traditional industries.

Following the expiry of the Statute for Upgrading Industries and reduction of tax incentives granted under the Statute for Innovating Industries, the Ministry of Finance believes this new reduced corporate tax rate enhances fairness in taxation and puts all industry sectors on equal footing in driving development. This is compared to the Statute for Upgrading Industries, which was seen to primarily benefit only high-tech industries.

The tax cut should in general reduce the effective tax rate of pharma companies. For those enjoying tax incentives under the Act for the Development of Biotech and New Pharmaceuticals Industry, the existing tax incentives continue to be applicable, which includes R&D and personnel training tax credits, etc. The Act for the Development of Biotech and New Pharmaceuticals Industry will expire on 31 December 2021.

For improved tax efficiency, pharma companies should consider the impact of the reduced tax rate as well as fully utilise the available tax incentives under the Act for the Development of Biotech and New Pharmaceuticals Industry.

Economic Cooperation Framework Agreement ("ECFA")

On 29 June 2010, the ECFA was signed by China and Taiwan, marking a significant milestone in the development of cross-strait relations. The agreement includes the following:

- Duty reduction for 539 Taiwanese items (including medical equipment) and 267 Chinese items (including chemicals) to take effect in three stages from 2011–2013. Pharma companies are encouraged to review the early harvest list to determine whether importation of low-tariff material can help them to reduce costs as well as offer more competitively-priced products and services into China.

- Enhancement of protection of IP rights, including mutual recognition of priority rights of patents, trademarks, copyrights and plant variety, establishment of a mechanism for coordination of law enforcement, as well as establishment of a communication platform to facilitate exchange of opinion and communication from both sides.

- Liberalisation of service sectors investing into both Taiwan and China markets. This includes China opening up its healthcare sector with Taiwanese investors being allowed to set up wholly-owned hospitals in the Hainan, Fujian, Guangdong, and Jiangsu provinces, as well as the city of Shanghai. Additionally, preferential treatment over the World Trade Organization will be granted to Taiwanese investors seeking permission to enter the Chinese market.

The signing of ECFA coupled with the tax cut to 17% introduces new opportunities for foreign pharma companies. With the steady increase in the demand of medical equipment in the China market, and the shifting of the supply chain to Asian countries, Taiwan may play an important role in exploring the expansion into the Chinese market. It may also prove beneficial for foreign pharma companies to reconsider setting up manufacturing plants in Taiwan to make use of the reduced corporate tax rate, tax incentives, and duty reduction. These new developments will make Taiwan an attractive connecting bridge for foreign pharma companies that want to invest in China through Taiwan, as well as those that are considering direct investments in Taiwan.

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Thailand

Increased emphasis on Transfer Pricing

The Thai Revenue Department (RD) has been putting greater emphasis on the pharmaceutical industry for transfer pricing audits. Many large multinational companies have been requested by the RD to respond to series of questions relating to their adopted transfer pricing policies and to submit Transfer Pricing documentation. Some have even been invited to testify in front of the Revenue officer in person. This action of the RD is expected to continue.

Although pharmaceutical operators in Thailand adopt business models ranging from limited risk entities to full risk entities, the RD is only familiar with the limited risk model and expects to see stable profit margins, and at similar levels, for all operators. In dealing with the RD on transfer pricing for this particular industry, the Transfer Pricing documentation should thoroughly explain the adopted business model and the operating results of operators should be consistent with the adopted business model.

For those who have not reviewed their transfer pricing policies and practice whether or not they are consistent with the adopted business models and functional profiles or those who have not prepared Transfer Pricing documentation, now may be the time to start.

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