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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 5, April 2011

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Editor's Note

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

In this issue, we have two special reports for you. The first is on Saratoga, PwC's human capital measurement and benchmarking arm, which recently set up an Asia-Pac dedicated centre in Singapore. This initiative has started to benchmark Asia-Pac companies and build the database to complement the existing, extensive database available from US and EU based companies.

The second special report is to inform you on the 2011 Indian budget for the Pharma sector.

Taiwan and China signed a new drug development pact and agreed on mutual recognition based on compliance with international guidelines. You can read more details on this in the compliance section.

Good news if you want to register your products in Taiwan and the products are already on the US and EU markets, as the review period will be cut in half. Read about it in the regulatory section.

Recently the Indian government has proposed new measures to improve clinical trials, more stringent penalties to offenders who trade in spurious drugs and mandatory bar-codes on products for export starting 1 July 2011. More details on these three key developments in India in the regulatory section.

In Australia, the National Health Amendment Bill has now become law with some minor changes. Follow up on this topic from our last newsletter in the pricing and reimbursement section. In the same section, you can read how the Chinese government is progressing with price cuts of drugs and taking away the premium pricing that some of the originator drugs were enjoying.

Catch up on the latest tax news from multiple territories: Indonesia, Japan, Korea, Malaysia, New Zealand, Singapore and Taiwan in the tax section.

We trust that the information is of use to you and your organisation. If you like to discuss any topic in more detail, feel free to reach out to your PwC territory contact or the experts mentioned in the article.

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Special Report

PwC Saratoga – Asia-Pacific Centre in Singapore

Quantifying human capital impact in the pharmaceutical industry

Saratoga, PwC's human capital measurement and benchmarking arm, has established a dedicated Asia-Pac centre in Singapore. Saratoga is a recognised global leader in human capital analytics with over 30 years experience helping clients in measuring the impact and value of people performance. Saratoga's global client base includes 40% of the Fortune 500 and FTSE-100. The centre has been opened with support from the Singapore Government's Economic Development Board.

The set up of the Asia-Pacific PwC Saratoga Centre in Singapore enables benchmarking in the Asian region against Asian peers. A number of multinational pharmaceutical and life sciences companies have been using the Saratoga benchmark methodology in the West. Exponential growth in the Asian region is stimulating companies to professionalise their Asian operations. That includes comparing how their organisation is doing on people metrics versus Asian as well as Western peers.

Current market developments, including the growing demand from senior executives and shareholders for meaningful financial, performance and risk data, have increased the need for HR to demonstrate the value it delivers to the bottom line. Intelligent measurement around HR and people performance is fundamental to both demonstrate value and improve performance. This is especially critical to the pharmaceutical industry which relies strongly on the value that people bring to the business. It's people who represent the living brand and create the intellectual property which has direct impact on the bottom-line in the pharmaceutical industry. Hence people are clearly a key differentiator for pharmaceutical organisations.

Developing effective measurement practices is not something that happens overnight. Experience shows that it requires an ongoing process of learning, refinement and continuous improvement. We can help.

For example, we've worked with a global pharmaceutical organisation to develop a scorecard that aligned HR competence alongside the business strategy. This HR transformation used PwC Saratoga's globally recognised methodology.

Case study: HR benchmarking – Global pharmaceutical organisation

The issue

The pharmaceutical company aimed to develop a suite of HR metrics and benchmarks that were aligned with their business and HR strategy. The implementation of HR metrics was considered a critical tool to identify the competence of HR in line with the overall transformation of the function.

Saratoga approach

- Over the course of a five-year relationship, PwC Saratoga supported the client with the identification of metrics and development of a performance scorecard.

- The duration of the relationship enabled PwC Saratoga to identify performance trends over time and the subsequent skills transfer developed the client's own measurement capability through the four key stages of the measurement journey:

  - Learning
  - Action
  - Monitoring
  - Trends and future opportunities

- PwC Saratoga worked with the client to benchmark at group and individual country business unit level against a bespoke sample of similar organisations, as well as internally between business units.

- PwC Saratoga provided the client with advice and support on the meaning, interpretation and application of the metrics, through alignment of PwC Saratoga measures with the organisation's key strategic themes. This process enabled a direct investigation of HR issues and challenges by geography and the presentation of recommendations for future action to address these challenges.

The outcome

- Selecting and implementing appropriate KPIs provided the client with the 'evidence based' reporting they needed in order to evaluate their performance in relation to their competitors.

- The client has since undertaken benchmarking activity annually, enabling them to track progress and to find, monitor and improve areas of their business identified as exhibiting lower levels of performance.

- The use of HR metrics has become embedded in the organisation and appropriate competencies developed, both in terms of data and people.

