

# *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*

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# Editor's Note

The PwC Pharma & Life Sciences experts are pleased to present you with the sixth issue of our Asia-Pacific pharmaceutical industry newsletter.

In this issue, we have two special reports for you. The first is on the Japanese health system and the initiatives to boost the use of generic drugs by medical institutes, pharmacies and Government in order to reach national targets.

The second special report is focused on Singaporean government's investment in health information technology and their biomedical science research capabilities.

In our compliance section we have included highlights of the latest developments in the adherence to standards regarding the manufacturing of medicines and the potential threat of counterfeit products.

Find out more about the push for creating a more affordable market of pharmaceuticals for the masses in the Asia Pacific in our pricing section.

Read about the latest news from multiple territories in the tax section covering R&D credits, WHT, Investment Allowances, tax incentives, GST, Thin Capitalisation and Transfer Pricing developments.

We trust that the information is of use to you and your organisation. If you would like to discuss any topic in more detail, feel free to reach out to your PwC territory contact on the last page, or the relevant experts listed after each article.

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# Special Report

## Japan

### Ministry of Health to drive increased generic substitution through the publication of successful case studies

The Ministry of Health, Labour and Welfare (MHLW) in Japan has determined that the share (by volume) of generic drugs in the Japanese market should increase to 30% by 2012. According to a survey conducted by the MHLW in 2010, the generic drug volume share was only 23.5%. In order to further accelerate the penetration of generic drugs, the MHLW has published a report based on case studies of local governments, medical institutes and pharmacies. The report outlines the best practices used by these bodies to increase generic substitution.

#### 1) Local Governments - Key Success Factors

In successful cases, local committees for enhancing the use of generic drugs have been set up by local governments. There are several common features of the committees achieving success. These include:

- Clearly defined objectives and roles of the committee that are maintained from the beginning to the end.
- A common understanding of the current status and a sharing of issues and solutions between members of the committee.
- Skills and capabilities of staff from the local government in planning and facilitating the committee are vital.
- Provision of practical support to medical institutes and pharmacies by the committees.
- Encouragement of large hospitals to use generic drugs since they have significant impact on the decision of medical institutes and pharmacies in the local area.
- Finally enhanced collaboration with health insurance societies. Often these companies have accumulated knowledge and data in cost-efficiency analysis.

#### 2) Medical Institutes - Points to Consider for Enhancing the Use of Generic Drugs

Successful case studies indicate that the director of pharmacy must drive adoption and use of generic drugs. However, management of the hospital must also support the pharmacy by clearly showing the vision to use generic drugs in their hospital.

In addition, the report highlights that implementation of an ordering system and use of generic names on prescriptions help the acceleration of the use of generic drugs

#### 3) Pharmacies - Points to Consider for Enhancing the Use of Generic Drugs

In the most successful cases, the report suggests, pharmacies and medical institutes have built trusting relationships. Where this occurs, pharmacists are able to dispense generic drugs, at their discretion. In these instances pharmacists have provided patients with information on drugs in order to support patients in deciding whether they should use generic drugs or not. Collaboration among nearby pharmacies is also important for them to use stocks efficiently.

#### PwC Comment

The above developments are important to generic pharmaceutical companies wanting to enter the Japanese market. Considering the aging population of Japan in the future, there should be great opportunity for them in this market. However, the penetration rate of generic drugs is still low compared with government targets, even after initiatives have been put in place. Further actions are therefore required to enhance the use of generic drugs.

Generic pharmaceutical companies seeking to enter the market will need to understand the specific needs of the Japanese market and take appropriate initiatives that respond to the requirements from the local market, that include provision of supports to stakeholders and provision of information requested by healthcare professionals.

Report: <http://www.mhlw.go.jp/bunya/iryuu/kouhatu-iyaku/>

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# Special Report

## Singapore

### One Singaporean, one health record

Information Technology (IT) is an important capability and a critical infrastructure in any modern healthcare sector. In recognition of this the Singaporean government has invested heavily in IT health. The National Electronic Health Record system (NEHR), which went live (phase 1) on 30 April 2011, aims to construct a patient-centric view for both healthcare workers and patients to make better care decisions. In particular, it seeks to integrate service delivery by making key medical information including patient demographics, allergies, clinical diagnoses, medication history, X-rays, laboratory investigations and discharge summaries fully exchangeable beyond acute hospitals to include the providers in the community.

MOHH, the corporate arm of Singapore's health ministry, was recently awarded a contract for the general practitioners' clinical management system (CMS) and electronic medical record system (EMR) to Singapore Telecommunication Ltd. About 50 general practitioners will be equipped with a standardised IT system during the first phase of implementation which is aimed at facilitating better quality and safer patient care in addition to optimizing clinic operations for better and more efficient patient service.

Singapore's commitment to developing an integrated healthcare system is evident through its heavy spending in health IT. It is hoped that patients will be able to move seamlessly across the healthcare system to get the most appropriate care in the most appropriate setting. The NEHR, CMS and EMR also hope to bring about cost savings for patients by eliminating duplicate or unnecessary tests, as well as reducing medication errors and adverse drug events that could result in unnecessary healthcare expenses.

### Strengthening Singapore's biomedical sciences (BMS) research capabilities

Singapore is planning to invest US\$2.8 million in BMS R&D from 2011 to 2015. This will be used to strengthen BMS research capabilities by improving the integration of research performers, both public and private. The BMS Industry Partnership Office (IPO) which is a multi-agency office set up in 2010 includes the National Medical Research Council (NRMC), Ministry of Health (MOH), the Agency for Science, Technology and Research (A\*STAR) and the Singapore Economic Development Board (EDB). This is the one-stop shop for BMS companies seeking to engage multiple

Singaporean agencies in research collaborations. The effects of this endeavour have resulted in several partnerships between public research performers and global corporations last year. Some notable partnerships include:

#### **Bayer**

Bayer Healthcare Singapore announced in December 2010 that it will invest an additional S\$14.5 million to R&D spending in Singapore to improve early diagnosis and treatment outcomes of cancer patients. Partnering with the National University of Singapore (NUS), National University Health System (NUHS), SingHealth and A\*STAR's Singapore Bioimaging Consortium (SBIC), Bayer HealthCare will launch five projects to investigate novel approaches in cancer treatments.

