

Asia-Pacific Pharma & Life Sciences Newsletter

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

Issue 7, December 2011

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



Editor's Note

PwC's Asia-Pac Pharmaceutical & Life Sciences network is pleased to present you with our seventh issue of the Asia-Pacific Pharmaceutical & Life Sciences industry newsletter.

The newsletter aims to keep you informed of the latest developments in the industry for pharmaceutical, biotechnology, medical device, diagnostics and healthcare companies.

The last quarter has seen a number of major developments throughout the region in respect of the pricing of medicines as governments seek to access cheaper medications following patent expiries, and to curb ever growing healthcare budgets during times of further credit tightening.

Our section on **Pricing** developments includes articles from throughout the region on moves by various Governments to create a more affordable market for pharmaceuticals in Asia Pacific.

In our **Compliance** section we have also included highlights of the latest developments in various standards regarding the manufacturing of medicines in the region and actions taken to avert the potential threat of counterfeit products. While our **Regulatory** section reports on recent moves to restrict investment in domestic Pharma companies.

Finally, in our **Tax** section, on top of some good news in the region in respect of R&D credits, new deductions for intellectual property, indirect tax reform and other tax incentives, there are some foreshadowed changes to Transfer Pricing rules which will need to be monitored closely.

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: PRTM joins PwC



In August of this year, PwC formally completed the acquisition of PRTM Management Consulting.

The successful completion of this transaction increases PwC's ability to serve clients in the areas of operations management, strategic execution and business model innovation. The addition of PRTM's extensive experience in operations management consulting, including strategy, supply chain, product development, customer value management and business model innovation, will strengthen and support PwC's commitment to deliver consulting services from strategy through execution.

Within Asia-Pacific, the legacy PRTM team brings particular strength in the pharma, medical device, diagnostics, and imaging industries. With significant experience in China, India, Korea, and Japan (among others), the PRTM team has deep pharma and life science industry capability within R&D, innovation, operational strategy, marketing and sales, as well as supply chain. The team includes industry experts with decades of experience as well as staff with advanced degrees such as PhDs and MDs. And their style of work - focused on hands-on execution and transformation activities - strongly compliments the PwC network capabilities in the region. Perhaps it is easiest to describe these new capabilities through a few project examples.

Asia Strategy: Our teams have recently worked with a top 15 global pharma company as they revamped their Asia strategy, in light of slowing growth in other regions of the world. As with many companies, Asia has become a key focus area to help stop the top-line decline as a result of key patent expirations. Our teams played a key role in working with the company to develop their new strategy. Our role was to assess current market and regulatory dynamics and provide third party insight into these areas. The work focused on understanding the current practices across the industry in terms of business models in Asia, and included a series of smaller surveys and a wide variety of discussions and interviews with various stakeholders in the industry within Asia; from regulatory authorities to specific company personnel. Using a wide variety of techniques, the team was able to construct an interesting picture of pharma companies in Asia - with one common theme being that almost no matter what the organisational structure, companies were generally not satisfied with their China organisation and were in the midst of change, in one form or another.

R&D Functional Excellence: As companies face increasing cost pressures, they are looking more and more to reduce cycle times and increase efficiencies within their organisations. Our combined team has significant experience helping companies improve in many areas within R&D

from specific regional footprint to functional capabilities in clinical operations, vendor management, safety data handling, and much more. Through our work we have been able to help a number of companies achieve a more than 50% efficiency improvement in their R&D.

Organisational Transformation: A recent project focused on global R&D organisational transformation for one of Japan's largest global pharma companies. Working with the company's president and management committee, our teams helped them to refine their innovation strategy as we worked with them to design and create business units for the company which directly supported this new strategy. In doing so, we did more than just design a new organisational structure; we worked with management to remove legal hurdles posed by the legacy organisational structure. Together we helped them completely revamp their Human Resource and compensation systems and revamp the other infrastructure needed to support these new business units. The resulting productivity improvements have been tremendous.

Enterprise Profitability Improvement: The team previously assisted a company assess the manufacturing assets of a company it recently acquired. Reviewing the capabilities and cost structures of the manufacturing facilities in Japan, the team was able to help them identify millions of US\$ in savings opportunities and enabled management to make an informed decision to keep the facility in operation on the basis of the practical improvements identified.