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Special Report

Impact of India's Budget 2011 on Indian pharma sector

Overall, the budget does not have any significant announcements that would improve access and affordability and create more investment in the sector. An increase in the allocation for the healthcare plan to Rs. 26,760 crore and an increase in coverage of the Rashtriya Swasthya Bima Yojana are positive steps that will bring more people in the net and contribute to the pharma sector's growth. Excise duty has been increased from 4% to 5%, however this will have minimal effect on drug prices. Cold chains are now classified as an infrastructure sub-sector, a change that will have a positive impact on the pharma cold chain. The new designation should help injectables, vaccines and biologics in particular to increase their reach and penetration, especially in tier-II to tier-VI and rural markets. The creation of a National Innovation Council is a welcome step.

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Compliance

Taiwan

Taiwan and China sign new drug development pact

On 21 December 2010, Taiwan and China signed a new agreement on medical and health cooperation covering four areas: prevention of infectious diseases, the management and development of drug safety, emergency rescue operations and the study of Chinese medicine and its safety management. Two important outcomes of the pact for pharma manufacturers include the proposed harmonisation of medical standards and upcoming cooperation on clinical testing of new drugs.

According to the agreement, Taiwan and China will negotiate guidelines for product testing, registration and manufacturing management based on the ICH and GHTF standards. The application scope includes pharmaceuticals, medical equipment, health foods and cosmetics. A mutual recognition based on compliance with international guidelines, such as GLP, GCP and GMP, was also agreed. This will help speed up the launch of new medical products across the Taiwan Strait.

Regarding the clinical trial of new drugs, the Taiwanese and Chinese health authorities agreed to adopt the same standards, which they hope will accelerate the process of obtaining market clearance for certain pharmaceuticals. At present, drugs that have undergone product registration with clinical trials in Taiwan or China usually have to be submitted for clinical trials in the other territory.

The forthcoming standards will no longer require the repeat of clinical trials. In the future, for example, drugs that have clinical trial data from Taiwan will not need to conduct duplicate trials in China to sell in the new market and vice versa. This will significantly reduce the lead time for product launch by as much as five to ten years. However, Taiwanese officials might review clinical trial and other facilities in China to certify satisfactory compliance with Taiwan's guidelines on quality.

Taiwan's budding biotechnology industry has been limited by the island's small market, so the new pact will help accelerate the entry of Taiwanese products into the larger Chinese market.

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Japan

Following discussions over the last two years, the Japan Pharmaceutical Manufacturers Association (JPMA) has released guidelines to improve the transparency of its member companies' relationships with medical institutes.

Member companies now need to prepare their own "Policy for ensuring transparency" based on these guidelines. They will need to disclose data covering fiscal year 2012 in fiscal year 2013. They must initiate the development of processes for getting consent from medical institutes on information disclosure. Systems must be in place soon in order to collect and disclose information on payment.

It is expected that the policy will include:

1. basic stance of the company regarding transparency

2. means and timing of disclosure

3. timing to initiate disclosure

4. scope of disclosure
   - development cost
   - academic research grant
   - payment for writing a paper, making a speech, performing consulting, etc.

5. provision of information through lectures, seminars, paper materials, etc.

6. entertainment

The JPMA has spoken with representatives from associations of medical institutes. There seemed to be no major objections from them.

Adoption of this guideline will depend on the commitment of each company and the cooperation from medical institutes.

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Mergers & Acquisitions

Korea

Samsung, Korea's largest conglomerate, has entered into a JV with Quintiles, an integrated biopharmaceutical services company, to engage in the contract manufacturing of biopharmaceuticals in Korea. With KRW 300 billion (approx. USD 266 million) of funding, the JV will begin construction of a manufacturing plant in the Incheon Free Economic Zone in Songdo. The facility should be fully operational by April 2013. The plant will be equipped with cutting-edge technology and an 8,000-gallon (30,000 liters) mammalian cell culture bioreactor capacity capable of producing 1,300 pounds (600 kilograms) of biopharmaceuticals.

Samsung will own 90% of the JV through Samsung Electronics (40%) and Samsung Everland (40%) and Samsung C&T (10%). Quintiles will own the remaining 10%. The formation of the JV is particularly noteworthy as it represents Samsung's first foray into biopharmaceuticals and demonstrates that Samsung fully intends to make good on plans announced last year to invest KRW 2.1 trillion in the sector by 2020. Samsung also plans to develop biosimilars and begin producing them by 2016. Half of the budget is earmarked for developing biosimilars, while the other half will be used to build production plants.