#### **GlaxoSmithKline (GSK)**

In October 2010, GSK announced the start of four new academic collaborations under the newly-established Academic Centre of Excellence (ACE) - a virtual community that promotes partnership between academics in Singapore and GSK's global Discovery Performance Units on early-stage drug discovery projects. The four projects will focus on areas such as ophthalmology, regenerative medicine & neuro-degeneration; and will also involve identifying new biomarkers, new model systems and mechanisms of action on innovative medicines.

#### **Roche**

In January 2010, Roche announced that it will be investing S\$130 million over five years to establish a Roche-Singapore Hub for Translational Medicine in Singapore - This will be Roche's first strategic translational and clinical research site in the world. The hub aims to enhance the understanding of how scientific advances from preclinical research can be transferred in practice to patients. The hub will bring together expertise from Singapore's scientific and medical institutions with Roche's capability in translational medicine and clinical development.

*Source: EDB publication "Singapore Investment News" April - June 2011 edition*

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# Compliance

## India

### India becomes fully compliant on Good Laboratory Practices

India has now achieved the status of full adherence to Good Laboratory Practices (GLP) certified by the Organisation of Economic Co-operation and Development (OECD). The 34-member OECD includes some of the world's most advanced countries such as the US, the UK, Canada, Australia, Sweden, Switzerland, Denmark, Hungary and Korea.

With this certificate India has become the third key emerging economy, after South Africa and Singapore, to join the OECD system for mutual acceptance of data in the assessment of chemicals. This will ensure that the results of non-clinical chemical safety tests done in India will be accepted in all other member countries. Earlier, manufacturers wanting to export pharmaceuticals and agrochemical products were forced to outsource testing overseas.

#### How this is done?

GLP-compliance certification is voluntary in nature. Test facilities or laboratories have to apply in the prescribed application form. At present there are 18 GLP-certified facilities in India out of which six are in pharmaceutical and agrochemical companies. Of the balance, 11 are contract research organizations and one is a government laboratory—housed at the National Institute of Pharmaceutical Education and Research in Mohali, Chandigarh, India.

After the application for GLP certification is received, a pre-inspection of the laboratory is carried out by the GLP inspectors, followed by a final inspection. GLP-compliance certification is valid for a period of three years and the GLP secretariat organizes annual surveillance and a re-assessment during the third year for maintaining the certification. This year the National GLP Compliance Monitoring Authority (NGCMA) has received 10 new applications from different parts of the country.

#### Why this is important?

This development demonstrates the confidence of the OECD council in India's compliance monitoring system and the transparent procedures and processes for monitoring and complaint redressal that are present in India.

Technical barriers to trade will be eliminated with this development. Companies will be able to save the cost of getting test data generated in GLP-compliant facilities outside the country. Indian test facilities will also save the expense of hosting multiple foreign inspection teams.

In the last five years exports of pharmaceutical products, pesticides, industrial chemicals, veterinary drugs, medical equipment, food and feed additives have grown substantially. Adherence to global quality standards will provide scope for further growth in pharmaceutical exports.

#### PwC Comment

The achievement of full adherence to GLP will provide Indian pharma companies with increased opportunities to export chemicals and other pharmaceutical products to markets around the world. For MNCs invested in India this provides increased scope to save costs by using test facilities located in India. As more GLP compliant laboratories come on line, the ability to access these benefits will only increase.

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# Compliance

## Singapore

### Fight against counterfeit medicine

Singapore's Health Sciences Authority (HSA) signed a Cooperation Agreement with the International Criminal Police Organization (Interpol) on 8 June 2011. The agreement allows the HSA to devise and tailor training programmes to build up law enforcement officers' capacity to identify and test for counterfeit medical products.

HSA hopes to share its expertise and experience, and facilitate effective information sharing and by coordination of regulatory enforcement actions among partner agencies.

The United States based Centre for Medicine in the Public Interest estimated that global sales of counterfeit drugs topped US\$75 billion last year, a 90 per cent rise in the past five years. According to a spokesperson from HSA, fake drugs account for about 30 per cent of all medication in Asia, Africa and Latin America. World Health Organisation's data further shows that many of the fake drugs are sold online to people looking for discounted medication.

Through the newly setup HSA Academy, HSA hopes to work closely with Interpol to build up greater anti-counterfeit awareness and knowledge base as well as capabilities and skills sets for the Asia Pacific region. The new Interpol Global Complex in Singapore, which would be fully operational in 2014, would be a key international platform for training in this area.

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## Taiwan

### Limited impact from DEHP scare on pharmaceutical companies

Taiwan's Food and Drug Administration reported in late May that an emulsifier used in various foods, beverages and medicines was discovered to contain di-ethyl-hexyl-phthalate (DEHP). DEHP is an industrial plasticiser which is banned as a food additive as it is known to be highly carcinogenic. The revelations sparked recalls of certain Taiwanese products and prompted tighter safety checks.

DEHP was seemingly added to clouding agents as a low-cost replacement for the more expensive palm oil to enrich the colour and enhance the consistency of ingredients.

The DEHP issue also raised public concerns about the safety of raw materials and excipients used in pharmaceutical products. Even though affected pharmaceutical products were in the minority, Taiwan's Department of Health ordered the local pharmaceutical industry in June to check its raw materials for toxic plasticisers as part of its efforts to restore public confidence.

Overall, the DEHP issue is not expected to have a serious negative impact on Taiwan made pharmaceutical products over the long term. In addition to swift rectifications, the government has tightened compliance controls on preventing similar scandals from occurring in the future.