Sales and Marketing Strategy: The team is working actively with three clients now on how best to balance three critical levers in the marketing area. On the one hand, we have traditional sales forces which are declining around the world. This change is being enabled by the advent of strong "e-marketing" tools and improved sales force automation technologies. Meanwhile, there is a strong trend towards increasing scientific and medical content. Our work includes sales force automation tool implementation work, medical marketing organisation and process design, sales force compliance review and training, and marketing strategies.

We trust that the above gives you a taste of the opportunities and expertise PwC & PRTM can bring to your organisation and we look forward to introducing our new capabilities to you in person soon!

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Compliance

China

Industry initiatives to improve pharmaceuticals

New GMP in Implementation Stage

The State Food & Drug Administration (SFDA) released detailed regulation on the Food Merchandising Practise for Pharmaceutical Products (GMP 2010) certification process in August 2011. GMP 2010 was officially issued in March 2011, with improved safety, efficacy and quality control elements built into its basic standards, with the new edition aiming to bring Chinese domestic standards up to western standards. Industry analysts estimated that the total costs of upgrading to the new GMP standards will cost the industry USD 5bn and the closure of one third of existing manufacturing facilities. The Ministry of Health (MOH) has mandated that more easily tainted items such as blood products, vaccines and injections must meet the new GMP standards before December 31, 2013, while products in other categories should be compliant by December 31, 2015.

Since the release of the regulations on the new certification process, there are now 20 pharmaceutical companies that have acquired the new GMP certification (based on data from SFDA's database).

New Good Supply Practice (GSP) in Draft Stage

SFDA opened a new draft GSP for public comment in August 2011. The new GSP draft is a continuing effort by SFDA to upgrade the pharmaceutical value chain to more rigorous standards following the issuing of GMP 2010.

The draft new GSP represents higher standards by the SFDA to regulate the drug distribution process as a supply chain rather than through the conventional classification of "wholesalers" and "retailers". The draft covers all components of the drug distribution process including purchase and sales, inventory and delivery, post-sales services, third party logistics and e-logistics. The new draft GSP also aims to achieve full regulation of the drug manufacturing and distribution process through IT technology.

It is expected that the final ruling of the regulation will be released in the coming months.

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Singapore

Online supply of illegal medicines has to stop

The Singapore Health Sciences Authority (HSA), as part of its global collaboration activities, participated in an international internet week of action targeting online sale of unregistered, counterfeit and illegal medicines to the public.

The operation focused on websites supplying illegal and dangerous medicines (ranging from discussion forums, web blogs, auction sites, online classified advertisements and company websites) and is the largest global internet-based action of its kind in support of the International Medical Products Anti-Counterfeiting Taskforce.

During this concerted international internet week of action to safeguard public health, the HSA intensified its checks on suspicious local websites offering medicines and health products on top of its on-going internet surveillance program. Regulatory actions were also taken against illegal online sales.

With the growing popularity of online shopping, including the online purchase of health products such as contact lenses and other medicines, HSA has rolled out a public education campaign which leverages on multiple media channels such as print and radio as well as popular social media platforms, to raise public awareness on the health dangers of buying such products online.

Visit the **Health Sciences Authority** for more details.

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India

Government of India announces new norms for Foreign Direct Investment (FDI) in Indian Pharma Industry

Prior to 2011, FDI in the pharmaceutical sector in India was allowed through the 'automatic route'. However, given the trend of acquisitions of domestic Pharma companies by global players, the government has expressed concerns about the ongoing accessibility and affordability of medicines in the Indian market. To ensure that such deals do not result in monopolies and an increase in drug prices, the government has announced new norms for FDI in the pharma sector.

A high-level committee has been appointed by the government of India to look into this. As a result of this the government has decided the following:

1. 100 % FDI through the 'automatic route' would only be allowed for green field projects;
2. 100% FDI through the Foreign Investment Promotion Board (FIPB) approval route for brown field investments in the pharma sector for a period of six months;
3. During these six months, necessary enabling regulations will be put in place by the Competition Commission of India (CCI) for effective threshold limits on mergers and acquisitions to ensure that there is a balance between public health concerns and attracting FDI in the pharma sector;
4. After six months the oversight will be done by the CCI entirely in accordance with the competition laws of the country (i.e. FIPB nod will not be required).

PwC Comment

As a result of the added regulatory oversight of FIPB and CCI, it is expected that these developments will add significant time to the process of acquisitions in India and may create further uncertainty for M&A in India.