Source: Bloomberg, Quintiles Press Release, Korea Times, ABC News

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Taiwan

The growth of the biotechnology industry in Taiwan has always been relatively sluggish. Most players in the industry are in businesses with low capital requirements and barriers to entry. The sector is made up of three major segments, pharmaceuticals, medical device manufacturing and medical services, which we discuss in more detailed below.

Pharmaceutical companies in Taiwan are mainly specialised in the making of Active Pharmaceutical Ingredients (APIs) and/or generic drugs. Only a few companies have started to venture into the area of new drug research and development, and all of them are still in either R&D or clinical trial stages, according to statistics published by the Ministry of Economic Affairs in Taiwan. Furthermore, the products manufactured by pharmaceutical companies in Taiwan are mainly for use in the domestic market rather than for the export market. Companies looking to ship drugs overseas face significant barriers to entry.

Getting drugs approved by the governing body of other countries, such as the FDA in the US, can be very costly, for example. Only a few large API manufacturers have managed to tap into export market. As a result, pharmaceutical companies in Taiwan are generally modest in size and not sophisticated enough to be regarded as lucrative potential investments for those large pharmaceutical companies looking for a target or market entry opportunity in the region. As a result, not many significant pharmaceutical related mergers and acquisitions transactions were completed, or even initiated, locally in recent decades. There were a few exceptions. A handful of mergers and acquisitions took place in Taiway, but only when Taiwan subsidiaries of international pharmaceutical companies were included as part of a transnational deal.

The situation for medical device manufacturing companies in Taiwan is very different. The medical device manufacturers in Taiwan focus mainly on products that are low priced or less costly to produce, for example, glucose monitors, electronic blood pressure monitors, or the consumables/testers for large medical devices. Like most of the pharmaceutical companies in Taiwan, local medical device manufacturers are usually small to medium enterprises. The devices made in Taiwan are famous worldwide for their high quality and affordable prices, though the medical device-making business has always been more vibrant and profitable. Not surprisingly it has also been more attractive to potential investors.

The well-established national health insurance scheme in Taiwan has created a large market for private clinics. As a result, the Department of Health in Taiwan outsourced 17% of medical operations of hospitals/medical centers to private clinics or medical practitioners. The market for medical service in Taiwan has seen quite a number of well-known mergers and acquisitions deals take place. For instance, in 2010, in order to gain greater market shares in Asia-Pacific region, Fresenius Medical Care (FMC), one of the largest providers of kidney dialysis products and services in the world, acquired Asia Renal Care from Bumrungrad International Limited. After the acquisition, FMC became the largest service provider for kidney dialysis in Taiwan.

In 2010, the Economic Cooperation Framework Agreement (ECFA) was signed between mainland China and Taiwan. Items on the early harvest lists in ECFA will be allowed to receive zero or lower tariff treatment. Biotechnology products such as chemicals used for manufacturing generic drugs were included the early harvest list. The cost for pharmaceutical companies in Taiwan to manufacture generic drugs could potentially be reduced, thus making their products more price competitive in the Chinese market. Moreover, certain medical devices and services were also included in the early harvest list. Therefore, it is envisaged that the positive effect of the ECFA will benefit the biotechnology industry in Taiwan as a whole through a more liberal cross-strait business environment and the access to the vast market of mainland China.

In the post-ECFA era, in view of the potential benefits and business opportunities that could be generated from growing economic cooperation with China, we may see the biotechnology industry in Taiwan start to flourish and gain sophistication and momentum. In turn, Taiwan could become the destination for large multinational bio-technology giants in the US and Europe to look for a potential target to acquire or business partners to work with.

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Regulatory

Australia

Proposed changes to medicine labeling

The Therapeutic Goods Administration (TGA) has released an industry consultation paper on proposed revisions to guidelines on the Required Advisory Statements for Medicine Labels (RASML).

Following consultation, the RASML will become a legislative instrument, and the TGA will set out an effective process for updating RASML regularly. The objective of this process is to ensure stakeholders obtain the latest updated information on over-the-counter and complementary medicine labels. Non-prescription products containing aspirin and anti-inflammatory products containing diclofenac, ibuprofen and ketoprofen, are some of the products that will be affected by the new labeling requirements.

Federal Court claim on "interchangeability" of medicines

The concept of "interchangeability" of medicines is used to determine whether drugs may be considered interchangeable or substitutable because they have very similar safety and efficacy profiles, and health outcomes. This concept is used by the Pharmaceutical Benefits Advisory Committee (PBAC) to group drugs that are considered interchangeable and then have them reimbursed under the PBS at the level of the cheapest drug in that group. However, a clear and accepted criteria for the determination of interchangeability does not exist.