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# Mergers & Acquisitions

## Korea

The Korean pharmaceutical industry is going through a phase of major transformation due to changes in its environment. The signing of the Free Trade Agreement between Korea and the United States (KORUS FTA) has had a profound effect on the pharmaceutical industry. Lower tariff barriers will act in favour of foreign multinational firms that have original rather than generic medical products. Moreover, recent government regulations have increased the need for innovation amongst domestic firms.

As a result, the recent developments have enhanced the Korean pharmaceutical industry's efficiency and domestic firms are taking various approaches to address the challenging market environment. The general types of actions taken include:

- Alliances between chemical drugs companies and biologics companies;
- Strategic partnerships of domestic and foreign pharmaceutical companies;
- Korean conglomerates expanding their pharmaceutical business or newly entering into the pharmaceutical market.

In terms of forming a strategic alliance or partnership, Tozai Holdings recently formed a strategic alliance with a chemical drugs company and biologics company. Tozai Holdings acquired 27.9% of Dongkoo Pharmaceutical company on February 22, 2011 for US\$4.76 million. The two companies will form a joint R&D scheme to develop new pharmaceutical products and pioneer new markets.

Ildong Pharmaceuticals has also formed a joint marketing agreement with Cowellmedi Co., a Korean bio venture company, on July 19, 2011. The companies expect that Cowell BMP's effectiveness and Ildong's marketing expertise will be able to create synergy effects.

Another example of a domestic firm expanding its territory with a foreign firm is Dong-A Pharmaceutical, the largest pharmaceutical company in Korea. Dong-A formed a strategic partnership with GSK, the 5<sup>th</sup> largest pharmaceutical company in the world. On March 18, 2011, GSK's CEO became a board member of Dong-A, which has strengthened the partnership between the two firms. In 2010, the two companies formed a partnership to enhance domestic operations and marketing. GSK invested KRW\$142.9 billion to acquire 9.9% of Dong-A and became the largest shareholder.

Samsung Electronics also has formed a Joint Venture with America's Quintiles, a bio-pharmaceutical services company, in February of 2010. The total equity amount of the newly established firm is estimated at KRW 300 billion. The companies have expressed their dedication to spend massively on R&D to develop new bio-pharmaceutical products.

Samsung Electronics also acquired Medison, a medical equipment manufacturer in Korea. Medison was the market leader (35% market share) in Korea and was ranked 5<sup>th</sup> globally (6.7%). Samsung Electronics completed the acquisition of 43.5% of Medison's shares in February 17, 2011.

### ***PwC Comment***

Due to the external factors such as FTA and tighter government regulations, market competition is getting tougher. Finding suitable strategic partners in the pharma, bio and chemical industries to penetrate and hold the market is an approach that many Korean pharma firms are considering. As more active movements from the domestic pharma industry are expected, existing and prospective Korean pharma companies may need to consider how they can collaborate with current pharmaceutical and biologic and chemical operators to maximise competitive advantage.

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# Mergers & Acquisitions

## Taiwan

To benefit from China's healthcare reform, Taiwanese pharmaceuticals & life sciences companies are well positioned to tap into the Mainland for this newly emerging market and associated new found opportunities. Specifically, the medical device sector is an area where Taiwanese manufacturers have cultivated long-established relationships with global players thanks to high quality and low prices. Nevertheless, the bio-pharmaceutical sector, after all the efforts and time devoted in research and development by the Taiwanese pharmaceutical and biotech companies, is gradually gaining recognition on the global stage. One could envisage business alliance or co-operation, transactions, and deal flows in the biopharm sector gaining momentum and becoming the leading flagships of the next major tide in the post-ECFA era.

As Chinese firms have been looking to secure and escalate their positions in the biopharm ecology and value chain by expediting and expanding new drug pipelines., the strong R&D capabilities and global reach of Taiwanese biotech companies could be first in line for potentially potent partnerships with those Chinese firms pursuing synergies. For example, TaiGen Biotechnology Co. runs a model that ties in Taiwan and China with global pharmaceutical companies. This model seamlessly illustrates the key values associated with Taiwanese companies:

- An innovative pipeline with full IP protection;
- A group of highly productive discovery scientists; and
- A clinical team that can conduct multinational trials and subsequently engineer rapid penetration to the local market at a more economic cost.

After several years of persistent endeavours, a number of Taiwanese companies have achieved breakthrough milestones for new drug development. They are diligently conducting multi-centre, multi-national U.S. FDA compliant clinical trials, targeting diseases of unmet medical needs in Asia, typically not the prime focus of large multinational pharmaceutical companies.

Aside from those companies focusing on new drug development, several Taiwanese niche Active Pharmaceutical Ingredients (API) and generic drug companies are also positioned to benefit from growing demand in API. Whether or not the abundant business opportunities fall on the laps depends on each individual company's capability and overall strategic direction. Taiwanese API specialists are broadly recognized for better quality, carving out

distinctive niches and differentiating themselves by 'picking the correct drug'. These drugs often display attributes of high-prices, high-technical barriers and high-margins. Prime examples are the anti-cancers portfolio of ScinoPharm Taiwan Ltd and the Taiwan FDA certified pipelines of Formosa Laboratories Inc.

### **PwC Comment**

Taiwanese pharma companies should consider investing in partnerships and suitable targets for downstream integration, predominantly dosage form drug manufacturers or companies with highly regarded distribution channels.

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# Regulatory

## India

### The Department of Pharmaceuticals, Government of India plans to make marketing code mandatory

On June 2 the Department of Pharmaceuticals (DoP) released a draft Code of Marketing Practices for the Indian pharmaceutical industry, to ban unethical marketing practices such as offering monetary benefits to physicians to control prescribing power.

The draft code outlines that no pecuniary advantages or 'benefits in kind' may be offered to persons qualified to prescribe. All promotional, scientific or professional meetings, and other similar events, sponsored by a pharma company, must be held at an appropriate venue in the country that is conducive to the main purpose of the event.