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Japan

Pharmaceutical and Medical Devices Agency prepares International Vision

The Pharmaceuticals and Medical Devices Agency (PMDA) is a regulatory agency in Japan which protects the public health by assuring safety, efficacy and quality of pharmaceuticals and medical devices. The PMDA conducts scientific reviews of Marketing Authorisation applications for pharmaceuticals and medical devices, and monitoring of the post-marketing safety. The agency is also responsible for providing relief compensation for sufferers of adverse drug reactions and infections by pharmaceuticals or biological products.

The PMDA prepared an International Strategic Plan in February 2009 with the recognition that it would be necessary to cooperate internationally to make state-of-art pharmaceutical and medical technologies available to the public sooner. International circumstances have changed since then, especially in the relative importance of the countries that were not in the original scope of the ICH. Taking this opportunity, PMDA has prepared the PMDA International Vision in order to set their targets in 5-10 years. PMDA aims to realise the following objectives as one of the advanced regulatory authorities in pharmaceuticals and medical devices:

1. Ensure PMDA keeps top-level capabilities in:
 - quality and speed in three areas, i.e. scientific reviews, safety measures and relief compensation;
 - quality and quantity in regulatory science studies;
 - quality, quantity and dissemination speed of information offered internationally.
2. Keep close partnership with Asian countries to realise common interests in Asia through:
 - collaboration to improve drug regulatory systems in Asia;
 - offering opinions internationally as a member of Asian countries.
3. Contribute actively to international harmonisation of standards to bring benefits both to Japan and global community.

PwC Comment

Pharmaceuticals and medical devices companies outside Japan can expect less stress in getting Japanese regulatory information in English potentially resulting in more business opportunities within the Japanese market.

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Mergers & Acquisitions

Taiwan

Taiwan pharmaceutical companies pursuing cross-border alliances

The past year has seen an increasing number of Taiwanese biotechnology and pharmaceutical companies enter into cross-border alliances with foreign counterparts to jointly develop new drugs for various markets. We highlight below some of the more prominent tie-ups by local pharma manufacturers, as well as other areas for possible cooperation targeting the China market.

Eyeing the large American biotech market, in September 2010, Taiwan's ScinoPharm and the Ruentex Group signed a strategic alliance agreement with California-based drug developer Tanvex Biologics. ScinoPharm, a leading active pharmaceutical ingredient developer and manufacturer, and its financial backer Ruentex, will work with Tanvex to operate a new plant in San Diego, which will focus on developing biotech products targeted at biosimilars and biobetters, which Tanvex specialises in.

Targeting Japan's generic drug market, in April 2011, Taiwan's Yung Shin Pharma signed a Memorandum Of Understanding (MOU) with Japanese drug maker Wakamoto Pharmaceutical to set up a joint venture by the end of September 2011. The joint venture will leverage Wakamoto's brand name and distribution channels to market products developed by Yung Shin, which has already established its own presence in the US and China. In return, Wakamoto aims to utilise Yung Shin's expertise in the development of new generic drugs.

More recently, in August 2011, Taiwanese biotechnology firm GlycoNex signed an MOU with three Japanese firms—including Mitsubishi Gas Chemical—to build a pharmaceutical plant in Taiwan to develop anti-cancer drugs for the global market. GlycoNex also plans to build more factories in both Taiwan and China to mass-produce its own protein drugs as well as for other multinational companies.

With Taiwan and China moving steadily towards increased co-operation in healthcare and pharmaceutical matters, local companies see plenty of opportunities for more collaborative tie-ups. For instance, a cross-Strait co-operation agreement on medicine and public health affairs came into force in late June this year, which aims to cut the unnecessary duplication of studies and improve product quality. Also, China has recently adopted policies to upgrade domestic healthcare. Foreign investment is encouraged in the development of the healthcare sector, including the strategic biotechnology industry.

PwC Comment

Based on our market observations and client interactions, PwC sees four market opportunities as offering potential for tie-ups with Taiwanese biopharmaceutical and medical device companies, given their particular competitive advantages and deep understanding of the Chinese market:

1. Rising demand for medical devices from hospitals in China as a result of ambitious government plans to expand China's primary care service infrastructure and systems in 2011-2015.
2. The development of drugs for prevalent diseases in Asia, including various liver diseases and certain types of cancer, which are not the main focus of large multinational pharma companies.
3. The development of new drug formulations, which allow for a shorter registration time, involve less R&D investment, and have lower development risks compared to new drugs; and
4. The transfer of Taiwan's healthcare experience to China to support its domestic healthcare upgrading in areas such as specialised IT systems that local companies cannot yet deliver.