It is hoped that greater clarity will be attained through the recent proceedings commenced by AstraZeneca Australia in the Federal Court against the Minister for Health and Ageing and 17 current and past members of the PBAC. In this case, the court will be considering whether atorvastastin (Lipitor) and rosuvastatin (Crestor) should, or should not, be treated as interchangeable on an individual patient basis. The outcome of the court proceedings are likely to have important consequences on future interpretations of what is an interchangeable medicine. In the meantime, a recent Senate inquiry into consumer access to pharmaceutical benefits and the formation of therapeutic goods recommended that PBAC:

- develop agreed principles of what constitutes "interchangeable on an individual patient basis"
- develop criteria by which the interchangeability of a medicine will be determined
- publish both the agreed principles and criteria.

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Taiwan

Procedures simplified for marketing of new drugs

Taiwan's Department of Health (DOH) recently announced that it is speeding up its pre-market review of new drugs, which should help get them on the local market faster. The review period for new drugs that have already been approved by the Food and Drug Administration (FDA) of the United States or the European Medicines Agency (EMA) of the European Union will be cut in half.

Pharma companies will not have to wait for review by the DOH's Drug Advisory Committee. Instead they will be able to send the relevant information to Taiwan's Food and Drug Administration, which will carry out a review focusing on the foreign evaluation reports, whether or not the new drug contains any racial differences, and whether or not it is suitable for Taiwanese to use.

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India

The Government of India has over the last few months proposed various guidelines, regulations and amendments to regulate the Pharma and Healthcare industry in India. We discuss below some of the key developments in relation to the same.

More stringent measures to improve clinical trials in India:

All the stakeholders involved in the conduct of clinical trials in India, be they sponsoring Pharma companies, Contract Research Organizations (CRO), institutions and investigator or independent ethics committees, will now be subjected to detailed inspection by drug authorities in India.

To ensure safety of the study subject, which is of utmost importance, the Central Drugs Standard Control Organization (CDSCO), India's central drug control organisation, has recently issued guidelines regarding the inspection of clinical trials being conducted in India, under the clinical trial inspection program. The main objective of the Program is to verify GCP compliance, the safety and well being of subjects involved in the trial, the credibility and integrity of data generated from the trial and compliance with various regulatory provisions as per the Drugs & Cosmetics Rules. The Program will cover all clinical trial sites and CRO's facilities which are involved in the clinical trials of drugs, including biological and medical devices as identified under the Drugs & Cosmetics Act, 1940.

Inspection can be conducted any time before, during or even after the trial is completed on the instruction by DCGI and will include verification of all the documents related to the trial, study site, protocol and other documents including informed consent forms, case records etc. Further, the inspection will also verify and examine details regarding independent ethics committees.

Blowing the whistle on fake/spurious drugs

Considering the gravity of the situation of fake and spurious drugs in India, the Government of India recently amended the Drugs & Cosmetics Act, 1940 by the Drugs & Cosmetics (Amendment) Act, 2008 to provide more stringent and stricter penalties to offenders who trade in spurious drugs.

To beef up the war against the menace of spurious and misbranded drugs, the authorities have recently launched a scheme for whistle blowers. Under this scheme whistle blowers would be given monetary rewards for taking the risk of providing information to the officers which leads to seizures of spurious, adulterated, misbranded drugs, and cosmetics and medical devices, as well as those which do not meet quality standards. This reward scheme will be applicable to both the informers as well as the officers of CDSCO.

The whistle blower scheme by the Government is a welcome initiative and is expected to encourage the officers and public at large to assist government in curbing the menace of counterfeit and spurious drugs in India.

Drugs for exports must carry a barcode

The government has made it mandatory for drug-makers to ensure that every product exported out of the country carries a barcode. This measure is designed to put an end to allegations overseas that some local firms ship out counterfeit medicines. The new norms will be applicable from 1 July 2011. Industry experts say the new rules will increase the cost of exports for Indian medicines and will impose a cumbersome compliance process.

A barcode is machine-readable data, which contains information about the product including details about the manufacturer. It will allow authorities to track each and every medicine exported out of the country. The drug control authorities at the ports can also retain a sample of the drug for reference and tracking. The barcode will also prevent Chinese companies from selling fake drugs with a 'Made in India' tag in some African countries like Nigeria.

About 3,500 Indian drugmakers export medicines worth $10 billion each year to over 100 countries.

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China

New GMP issues and standards improved

The new GMP (GMP 2010) will be effective from 1 March 2011, and replaces the last GMP version issued in 1998. All newly established pharmaceutical manufacturers and all newly built (rebuilt and expanded) plants shall meet GMP 2010 requirements. Existing pharmaceutical manufacturers shall meet GMP 2010 requirements within no more than five years as a transition period. The new GMP strengthens the construction of drug production quality control; sets out stringent requirements on the qualification of employees; improves the measures for drug safety and increases the standards for production environment.