This code is self regulatory and will be made mandatory following a review by the government.

The code is similar to guidelines proposed by the Medical Council of India (MCI), a statutory body governing medical education and practicing doctors. Industry body, The Organisation of Pharmaceutical Producers of India (OPPI), which already has an existing code for its members, is in the process of comparing the draft with its own 'code of marketing practices'.

### Limited Liability Partnership ('LLP')

The Foreign Investment ('FDI') regulations has been recently liberalised to permit FDI in LLPs (with prior approval of the Foreign Investment Promotion Board ('FIPB')).

An LLP is a hybrid form of business entity combining the best features of Company and Partnership, having operational flexibility as well as distinct tax advantages. FDI in LLPs would be permitted only in sectors where 100% FDI is permitted under automatic route without any performance-linked conditions.

Currently, FDI in the pharma sector is permitted at 100% without any conditions. Given the potential tax advantages, it is critical to evaluate feasibility of LLP structure for any new venture as well as existing operations.

### 49% cap proposed by Department Industrial Policy and Promotion ('DIPP')

The government of India is considering imposing a restriction on the shareholding capacity of foreign firms in domestic operations. Currently, a foreign firm can have a 100% holding while operating in India.

DIPP has recently floated a discussion draft inviting public comments on the proposed move to put a cap on FDI in the pharma sector to 49%.

It seems that the move is an outcome of the recent acquisitions of several large Indian pharma companies by global giants. The list includes Japan's Daiichi acquiring control of Ranbaxy, the stake sale by the Piramals to Abbott, acquisition of Shanta Biotech. While, this has led to an increase in research base, efficiency of manufacturing firms and strong marketing capabilities, it has also led to a significant increase in drug prices.

The decision in this case has been triggered by concerns that the government would be unable to pursue its policy of affordable medicine and may find it tough to use manufacturing facilities in the country to cope with epidemics and health emergency.

If the proposal is accepted, apart from resulting in restrictions on MNC pharma companies, it would also mean that the LLP route would not be available to them.

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# Regulatory

## Taiwan

### Reforming Taiwan's healthcare system

Taiwan recently passed the 'second-generation' National Health Insurance Act. The new law should contribute substantially to restoring financial stability in Taiwan's healthcare system, but equally important for pharmaceutical companies is how it will be implemented.

For the pharmaceutical sector, the most noteworthy achievement of the new law was the inclusion of a mechanism for establishing a Drug Expenditure Target (DET) system, which aims to create a more stable pharmaceutical market for the benefit of patients, manufacturers and government.

Under DET, the Bureau of National Health Insurance (NHI) and industry representatives should annually agree on a growth target for drug expenditures under the NHI system for the coming year. This is based on the current year's actual amount, plus a reasonable growth percentage. If that target is exceeded, industry commits to making up the difference through various possible mechanisms.

Another provision in the new law also calls for the introduction of a Health Technology Assessment (HTA) system to monitor the cost-effectiveness of new drugs and medical devices. With the introduction of HTA reviews, companies may have more difficulty importing new products into Taiwan, needing to spend more time and money to demonstrate a product's efficacy and cost savings.

Although the effective date of the 2G NHI law has not yet been confirmed, industry representatives are urging the government to implement the new DET system as soon as possible to replace the planned Price Volume Survey (PVS) for 2011. This is largely due to the continuous post-PVS price cuts of recent years having been extremely disruptive to Taiwan's pharmaceutical industry.



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# Pricing

## India

### **In an attempt to make medicines affordable for masses, National Pharmaceutical Pricing Authority (NPPA) plans to start SMS-based service for sending brand names of drugs with prices**

As an initiative of the National Pharmaceutical Pricing Authority (NPPA), the country's drug price regulating body, an SMS based service that will provide patients with a list of all drugs containing that same ingredients as the similar to one they require. The patient can SMS the brand they are prescribed and an appropriate list of alternatives (along with their prices), will be provided in reply.

Since there is a significant difference in the price between the costliest and cheapest brand of drug, this program looks promising in reducing healthcare costs. This will allow consumers to choose the cheapest brand of a drug prescribed by doctors. It also seeks to lessen the impact of sales promotions through monetary benefits to control prescribing power of physicians.

The government has initiated two other projects to help mitigate rising healthcare costs. There are plans to set up 3,000 Jan Aushadhi stores to sell generic drugs at heavy discounts to branded drugs. It is also directing doctors in central government hospitals to prescribe inexpensive generic drugs. The Government of India also plans to bring medicines made from 289 essential bulk drugs under price control. At present, about 1,500 medicines that use 74 bulk drugs are sold at prices fixed by the government.

Although the above reforms aim to significantly reduce healthcare costs for the masses, there could be some medical issues and legal bottlenecks. Sometimes substitution drugs have adverse effects, thus alternatives might need to be taken after prior consultation with a physician, which in turn, might defeat the purpose of providing safe and cost effective alternatives. Additionally, it is illegal for pharmacies to provide substitutes for prescription drugs.

*Source: The Economic Times of India, Business Standard*

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## Korea

### **Ministry of Health and Welfare targets reduction in reimbursement pricing on medical devices**

The Ministry of Health and Welfare (MHW) in Korea is currently looking for ways to rein in rising domestic healthcare costs. They are seeking to enforce limitations on reimbursement prices (MRPs) of medical devices as a multiple of import prices into Korea. If implemented, proposed changes could have a significant impact on the profitability of medical device companies importing their products into Korea.

Historically, the MRPs on medical devices were limited to a multiple of 1.78 times the import price into Korea. These pricing restrictions, however, were not actively enforced and many medical device companies importing products into Korea actually received MRPs exceeding this multiple.