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Australia

A step in the right direction on PBS deferrals

As reported in Issue 5 of our newsletter, in February 2011, the Australian Federal Government deferred the listing of eight new medicines and vaccines on the Pharmaceutical Benefits Scheme ("PBS") which had been previously recommended for listing by the independent adviser to Government, the Pharmaceutical Benefits Advisory Committee ("PBAC").

In addition the Government decided that all future PBS listings would require Cabinet approval, effectively moving away from the previous \$10 million threshold before Cabinet approval was required. These decisions were contrary to the intent of the Memorandum of Understanding ("MOU") between the Government and Medicines Australia (the industry body for originator Pharma companies) and were met with significant outcry from the pharmaceutical industry and professional health groups.

Following significant industry lobbying, the Senate Finance and Public Administration References Committee considered the issues raised by the deferrals and recommended that the Government:

- withdraw the statement made in February 2011 to defer the listing of new medicines and the new rules that applied to listing of medicines;
- make clear that the listing of new medicines do not require savings to be made in other areas of the health portfolio;
- restate its commitment to making an explicit decision regarding the listing of new medicines on the PBS within the terms and intent of the MOU signed with Medicines Australia on 6 May 2010 and resigned on 28 September 2010;
- reinstate the '\$10 million rule' so that medicines that have a financial impact of less than \$10 million in each year over the forward estimates can be listed on the PBS by the Minister without Cabinet approval.

The Government has now agreed to list the medicines that had previously been deferred by Federal Cabinet and reached an agreement with Medicines Australia, the Generic Medicines Industry of Australia and the Consumer Health Forum (which included the Australian Medical Association (AMA) representing GPs) as to how new listing will be treated. In this agreement, the Government has committed to not defer listing new medicines that carry an annual cost of

under \$10 million. However, this agreement will only operate until 1 October 2012.

Medicines Australia chief executive Dr Brendan Shaw has welcomed the agreement and stated that his organisation and the other signatories to the agreement "have also agreed with Government to discuss possible policy options in the future."

PwC Comment

The industry hopes that the Government will comply with this agreement in order to provide a predictable business environment in which pharmaceutical companies can make decisions about future investment and employment.

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Pricing

China

National healthcare growth maintenance initiatives

In an effort to contain the growth in healthcare expenditures in China, this March, the National Development and Reform Commission (NDRC), lowered the maximum retail prices of 162 drugs (of 1,300 specifications) in the therapeutic categories of antimicrobial and circulatory system drugs. The average price reduction is as high as 21% and it is estimated the annual savings on the part of patients will reach nearly RMB 10 billion annually.

In August, the NDRC issued the second price cut of this year. The uniform maximum retail prices of 82 drugs (of 363 specifications) and individually-set maximum retail prices of 48 drugs (of 96 specifications) are reduced by an average of 14%, which is deemed a rather mild cut compared with earlier actions. Therapeutic classes affected this time include diabetes drugs, growth hormones, and drugs for osteoporosis, post-menopausal syndrome and Parkinson's disease. Among all, diabetes drugs are the most affected class. At the same time, the NDRC also withdrew a number of individually-set maximum retail price drugs as they are no longer produced or imported.

The primary objective of these cuts is to bring down prices of drugs with high average daily costs and to narrow the gap between off-patent originator drugs of MNCs and local products, according to the NDRC. As 80% of the affected products with individually-set prices are from foreign players, some local pharma industry experts believe that the latest price initiative is targeted at MNCs. Also, it is predicted that the NDRC may target four other therapeutic areas, including oncology, blood system, gastro-intestinal and respiratory system drugs for its future price cuts.

So far, the NDRC has launched 28 rounds of price cuts since 1998.

Source: *Pharma China*

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India

National government's price control measures

The Government of India, through a draft National Pharma Pricing Policy (NPPP) aims to control prices of 348 drugs based on the National List of Essential Medicines recently prepared by the Health Ministry of India (60% of drugs marketed in the country).

The draft policy seeks to regulate prices of drug formulations only, unlike the existing principle of controlling prices of specified bulk drugs and their formulations as adopted in the existing drug policy, 1994.

The key changes from the existing policy are namely:

1. The adoption of market based pricing (MBP) for fixing formulation prices instead of cost based pricing (CBP) followed currently;
2. The current ceiling limit of 10 % on the yearly permissible hike of prices of non-scheduled drugs may be revised to 15 %; and
3. Control of formulations prices only.