According to an official from the State Food and Drug Administration (SFDA), around 500 small- and medium-sized drug producers may not be able to meet the requirements of the new GMP standards. And in some sectors (e.g. blood products, where 80% of companies may not meet the new GMP standards), the situation may go from bad to worse.
Source: PharmaChina

The implementation details are under development and will be announced by SFDA at a later stage.

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Pricing & Reimbursement

Australia

In our last newsletter (Issue 4) we set out the then-current position in relation to proposed amendments to the Pharmaceutical Benefits Scheme (PBS) which were still subject to a Senate enquiry. The National Health Amendment (Pharmaceutical Benefits Scheme) Bill has now become law with some minor changes; however the following provisions have already commenced:

- From 1 February 2011, a price cut of 2% was made to all medicines listed on Formulary F2A and a 5% price reduction was made to all medicines listed on Formulary F2T.

- From 1 February 2011, the price reduction on when a medicine moves from Formulary F1 to F2 following the introduction of the first generic was increased from 12.5% to 16%.

- From 1 December 2010, a strengthened price disclosure regime now applies to all medicines listed on Formulary F2 with a guaranteed 23% weighted average price reduction for the first round of mandatory price disclosure, occurring on 1 April 2012.

These changes are estimated to save the Government a $1.9 billion over five years.

Some of the rationale behind the industry's agreement in entering into a Memorandum of Understanding (MOU) back in May 2010 was to provide for a more efficient PBS and to enhance certainty for the industry around pricing for new originator drugs.

Further changes create uncertainty

In a break with long established convention and practice, the Federal Government has recently made a decision to indefinitely defer the listing of some eight new medicines and vaccines to the PBS. It has also decided that all future PBS listings will now require Cabinet approval, effectively removing the previous $10 million threshold before Cabinet approval was required. Although the Minister has always had the discretion to take any new medicine for listing to Government for consideration, it was rare to do so if that drug had already been recommended by the Pharmaceutical Benefits Advisory Committee (PBAC), the Government's own expert advisory committee which recommends new drugs for listing on a price effectiveness or minimisation basis.

The Government's reasoning

Unless medicines will save lives or where there is no existing treatment already available, the Government has told the pharmaceutical industry that it will delay listings to the PBS until the Federal Budget has returned to surplus, forecast for 2012/2013.

A spokesman for the Health Minister, Roxon, said that "given the current difficult fiscal circumstances, the Minister feels it is appropriate to subject all Government decisions that are of a fiscal impact to scrutiny".

The Minister for Innovation, Industry, Science and Research, Senator Kim Carr, also indicated that those drugs which have been deferred would only be reviewed "when the fiscal circumstances improve".

This has created uncertainty for the industry in relation to the approval process, the ability to list new drugs and for patients to gain access to those drugs which may not save lives but would have favourable outcomes.

The industry association, Medicines Australia, has clearly told the Government that this is a bad decision which should be overturned and that it:

- overly politicises the listing process whereby medicines are to be listed on the basis of political priority, not patient need, efficacy of treatment or value for money
- bypasses its own independent panel of experts – PBAC – who have already decided that these medicines represent value for money, are clinically effective and should be listed
- undermines the political predictability and business certainty in the industry envisaged in the MOU with Government.

We have seen global trends by governments and payers to initiate radical price cuts and introduce transparency into the system to obtain lower prices for generics. These events in Australia need to be monitored closely as they may be an indicator of what might happen more broadly in the way governments act fiscally to rein in the costs of pharmaceutical drug expenditure.

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China

174 drugs prices have been cut by 19% on average and pricing privileges of 16 products have been withdrawn

The healthcare burden of the Chinese population is high due to over medication and high profit margins of drug products, which is generally shared among manufacturers, distributors and hospitals/pharmacies. Reduction of the price of drugs and the provision of affordable medical services are major objectives of the recent healthcare reform. With this objective, the National Development and Reform Commission (NDRC) has introduced new drug pricing policies to cut drug prices and to achieve "zero-markup" in hospitals. Following the release of "Measures for the Administration of Drug Price (Draft)" in June 2010, the NDRC has initiated rounds of drug price cuts.

Effective from 12 December 2010, the price of 174 drugs (in 17 therapeutic areas) from over 40 pharmaceutical companies were cut by an average of 19%, according to NDRC. Among them, 107 are leading originators from MNCs.

Before 2005, the NDRC had previously offered individual premium pricing to leading originators with higher quality to encourage technical innovation and quality improvements. Together with the announced price cuts, pricing privileges of 16 products (14 from MNCs) have been withdrawn due to changes in relevant qualifications/status.