Last year, the Ministry issued formal requests for information to medical device companies regarding import prices on products imported into Korea for the purposes of reviewing MRPs as a multiple of import prices. This review was performed on a small subset of medical devices. This year, the Ministry has decided to perform an expanded review to include classifications that encompass over half of all medical devices. The MHW is contemplating introducing new restrictions on MRPs on medical devices based on a revised multiple, but with a view toward active enforcement.

Enforcement of these restrictions will likely result in significant reductions in MRPs. In turn, this will have negative impacts on the profitability of medical device companies doing business in Korea. Changes in profitability, in turn, will likely increase corporate tax (particularly transfer pricing) and customs audit risk. The Korean pharmaceuticals industry is subject to similar regulatory MRP multiple restrictions which have not been actively enforced. Current developments in the medical device industry may portend future developments in pharmaceuticals.

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# Pricing

## Taiwan

### Industry pushes for early implementation of new DET system

As noted earlier, Taiwan will implement a new Drug Expenditure Target (DET) system as part of wider healthcare system reforms, to deal with the drug price gap (also known as the black hole) that has long been a major concern for foreign multinational pharmaceutical firms operating in Taiwan.

The drug price gap refers to the difference between the after-discount actual transaction prices that hospitals and clinics negotiate with pharmaceutical companies and the much higher amounts that the Bureau of National Health Insurance (BHNI) reimburses for the same drugs.

To close the gap, BNHI has periodically conducted Price Volume Surveys (PVS) to collect “market” price data from hospitals and pharmaceutical companies for calculating new, lower drug reimbursements. The hospitals, in turn, typically re-negotiate contracts with pharmaceutical companies after each PVS (as they have come to depend on that income from the price gap), driving prices down further while perpetuating the reimbursement gap at lower price levels.

Six such rounds of surveys and price cuts have already been held since 2000, which have made drug prices in Taiwan among the lowest in the world, discouraging companies from introducing advanced products into the Taiwan market. Mainly due to post-PVS price cuts totalling a massive NT\$20 billion (US\$680 million) in 2009, NHI (National Health Insurance) pharmaceutical spending grew only 0.9% in 2010.

The process threatens to drive foreign pharmaceutical firms out of the Taiwan market as their profit margins dwindle through each successive PVS cycle. To address such concerns, Taiwan’s parliament recently passed legislation that will implement a DET approach that could improve the transparency and predictability of pricing and reimbursement in the market.

Under the DET, the BNHI and pharmaceutical industry representatives should annually agree on a growth target for drug expenditures for the coming year, which would become the basis for any price adjustments. If that target is exceeded, industry commits to returning the difference.

Industry representatives had hoped that the new DET system would be implemented immediately to replace the planned PVS for 2011 and subsequent drug price adjustment. However, the government has not yet set a clear timeline for implementation, and the BNHI has so far shown little willingness to cancel the seventh PVS, which risks further damaging Taiwan’s pharmaceutical market.

#### ***PwC Comment***

The above reforms, if implemented, may make it more worthwhile for Pharma companies to bring new drugs into Taiwan. In the meantime, the seventh PVS, may further erode pharma’s appetite for bringing new drugs into Taiwan.

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## Australia

### Landmark transfer pricing decision

On 1 June 2011 the Full Federal court upheld the decision in *SNF (Australia) Pty Ltd v Commissioner of Taxation (SNF)* with a unanimous judgement that the Commissioner's appeal should be dismissed. This decision has potentially widespread implications for the application of Australia's transfer pricing rules and the Australian Taxation Office's (ATO) interpretation of transfer pricing methods.

Importantly, the decision reaffirmed that where taxpayers have sufficiently reliable comparable uncontrolled transactions, the transaction methods (e.g. the Comparable Uncontrolled Price (CUP) method), should be applied in preference to other profit based methods. In this way the SNF case highlights the need to know and examine internal transactional data which, for the pharmaceutical industry, may include looking at global third party supply arrangements or co-marketing, collaboration and/or other joint venture arrangements.

While it is likely that the ATO will continue to use profitability as a key measure of transfer pricing risk, the findings of the SNF case challenge the ATO's focus on profit outcomes in transfer pricing audits. Specifically, the Court's decision acknowledges that poor trading results may be attributable to factors other than transfer pricing. This may be helpful to pharmaceutical distributors in instances where factors in the local market or regulatory environment (such as PBS pricing changes) have a negative impact on profitability. In such cases, it is important to analyse these factors and document them clearly, demonstrating that transfer pricing has not caused poor profit outcomes on particular products.

The statutory appeal period in the High Court has recently passed and no appeal had been filed, we anticipate that the ATO will issue a Decision Impact Statement summarising its views on the implications of the SNF decision in the near future. Furthermore, we do not discount the possibility that the ATO may be working behind the scenes to seek a change in Australia's transfer pricing law.

#### **PwC Comment**

Taxpayers in the pharmaceutical industry should expect the ATO to adopt a 'business as usual' approach in any ongoing transfer pricing investigations and Advance Pricing Arrangement negotiations, with an increasing focus on internal comparable transactions in the future.

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### Research & Development Tax Credit reform

After a long gestation, the new Australian R&D Tax Credit is set to be passed through the Senate during the August sitting of Parliament. The new R&D Tax Credit will take effect from 1 July 2011 and will replace the old program.

The objective of the new program is to provide a tax incentive by encouraging industry to conduct experimental activities for the purpose of generating new knowledge.

The new program allows members of multinational groups to access the R&D Tax Credit where the local organisation carries out the R&D activities and is reimbursed for its costs, while a foreign member owns the resulting intellectual property.

This should allow pharmaceutical companies greater access to the R&D Tax Credit, with an increased benefit for R&D conducted in Australia. This new reform will provide a 40% R&D offset for companies with more than A\$20 million in group turnover (equivalent to a '10 cents in the dollar' benefit) and a 45% R&D tax offset for companies with less than A\$20 million in group turnover (equivalent to a '15 cents in the dollar benefit'), which is refundable if the company is in tax losses. As for multinationals, intellectual property can be held in Australia or overseas by a related party (i.e. contract R&D performed in Australia is now eligible) and Australian permanent establishments can now also claim.