PwC Comment

If implemented, in the short term, we expect that there would be a slight negative impact on both domestic and MNC companies. However over time, it is expected that companies will devise strategies to mitigate the effect of this policy, although it is likely that this will impact both the top line and bottom line growth of pharmaceutical companies.

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Pricing

Japan

National Health Insurance system revises prices downwards.

The ethical drug prices in Japan are regulated under the National Health Insurance System. The National Health Insurance (NHI) reviews the prices of drugs every two years. Recently the NHI has revised prices downwards. It is increasingly important to consider the balance of cost and benefit, and the pharmacoeconomic evaluation when the NHI price is considered. The NHI price Expert Group of the Central Social Insurance Medical Council has also been discussing topics related to the improvement of the NHI price System itself.

They intend to determine if the “*incentive for creating an innovative drug*” is working, and discuss the NHI price revision method for drugs whose healthcare needs are high. These are some of the topics with high priority, but the following topics will also be addressed in this group taking into account the promotion of the use of generic drugs:

1. There are more than 20 generic products for some chemical entities. It may be a burden for a pharmacy to keep stock of this number of chemical products.
2. It is difficult to provide a satisfactory explanation on the large variability in the NHI prices between products of a single chemical entity.
3. Initial price of a generic drug is 70% of that of the branded drug. This may not encourage patients to move away from the branded to generic drugs.

In addition, the method for calculating the NHI price for both newly approved drugs and listed drugs will be reviewed by gathering data and information on each topic.

The NHI price system in Japan is finely designed to result in a complicated system. The NHI price Expert Group of the Central Social Insurance Medical Council reviews the above topics and discusses them at their monthly meetings

According to the Central Social Insurance Medical Council, the outline of the revision of the NHI price system will be presented to the Industry by the end of this year.

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Korea

Government announces ‘One-Shot Drug Price Cut’ policy

The South Korean government has announced a drastic ‘One-Shot Drug Price Cut’ policy for country. The reason why it is called “drastic” is in respect to its timing.

To date the pricing of generic drugs have gradually fallen since the expiry of the patent for the original drug until the price reached approx. 70-80% of the original drug price. However according to the ‘One-Shot Drug Price Cut’ policy, generic prices will be cut to 53% of the original price. During the first year of the patent expiration, the original price of the branded drug will also be reduced to 70% (30% cut) and the generic price will be reduced to 59% (41% cut) of the original price and then to 53% (47% cut) in year 2.

The policy applies to about 7,500 drugs, which is estimated at saving the Government Health Insurance up to about 1.7tn KRW and could block the rebate from pharma companies to doctors. The Government is also hoping that this will result in domestic companies finally changing their strategy towards R&D development, not solely sales oriented.

Currently this policy is awaiting proclamation and is intended to be implemented from January 2012 with existing drug prices being cut from April 2012. Most experts and industry commentators believe that this change “will” come true; and Korean and multinational pharmaceutical companies operating in Korea will eventually face significant price cuts

PwC Comment

As a result of this change, we believe that Korean pharma companies will look to change to survive. Small Cap companies will consider business restructuring; starting new complimentary businesses or potentially in more severe cases withdrawing completely. Mid cap companies are divided into two groups; one having much more resources to resist this turbulence whilst the other group not having the ability to withstand these changes alone. The former will most likely buy the latter so as to expand their capacity to increase the number and volume products being manufactured locally. For the large cap companies, there could also be strategic M&A opportunities among them to make up their weakened market position.

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Pricing

Taiwan

Industry protests against new drug prices

A new round of drug price cuts by Taiwan's Bureau of National Health Insurance (BNHI) has aroused strong opposition from the pharmaceutical industry. Following a survey of market prices and volumes, the BNHI announced on 21 October that it would cut the reimbursement prices of 7,300 drug items from 1 December, with the immediate impact seen on new and original drugs. The industry believes the price cuts will prompt hospitals and clinics to replace original drugs with cheaper substitutes.

At the same time, the BNHI will allow price increases on about 1,000 generics as a reward for quality improvement. To encourage local manufacturers to meet Taiwan's target for the implementation of the Pharmaceutical Inspection Convention Scheme (PIC/S) Good Manufacturing Practice (GMP) standards by 2014 (ahead of time), the BNHI has been giving price incentives to generic manufacturers that meet minimum quality standards. However, some critics argue that, after the latest price increase, some generics will be more expensive than the original drugs they are supposed to be a cheap alternative for.