It is also reported that the NDRC is planning another round of price cuts on exclusive traditional Chinese medicine products (exclusive TCMs) which are on the National Essential Drug List (NEDL).

Source: Wicon Pharma China

Looking forward, it can be expected that drug products from MNCs (especially off- patent products) will face more price pressure as the NDRC attempts to narrow the gap between manufacturer-set prices and market prices, such that market prices will become more reflective of actual cost.

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In order to set the price of new drugs, pharma companies previously had to obtain a domestic certificate of pharmaceutical product and then apply to the Bureau of National Health Insurance (BNHI) for drug price approval. Since December 2010, however, an application can be submitted to the BNHI for a new-drug price after obtaining an approval letter from the DOH. It is now permitted to carry out pricing discussions first, so that the price can be approved immediately after the certificate of pharmaceutical product is issued. This is expected to reduce the approval time for new-drug prices from three to two months.

Clinical trial review is also being simplified. In the past, many clinical trials were either fully or partially completed overseas before being continued in Taiwan. To make it easier to put new drugs on the local market, and to do so simultaneously with their marketing overseas, when transnational clinical trials are being carried out abroad, or when multi-national, multi-centre clinical trial programs are being carried out jointly by Taiwan and other medically advanced countries, the DOH will evaluate only whether they conform to ethical principles and the interests of domestic disease sufferers, with no technical data review. This will greatly shorten the review timetable.

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India

Medical devices to come under price control; NPPA to place them under new schedule

Prices of medical devices in India are currently being fixed by device manufacturers with almost no government intervention. Quality control of medical devices is of critical importance as implanting a poor quality or defective device can cost the patient their life. That's why the call for better quality and price controls for medical devices has been growing in the Indian market. At the moment, medical devices are price controlled under the classification of 'drugs', by the National Pharmaceutical Pricing Authority (NPPA) – India's central drug price regulator. In order to better understand market conditions and improve price controls, the NPPA recently carried out a study that showed that prices of medical devices like stents, catheters, orthopaedic implants and heart valves vary wildly in the market. According to their study, prices of catheters vary from Rs. 11,000 to Rs. 78,000 (US$ 245 to US$ 1,734) and prices of devices like stents and drug eluting stents ranged from Rs. 100,000 (US$ 2,200) to Rs. 150,000 (US$ 3,500). Consequently, the government has taken the view that the profitability of these products is not justifiable. The NPPA has been asked to collect more data on the prices of medical devices in the country, and devise a new schedule for medical devices to be added to the Drugs Price Control Order (DPCO), the law under which drugs' and devices ' prices are controlled by the government.

Source: Pharmabiz

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Indonesia

Guidelines for the implementation of the Mutual Agreement Procedure (MAP)

In November 2010, the Director General of Taxation (DGT) issued Regulation No. 48/PJ/2010 as guidance on the implementation of the Mutual Agreement Procedure (MAP) (PER-48).

A MAP article in tax treaties allows tax authorities of treaty countries to interact with the intention of resolving international tax disputes. Often, these disputes involve cases of double taxation (juridical and economic) as a result of inconsistencies in the interpretation and application of a treaty.

An applicant taxpayer will negotiate with the DGT, who will prepare a draft mutual agreement which will be presented to the taxpayers. The mutual agreement will only be binding if the taxpayers accept the draft. This is consistent with common practice in MAP cases in other countries.

Updates on transfer pricing Issues – Advance Pricing Agreement (APA)

As part of the aforementioned amendments, the DGT issued Regulation No.69/PJ/2010 (PER 69) as guidance on the implementation of Advance Pricing Agreements (APAs).

An APA is an agreement between the DGT and taxpayers and/or another country's tax authority on the future application of the arm's length principle to transactions between related parties. APAs are a cooperative compliance tool intended to provide certainty on transfer pricing issues to taxpayers and tax authorities.

The APA application process is initiated by a pre-lodgement meeting between the DGT and the taxpayer, followed by the filing of a formal request to the DGT based on the pre-lodgement meeting. The APA is then discussed between the DGT and taxpayer, after which the DGT issues the APA letter. The formal agreement is then compiled by the taxpayer. Once compiled, the APA is ready for implementation and evaluation.

The changes will allow pharmaceutical companies to utilise APAs and MAPs in their international transactions and beyond.

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Japan

On 25 January 2011, a draft tax reform bill was submitted to the Diet for approval. Whilst the bill contains significant reductions to corporate tax rates and amendments to the transfer pricing rules, prospects for the proposal's enactment are uncertain.

Proposed tax reform – corporate taxes

Under the proposal, the national tax rate would be reduced from 30% to 25.5%. Consequently, the inhabitant tax, which is dependent upon the national tax, would also be reduced. In aggregate, large corporations located in the Tokyo Metropolitan Area could see their effective tax rates reduced from 40.69% to 35.64%. The corporate tax rate change would be effective for years beginning on or after 1 April 2011.