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## China

### China's tax authority clarifies domestic tax treatment on technical service and royalties under tax treaties

Due to remittance needs Chinese taxpayers are required to discuss or even negotiate with authorities on the tax treatment for cross border services and royalties. Unfortunately, domestic tax rules do not strictly follow international practice and interpretation. Different local authorities therefore often hold their own opinions, resulting in a practical lack of consistency. Consequently, it is quite common for tax authorities to treat outbound remittance of technical services as royalties.

As a result, domestic taxpayers are asked to withhold 10% Withholding Tax on the total amounts, even in some circumstances where a foreign company does not trigger a Permanent Establishment (PE) in China. This not only increases costs for taxpayers and heightens administrative burdens, but also creates treasury issues due to foreign exchange remittance restrictions.

Recently, China has been expending more effort in the interpretation of DTAs, hoping to make them more rational and aligned with international practices. Examples of these changes include The State Administrative of Taxation (SAT) issuing a circular to distinguish technical service income from royalty fees. The technical service income should be treated separately when the time spent by the foreign personnel in China has constituted a PE foreign service provider. Under such circumstances, the service income attributable to the PE should be treated as a business profit in accordance with the Business Profit Article under DTAs.

The SAT recently issued a circular to repeal the existing counting method of "six-month duration threshold" under a typical PE article of a DTA, which originally caused a lot of controversy and dispute between treaty residents and Chinese tax authorities.

The new circular abolishes the stance that even if an employee is present in China for one day in a particular month that it can still be treated and regarded as "one month". Such treatment should be welcomed by treaty residents.

While the Chinese government is re-negotiating some old tax treaties (e.g. new China-UK DTA has just been concluded) with competent authorities, the SAT is continuing efforts to provide practical guidance on some long disputed interpretations like "Technical Fees" under certain DTAs.

Public Notice No. 19 sets forth the assessment of tax liabilities on technical service fees under different circumstances. These treatments present the fundamental principle that once China was granted with the taxing right over the technical service fee income by the Relevant DTAs, the Chinese tax liability should be computed in accordance with the Chinese domestic income tax rules first, but limited to the cap as stipulated in the DTAs. These regulatory changes provide SAT's technical views and positions to the issues so as to eliminate disputes arising from inconsistent local interpretations.

Some changes provide better opportunities for taxpayers to reduce or even exempt their income tax from being withheld by Chinese payers. In the meantime, if a PE is triggered under a royalty arrangement, it will also increase the risk that the tax bureau would separately look at the PE and not only pursue the corporate income tax, but also scrutinize the individual income tax for people travelling to China.

#### **PwC Comment**

For the pharmaceutical industry, it is common that overseas companies provide intercompany services, IP licensing and other multifunction services to Chinese affiliates. Foreign pharmaceutical companies which offer licenses and/or services to Chinese companies may be subject to changes in practice on income tax treatments in the near future. Pharmaceutical companies are advised to revisit the intercompany charge arrangement and evaluate the impact on tax costs. It is also suggested that closely monitoring the individual's PRC presence under both royalty and service fee arrangements will minimise the PE exposure as well as potential Individual Income Tax filing obligations.

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## Indonesia

### Update on Investment Allowance

The Indonesian Government is currently updating the investment allowance to attract more inbound investment. This will be achieved by providing tax facilities (i.e. advantages) to taxpayers investing in particular sectors and/or in particular regions having a high priority at the national level.

The intended tax facilities will come in various forms. These include a reduction of net income, at a maximum amount of 30% of the total investment made; accelerated depreciation and amortization; longer loss compensation, although this will not be more than 10 years; and tax imposition upon dividends as referred to in Article 26 Income Tax to the amount of 10%, unless the tax rate in accordance with the applicable tax treaty is determined as being lower.

These tax facilities have been implemented through the issue of GR-1 in 2007 as last amended by GR-62 in 2008. GR-62 covers thirty-eight eligible types of investment (based on KBLI/Business Classification Field), consists of twenty-three types of investment in particular sectors and fifteen types of investment which are in particular regions. Included in the list are the pharmaceutical, milk, cosmetics and chemical industries.

Currently, there is a plan from the Government to add 118 (sub) business sectors to the tax facilities eligibility list by amending GR-62. However, when the amendment will be issued and the details of additional business sectors are as yet unclear.

#### **PwC Comment**

The expansion of tax facilities for the pharma and chemical industries should be reviewed to determine whether there are added benefits to investing in Indonesia.



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## Malaysia

### Healthcare is one of Malaysia's National Key Economic Area (NKEA) for wealth creation

Malaysia's Economic Transformation Plan (ETP) launched last year designated Healthcare as one of the 12 NKEAs to grow its economy. The Healthcare sub-sectors forecasted with growth potential are pharmaceuticals, health travel and medical technology products. The goal is to migrate from primarily a low-value product strategy to a more comprehensive product, services and asset strategy that better leverages Malaysia's competency. Malaysia aspires to generate RM35 billion (USD11.7 billion equivalent) incremental gross national income (GNI) contribution to reach RM50 billion (USD16.7 billion equivalent) by 2020.

The Healthcare NKEA aspires to targeting a 22 percent GNI growth rate that will deliver RM16.6 billion (USD5.5 billion equivalent) GNI by 2020. This is driven by higher exports of generic pharmaceuticals and enhanced generics and increased clinical research in Malaysia. The impetus for this aggressive growth is two-fold. Firstly, in terms of the significant extra capacity in the domestic pharmaceuticals industry which can be re-focused to higher value manufacturing; and secondly, to create a sustainable and thriving pharmaceutical industry through investment in research and development and innovation.

The selected Entry Point Projects (EPP)s within the Healthcare NKEA listed below are merely an indication of the projects to move Malaysia up the value chain (see table on right).