The revision will be the seventh in a series of biennial price reductions that have proven extremely disruptive to Taiwan's pharma industry. The return on investment for drug companies has been steadily declining due to BNHI's previous six rounds of price cuts over the past decade. The magnitude of the price cuts has grown from NT\$500 million (US\$17 million) in 2000 to NT\$20 billion (US\$663 million) in 2009. According to preliminary industry estimates, the latest price adjustment is expected to cut a further NT\$15 billion (US\$497 million), though the impact is yet to be fully evaluated.

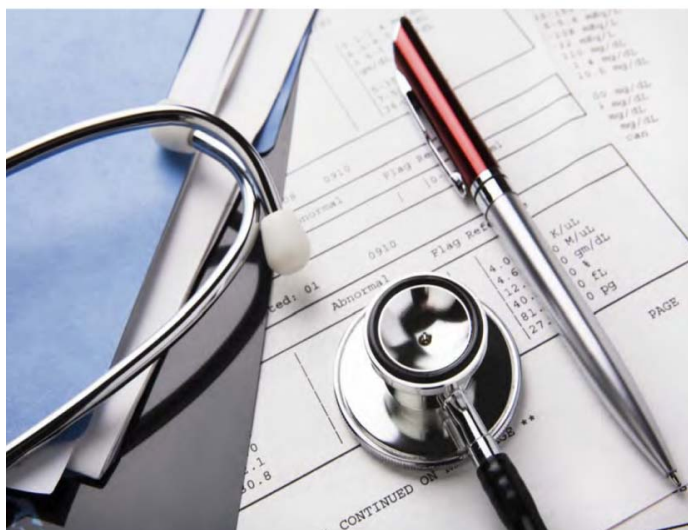
Drug manufacturers have persistently expressed their concern over the pricing situation in Taiwan, as each downward reimbursement price adjustment by the BNHI just sets off another round of demands from hospitals and clinics for discounts. Industry representatives had been pressing for the implementation of a drug expenditure target-based price adjustment mechanism—as provided for in the revised National Health Insurance Act—to replace the seventh price-volume survey, but to no avail.

PwC Comment

The new drug price cuts will have damaging implications for Taiwan's pharma industry. Their impact could potentially endanger access to essential and high quality medications, hinder investments into research and development, and force pharmaceutical companies to downsize their operations in Taiwan, or even withdraw their products from the local market.

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Australia

Changes to Transfer Pricing rules

There have been two recent significant developments in Australia's international tax rules which will impact all international pharmaceutical companies in Australia.

1. Australia's 'transfer pricing' (TP) rules, which are designed to prevent erosion of the tax base through profit shifting are to be re-written. The Government is proposing to replace the 30 year old existing rules, with a new set of rules based on international best practice.
2. A new annual disclosure form is being introduced which will require more details to be provided to the Australian Taxation Office (ATO) about cross-border transactions entered into between members of a multinational group.

In recent times, the preference for transactional data over the use of profit methods under the Australian domestic transfer pricing rules was initially proffered in the *Roche Products case*. Earlier this year the Full Federal Court went further in *Commissioner of Taxation v SNF (Australia) Pty Ltd [2011]*, in confirming this preference and stating that the OECD Guidelines are not law and do not have to be considered in interpreting TP rules

As a result,, the Government has issued a Consultation Paper outlining proposed changes to TP rules. At the heart of the TP rules is the '*arm's length principle*', which requires the pricing of cross-border transactions between related parties to be consistent with what would have been agreed between independent parties in comparable circumstances. The key changes proposed include:

- Formally recognising the Organisation for Economic Cooperation and Development (OECD) guidance in the Australian law, including endorsing the pricing methods approved by the OECD. The OECD pricing methods permit the arm's length price of a transaction to be tested at the price, gross margin or net margin level.
- Testing whether the profit allocation 'outcomes' of cross-border transactions are commercially realistic (as opposed to testing whether the price is arm's length).
- Making TP documentation mandatory if transactions with related parties exceed certain threshold.
- Allowing the ATO to recharacterise transactions between related parties in certain situations.
- Introducing a time limit on the years available to the ATO to issue amended assessments in TP cases.