In order to offset an expected revenue loss from the corporate tax rate reduction, it is proposed that the tax net be broadened in numerous ways, including the limitation of net operating loss (NOL) deductions to 80% of taxable income; limiting the use of accelerated depreciation for assets acquired on or after 1 April 2011; gradually eliminating bad debt allowance deductions by 25% annually with the eventual abolition of the allowance by 2014; lowering the deductible donation expense by 50%; lowering the current cap on the R&D tax credit; and abolishing the special depreciation for certain qualified facilities.

Transfer pricing

The draft bill also contains proposed amendments to the transfer pricing rules. The proposal would establish a mutually beneficial system that uses the most suitable method for an arm's length calculation that is agreed upon by both the taxpayer and the National Tax Agency (NTA), thereby eliminating the NTA's ability to give priority over certain methods. The plan would also clarify definitions for some methods of arm's length calculations, respecting a company's specific policies if the calculations fall within the arm's length range.

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Korea

Changes to the Korean transfer pricing regulations

In December 2010, amendments were made to tax regulations for international transactions. Many of the changes are intended to further align the Korean regulations with the current OECD Guidelines. Other changes provide additional clarification of the interpretation of existing provisions. Taxpayers will benefit from the application of a regulatory framework that is more consistent with globally accepted standards.

Summary of key revisions:

- Changes were introduced to promote a higher degree of fairness and flexibility in respect of managing transfer pricing affairs. This includes permitting downward adjustments for above arm's length transfer price results. Reviewing transfer prices on a multiple year approach will also be permitted,which will allow companies to take into account product cycles and economic conditions.

- Arm's length prices will be calculated based on selection of the most reasonable transfer pricing method, instead of being based on a hierarchy of transfer pricing methods as stipulated in the previous law.

- The calculation of the arm's length price will be determined based on analysis of: (1) the taxpayer's business environment and intercompany transactions, (2) internal and external comparable transactions, (3) the selection and application of the most appropriate transfer pricing method, and (4) the selection of comparable transactions with reasonable comparability adjustments.

- The penalty for failing to submit the requested documentation in relation to transfer pricing compliance requests has been increased from KRW30 million to KRW100 million.

- Taxpayers may be further exempt from penalty tax on underreporting if relevant amendments have been made to the annual corporate tax return within 60 days after discovering new information relevant to the selection of the transfer pricing method.

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Malaysia

Enhancing tax incentives for health tourism

As a measure to further promote health tourism, tax incentives given to healthcare service providers offering services to foreign clients in Malaysia have been enhanced.

In certain circumstances, Malaysian residents are exempted from the payment of income tax in respect of income derived from healthcare services business provided in Malaysia to foreign nationals. The exemption rate of 50% on the value of increased exports is to be increased to 100%, subject to a restriction of exemption to 70% of the statutory income for each year of assessment. This incentive will encourage health tourism in Malaysia. It will take effect from the 2010 year of assessment until the 2014 year of assessment.

Case Law recent development – deductibility of 'Congress' expenses

Special Commissioners of Income Tax decision involving a subsidiary of a global pharmaceutical company that was originally held in favour of the taxpayer has been reversed by the High Court.

The taxpayer, engaged in the business of trading in human pharmaceuticals and animal health products, incurred certain expenses to sponsor doctors, pharmacists and health care professionals to attend conferences related to products of the taxpayer as part of its promotional activities. The High Court found that such expenses were entertainment expenses within the definition of Section 18 of the Malaysian Income Tax Act 1967 and therefore disallowed.

Tax authorities – latest updates and developments

The Malaysian Inland Revenue Board has recently targeted pharmaceutical companies, resulting in an estimated 80% of pharmaceutical companies operating in Malaysia being desk audited or field audited. The audit concentration lies in the treatment of management fees/royalty payments and profit margins.

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New Zealand

Technology Development Grants

The New Zealand government has introduced Technology Development Grants as a new measure to encourage R&D expenditure. These grants are awarded for a period of three years and reimburse 20% of eligible R&D expenditure up to $2.4 million a year (excluding GST). To be eligible for application, a business must:

- maintain an average annual R&D intensity of at least 5% over the last three years
- average annual revenue of at least $3 million
- boast a strong R&D track record.

Businesses with limited or no in-house R&D capabilities can also apply for Technology Transfer Vouchers which provides 50% funding towards business R&D projects. This will enable more businesses to access research services and expertise from accredited publicly funded research organisations.