Pharmaceuticals enterprises that present a robust business plan in either manufacturing and/or innovative R&D activities showing potential contribution to the country's GNI would be favourably considered. Depending on the size of the investment and strategic objectives, customised tax incentives can be applied for. An example of customised tax incentives could be an enhanced tax holiday plus work permits for expatriates. This could reduce the group's effective tax rate whilst meeting its business objectives.

#### **PwC Comment**

Most international pharmaceutical organisations are looking at ways to improve their R&D productivity, reduce their costs, tap the potential of the emerging economies and switch from selling medicines to managing outcomes to prosper beyond 2020. Malaysia now presents an opportunity for international pharmaceutical enterprises to expand their supply chain business in this region whilst enjoying favourable effective tax rates.

EPP	Additional information
Creating a supportive ecosystem to grow clinical research	Place Malaysia in a competitive position within the global clinical research industry; Expected government funding of RM38 million (USD12.7 million equivalent).
Pursuing generics export opportunities	Transform Malaysia into a major force in the export of generic pharmaceuticals; Expected government funding RM96 million (USD32 million equivalent) over 3 years.
Reinvigorating health travel through better customer experience, proactive alliances and niche	Create a differentiated position for Malaysia and to broaden the customer base and beyond lower margin outpatient treatments.
Creating a diagnostic services nexus to achieve scale in telemedicine for eventual international outsourcing	Create efficiency within the existing domestic diagnostic services through public-private partnerships. Leverage a scaled business model that would pursue international diagnostic outsourcing opportunities via telemedicine and build on Malaysia's first-mover strength in having telemedicine statutes and regulations.
Developing a health metropolis: A world-class campus for healthcare and bioscience	Create a healthcare ecosystem in Greater KL/KV as a launching pad for a series of ecosystems in other locations.

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## New Zealand

### Extension of existing R&D incentive

New Zealand's Ministry of Science and Innovation (MSI) has made its Technology Transfer Voucher accessible to more businesses by reducing the minimum value for R&D project proposals from NZ\$200,000 to NZ\$60,000. The value of the vouchers range from NZ\$30,000 to NZ\$1 million (GST exclusive).

The Technology Transfer Voucher was announced by the Government in last year's Budget as part of a package intended to support and increase business led R&D. The Vouchers are aimed at organisations that require R&D expertise in high value manufacturing and services, including the pharmaceutical industry. Vouchers provide 50 per cent funding towards R&D projects to enable businesses to access research services and expertise from accredited R&D partners. The Voucher will only cover costs incurred by the accredited R&D partner and not costs incurred in-house by the organisation.

Currently there are fourteen publicly funded research organisations accredited to provide R&D services and expertise to organisations awarded a voucher. Once awarded a voucher, the organisation has three months to find and engage a research organisation for its R&D project.

Organisations can apply for a voucher to assist with funding the following activities including: product and/or process design activities (engineering or technical design expertise to determine prototype structure, function and/or materials); trial production runs or processes to demonstrate a technical concept of a project or part of a project; and product testing as part of the product's development (includes validation or demonstration of the technical capabilities of a product, process or service, scale-up, stability or reproducing a process).

The voucher cannot be used for: standard training courses; software purchases; design and production of advertising material; sales activities; business plans and economic appraisals; IP licensing; website development and online optimisation; testing to achieve compliance with statutory regulations or legislation or other relevant standard and purchasing of off-the-shelf plans, products, drawings & designs.

From 1 July, there will also be more accredited R&D partners for businesses to choose from when redeeming the voucher. To apply for the Technology Transfer Voucher an organisation must first register with MSI. Once accepted, organisations can apply online. MSI recommend that organisations should contact them if they are applying for a voucher exceeding NZ\$200,000 as more information may be required.

### Unsuccessful software development

The Minister of Revenue announced in June that new legislation will be introduced to provide for the cost of abandoned software development projects being deductible up front, applying from the current income year. The announcement follows Inland Revenue's statement in April that it had changed its view on the deductibility of unsuccessful software development expenditure which meant these costs would have become "blackhole" expenditure.

### GST on cross border supplies

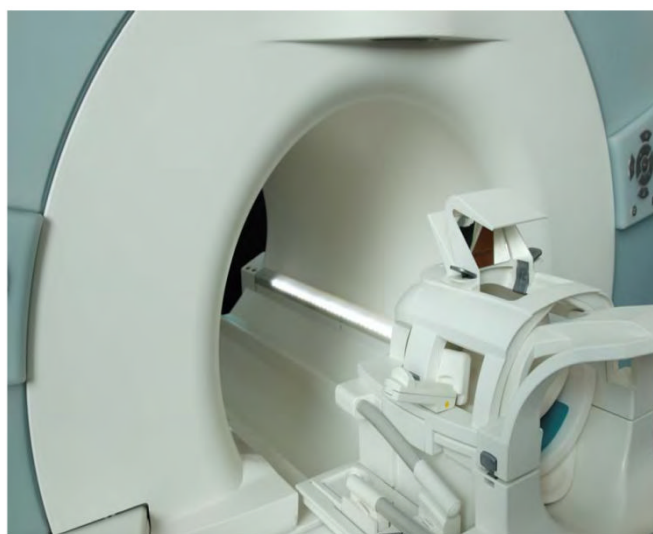
Inland Revenue has commenced a review of GST on cross-border supplies in a business to business context. The aim of the review is to relax the rules to allow greater GST recovery for non-residents and to allow the zero-rating of services supplied to non-residents who essentially have no function in New Zealand.

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## Thailand

### Regional Operating Headquarters (ROH) regime

Thailand's ROH regime has sought to promote the establishment of multinational regional headquarters in Thailand. The regime offers tax privileges for companies setting up ROHs to act as holding, services, financing and licensing companies.