The ATO is also introducing an International Dealings Schedule (IDS) to enable them to gather more detailed information about cross-border dealings between affiliates. In addition to requiring a greater level of disclosure of related party dealings, the IDS will cover such issues as business restructures, transactions with tax havens, hybrid debt,

trusts, employee share plans, financial derivatives (e.g. loans and guarantees) and derivatives. The ATO will use the information gathered in the IDS to assess the risk profile of taxpayers and to select cases for audit.

The changes will impact all pharmaceutical companies with an international presence to some extent. You are most likely to be impacted by the changes if:

- You have significant offshore operations or dealings with related parties offshore (whether that be tangible goods, financial transactions, services or intangible property);
- You are currently involved in an ATO TP dispute, or you have been rated as a 'high risk' taxpayer by the ATO;
- You rely principally on a transactional method (CUP, Cost Plus or Resale Price Method) to support the pricing of your intercompany dealings
- You have never prepared local TP documentation or rely on global studies for local documentation;
- You have implemented a cross-border business restructure, eg relocating functions, risks or intangible property from Australia to an offshore location;
- You have a high level of related party debt; and/or
- The local profits of are below industry norms.

In addition, the law will be amended to clarify that Australia's tax treaties have operated as an alternate taxing power to the domestic transfer pricing law.

The amendments are proposed to apply retrospectively from 1 July 2004. This aspect of the changes is particularly controversial as the treaty provisions are arguably wider in their application than the domestic law. The changes remain subject to parliamentary approval, with draft legislation to be expected in the first half of 2012, to apply from 1 July 2012.

PwC Comment

As a result of these changes, the compliance burden of all international pharmaceutical companies will increase due to the need to capture and disclose a greater level of data than before, as well as the need to refresh/update/draft (as the case may be) transfer pricing documentation according to the revised compulsory requirements.

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China

Indirect Tax Reform in China – VAT Reform Pilot Program officially announced

Currently, the turnover tax system in China creates inefficiencies for some industries. In recognition of this, China plans to make changes in the next few years. Eventually, the scope of Value Added Tax (“VAT”) would likely cover all the industries that are currently subject to Business Tax (“BT”).

The Chinese Government has just announced that an indirect tax reform pilot program (the Pilot Program) will be introduced to assess the impact on the new policies before they are fully implemented country-wide. The program will be piloted in Shanghai from 1 January 2012. On November 16 2011, the State Administrative of Taxation (SAT) and the Ministry of Finance and Commerce (MOFCOM) jointly issued detail guidelines (i.e. Circular [2011] 111) which consisted of the implementation measures and clarified the scope of VAT services and some transitional regulations.

The first round of Pilot Program will start with the transportation industry and “certain modern service industries” in Shanghai, which may possibly be extended countrywide for selected industries when the circumstances warrant it.

Further to the prevailing 17% and 13% VAT rates, two additional VAT rates of 11% & 6% will be added.

Circular [2011] 111 further clarifies that “certain modern service industries” include the following:

- R&D and technical services (e.g. R&D, technology transfer, technical consulting service, etc).
- Information technology services (e.g. software service, information system service, business process management service, etc).
- Cultural creativity service (e.g. design, trademark and copyright transfer, IP service, advertising service, exhibition service, etc).
- Logistic auxiliary services (e.g. shipping support service, forwarding, declaration, warehousing, loading, etc).
- Tangible property leasing services (including operating lease and financial lease).
- Certification and consulting services (including certification, verification, consulting services related to finance, tax, legal, management, operation, process, etc).

The Pilot Program will have significant impact to following pharmaceutical companies from both tax and financial perspectives:

- Foreign pharmaceutical companies that have established various PRC investments (e.g. marketing company, China/Asia R&D centre, regional share service centre, etc.) in Shanghai; and
- The overseas affiliates or licensor who charge services fee and royalties to the China entities.

From the supplier’s side, pharmaceutical companies are purchasing from their vendors (e.g. advertising company, IT service providers, logistics providers, etc) who will also be subject to VAT in Shanghai and eventually impact pharmaceutical companies’ bottom line.

Before the execution date of the Pilot Program (i.e. 1 January 2012), it is suggested that companies take early action to assess the impacts both from the supplier and customer side, such as:

- Additional VAT cost due to the increase of tax rate but lack of input VAT credit;
- Potential increment/decrement of financial subsidies in the following years;
- Tax position on outbound remittance (e.g. royalty, technical fee, etc.);
- Internal accounting and ERP system to fit in the VAT regime;
- Human resource & capability for tax compliance of VAT;
- Impact on the pricing policy as well as the existing contracts.

There are still various uncertainties on implementation and transitions.