Income tax rate change

New Zealand's corporate tax rate has been reduced from 30% to 28%, effective from the beginning of the 2011 income year. The reduction will also affect the standard uplift calculation for provisional tax and deferred tax balances. Personal income tax rates were also reduced from 1 October 2010.

Goods and Services Tax change

On 1 October 2010, the Goods and Services Tax (GST) rate increased from 12.5% to 15%. Further to this increase, from 1 April 2011, transactions between GST registered persons that involve the supply of land will be zero-rated.

IR compliance programme

Inland Revenue is currently focusing on cross-border financing arrangements and the use of complex hybrid instruments. In order to reduce compliance costs relating to transfer-pricing, Inland Revenue encourages companies to use advance pricing agreements (APAs) to increase certainty.

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Singapore

Highlights from Singapore Budget 2011

The 2011 Singapore Budget proposed to enhance the existing tax regime which allows a deduction for productivity and innovation related expenses. It also saw the introduction of the concept of pooling foreign tax credits and GST relief for materials imported for clinical trials.

1. Enhancements to the Productivity and Innovation Credit

The Productivity and Innovation Credit (PIC) was introduced in Budget 2010 and covered six areas; namely (a) research and development done in Singapore; (b) design work done in Singapore; (c) acquisition of intellectual property (IP) rights; (d) registration of IP; (e) automation through technology or software; and (f) training of employees.

With effect from Year of Assessment (YA) 2011, the tax deduction is increased from 250% to 400% of qualifying expenditure incurred with a cap increase from $300,000 to $400,000 for each activity. Businesses will be allowed to combine the $400,000 expenditure cap per year for YAs 2013 to 2015. This gives a total cap of $1.2 million. The cash grant has also been increased to a maximum of $30,000 for the first $100,000 of investments made. Further, the PIC is extended to cover R&D performed outside Singapore.

2. Foreign tax credit pooling

Currently, tax credits are claimed on a per-source, per-country basis, and any unused amounts cannot be carried forward or used against other sources of income. The Government will be introducing a foreign tax credit pooling scheme with effect from YA 2012 to encourage remittance of offshore income into Singapore.

3. Goods and Services Tax

GST relief will apply to imported clinical trial materials, regardless of whether the materials are for local testing, re-export or for disposal in Singapore. The Approved Contract Manufacturer and Trader Scheme will be extended to qualifying biomedical contract manufacturers.

GST zero-rating will apply to specified services supplied to overseas persons, so long as they are performed on certain goods kept in qualifying specialised warehouses in Singapore. To qualify, at least 90% of the specialised warehouse's customers must be based overseas, and at least 90% of the goods removed from the warehouse must be exported.

4. Other changes

Corporate tax rebates and grants

In YA 2011, companies will receive a 20% corporate tax rebate, capped at $10,000. Small and medium enterprises may also be entitled to a one-off non-taxable cash grant equivalent to 5% of revenue, capped at $5,000.

Pre-commencement expenses

With effect from YA 2012, businesses will be allowed to claim a deduction for their pre-commencement (revenue) expenditure incurred in the financial year immediately before the financial year in which they earn their first dollar of income.

Employee equity-based remuneration schemes
From YA 2012, a tax deduction will be allowed where the scheme is administered through a special purpose vehicle (SPV). To qualify, the SPV must be set up as a company or a trust, solely to administer the scheme for companies within the group and the SPV must buy the parent company's shares from the parent company or the market and hold them in trust for employees of the group.

The changes will improve the tax profiles of biomedical companies in Singapore and attract further investments from abroad.

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Taiwan

Thin capitalisation rule effective from 2011

In the recent amendment to the Income Tax Act, the Presidential Office introduced the new thin capitalisation rules for Taiwan. The changes are in addition to those enacted in late 2009 (refer to issue two of the Asia-Pacific Pharma Newsletter March 2010). Based on the promulgated regulation, from 2011 onwards deductible interest expense on inter-company loans is capped at a prescribed debt-to-equity ratio to be determined by the Ministry of Finance. The thin capitalisation rule generally applies to profit seeking enterprises, except banks, credit cooperatives, financial holding companies, bills finance companies, insurance companies, and securities companies.

To implement the thin capitalisation rule, a draft assessment rule governing deductibility of interest expense on inter-company loans is currently under discussion. The draft assessment rule defines related parties and defines inter-company loan and equity, and how to determine their respective balances. It also contains the contemplated debt-to-equity ratio, impact of transfer pricing regulations on thin capitalisation rule, information disclosure requirements and document retention requirements.

In light 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 capitalisation rule and ensure tax deductibility on interest expense recognized. Possible strategies include obtaining financing from local financial institutions instead; converting existing related party debt to capital, etc. Pharma companies should observe the development of the draft assessment rule stated above to efficiently manage their tax liability in Taiwan.

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