On 6 November 2010, a new ROH model came into existence modifying some of the criteria and benefits. An existing ROH will be able to elect to keep the old existing regime or move to the new model and a new ROH can choose either the old or the new ROH regime.

#### Old ROH Regime

The criteria for an ROH under the old regime were:

- A company formed under Thai law with minimum paid up capital of Baht 10 million
- Provided qualified services to qualified affiliates (companies with at least 25% common group ownership) in at least 3 countries other than Thailand
- Income from services provided to, or royalties received from, overseas affiliates must be at least 50% of the total income of the ROH company (reduced to one-third for first 3 years).

#### New ROH Regime

The modifications and criteria (in addition to the old rules above) under the new ROH regime are:

- The number of foreign affiliates that services must be provided to is modified
- "Operating expenses" related to ROH activities must be at least Baht 15 million per year or investment spending in Thailand of Baht 30 million per year
- Maintain "skilled staff" of at least 75% of total employees by end of third year
- Average compensation of Baht 2.5 million per person per annum for at least 5 employees by the end of the third year
- The foreign affiliate must have actual business operations.

#### New ROH tax concessions:

- Full Corporate Income Tax (CIT) exemption on net profit from ROH services provided to foreign affiliates for 10 years. (This can be extended to 15 years if cumulative "operating expenses" for 10 fiscal periods exceed Baht 150 million at the end of the 10<sup>th</sup> fiscal year.)

- 10% CIT for 10 years on net profit from ROH services provided to domestic affiliates including qualified royalties and qualified interest income (with extension to 15 years on the same conditions noted above)
- The exemption from CIT and domestic withholding tax for dividends received from affiliates is also limited to 10 years (with extension to 15 years on the same conditions noted above)
- Withholding tax exemption for dividends paid to foreign shareholders
- The expatriate flat rate of 15% is for 8 consecutive years.

An ROH that meets all of the above criteria but fails to derive 50% or more of its income coming from ROH services and foreign affiliate royalties, will be entitled only to the CIT exemption for foreign profit and the 10% rate for domestic profit and none of the other concessions.

Under the new tax package, the required registration form must be submitted within 5 years from 15 November 2010. In order to be eligible, an ROH income must be derived from certain qualifying services.

#### PwC Comment

The establishment of Regional Operating Headquarters in Thailand to support other AsiaPac entities should be considered in light of the benefits provided above.

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## Taiwan

### Thin-cap assessment rules effective from January 1, 2011 onwards

On January 26, 2011, the Presidential Office announced the amended Income Tax Act (ITA) introducing the thin capitalization rule was introduced. Subsequently on June 22, 2011, the Ministry of Finance (MOF) promulgated the assessment rules (Thin-cap Assessment Rules) for implementation of the thin capitalization rule, which is effective from January 1, 2011 onwards. The salient points of the promulgated Thin-cap Assessment Rules are highlighted below.

**Prescribed inter-company debt to equity ratio:** Tax deductible interest expense on inter-company debt is capped at a prescribed inter-company debt to equity ratio of 3:1.

Inter-company debt includes loans directly or indirectly provided by related parties, including third party loans guaranteed by related parties, and any other types of financing directly or indirectly extended by related parties. Nonetheless, companies eligible for “safe harbor rules” will not be subject to the prescribed inter-company debt to equity ratio. “Safe harbor rules” apply where i) the annual aggregate amount of net sales and non-operating income reported in the corporate income tax return is below the threshold prescribed by the MOF; ii) both “total interest expense” and “interest expense from inter-company debt” reported in the income tax return are below the threshold(s) prescribed by the MOF; or iii) a company has incurred tax loss prior to the deduction of interest expense, and such loss is not carried-forward under Article 39 of the ITA.

“Equity” is defined as “interest-free working capital” for a branch where the foreign head office is located outside of Taiwan; whereas for an enterprise whose head office is located in Taiwan, “equity” is defined as “total equity” or “paid-in capital and capital reserve arising from issuance of shares above par value”, whichever is higher.

**Disclosure requirements:** Unless the aforementioned “safe harbor rules” apply, taxpayers are required to disclose information (including actual inter-company debt to equity ratios, etc) related to their inter-company debt, if any.

#### **PwC Comment**

In view of the above, pharma companies with inter-company loans and those considering such financing options should revisit their financing strategies to be in compliance with the Thin-cap Assessment Rules and ensure tax deductibility on

interest expense recognized. The “safe harbour rules” threshold to be prescribed by the MOF should be noted to confirm whether exemption from the prescribed inter-company debt to equity ratio will apply. Other alternatives to alleviate the thin-capitalization rule may include obtaining financing from local financial institutions instead, converting existing inter-company debt to capital, etc.

### Amendment to the Value-added and Non-value-added Business Tax Act takes effect from April 1, 2011

From April 1, 2011 onwards, the amended Value-added and Non-value-added Business Tax Act (BTA) came into effect. Below we highlight significant changes that are important to pharma companies.

**De minimis exemption:** De minimis VAT exemption is provided for a prescribed individual transaction amount less than or equal to TWD\$3,000 for services purchased from a foreign enterprise.

**6-month assessment period:** In general, the tax office is required to assess business tax returns filed on time within 6 months following the next day of the stipulated filing due date. Where there are no additional taxes due or taxes eligible for refund, the tax assessment results may be provided via public notice. Alternatively, for supplemental payment and filings made voluntarily after the stipulated filing due date, the 6-month assessment period shall be counted from the next day following the receipt of the supplemental filing.

Therefore, where tax assessment results are not agreed by taxpayers, taxpayers should file a tax re-examination application with the tax office within 30 days following the next day of the assessment date. Alternatively, if taxpayers underpay business tax liability after April 1, 2011, the business tax return should be amended and tax deficiency should be paid before the 6-month assessment period elapses. Otherwise, taxpayers may not qualify for penalty exemption provided by Article 48-1 of the Tax Collection Act governing voluntary amendment/payment.

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