PwC Comment

Given that the Pilot Program is officially commencing on January 1, 2012, pharmaceutical companies doing business in Shanghai should assess how the new changes will impact their financials and operations. Companies should also assess its readiness for a smooth transition.

See PwC’s *China Tax/Business News Flash* for more info.

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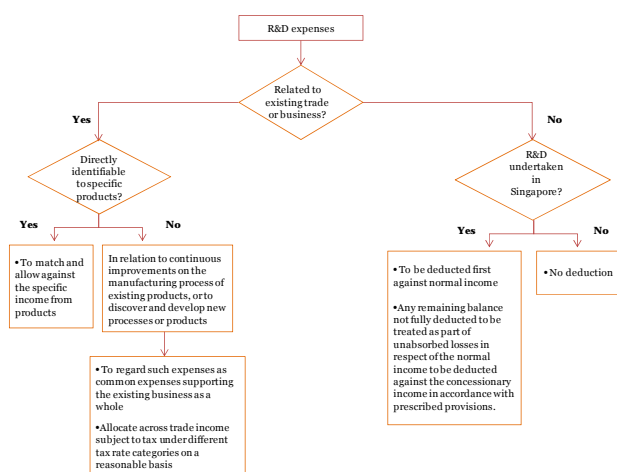
Singapore

Inland Revenue's release on R&D for manufacturing and headquartering activities

On 22 August 2011, the Inland Revenue Authority of Singapore ("IRAS") issued a Circular outlining how and why pharmaceutical companies are selecting Singapore for housing their R&D, manufacturing and headquartering activities.

The Circular also provides guidance, inter alia, on the tax treatment of qualifying R&D expenses and royalty payments as may be relevant for pharmaceutical manufacturing companies (which are involved in development, manufacturing and marketing of drugs).

[Link to the full Circular at the IRAS website](#)



Tax treatment of royalty payments in Singapore

The reference point for claiming tax deductions and withholding tax payments from royalties should be when the liability to pay the royalty crystallises. Therefore, a deduction should be claimed and withholding tax ought to be accounted for only when the (non-resident) recipient is legally entitled to the royalty income.

For royalty payments based on in-market sales, the Circular clarified that liability to pay royalties crystallises only when the intermediary sells the finished drugs to end consumers. For example, the royalty payable by a Singaporean company to its US headquarters overseas, is due only when the products are sold to end-consumers in a local market, which are sold through a third party distributor. In this example, although the Singaporean company may make a provision in the accounts (as per the Financial Reporting Standards) for the royalty expenses when goods are sold to the third party

Singapore Spotlight

Biomedical Science sector in Singapore gets boost of S\$790m from two new fund injections in November

In line with the Singapore's Research, Innovation and Enterprise 2015 plan, two multi-million dollar new initiatives have been introduced to strengthen public-private partnerships in Biomedical Science R&D. Their aim is to foster more partnerships and boost multi-disciplinary integration to catalyse clinical solutions. The Biomedical Sciences Executive Committee has announced two new funds to strengthen public-private partnerships in Singapore:

- The **Open Collaborative Fund (OCF)**, worth S\$590 million, is for the science and the clinical communities aimed at promoting partnerships between the two to work on research with greater potential economic or clinical impact.
- The **Strategic Positioning Fund**, worth S\$200 million, is for A*STAR's Biomedical Research Council to help catalyse and support new research areas and technology platforms.

distributor, the liability to pay such royalty would not crystallise until the time the third party sells the products to end consumers. This may create a practical difficulty in accounting when the liability to pay crystallises. The Singaporean company would have to keep track on when such products are sold in order to claim a tax deduction on the royalty payments and withhold tax. Failure to track accurately may result in errors in withholding tax filing and/or the late payment for withholding tax. Hence, proper planning prior to executing royalty agreements is advisable, and where necessary advance ruling may be sought to achieve upfront certainty.

For royalty payments based on ex-factory sales, the Circular clarified that liability to pay royalties crystallises upon sale of the intermediate product. Hence the royalty payments will be deductible at this point. Similarly, royalty payments to non-residents will be subject to withholding tax when the intermediate product is sold.

[Link to the full Circular at the IRAS website](#)

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Hong Kong

Extending tax deduction for purchase costs of intellectual property

A bill proposing to extend the tax deduction for the costs of purchasing intellectual property was passed by the Legislative Council on 7 December 2011. It is expected that this new tax deduction will be available for year of assessment 2011/12 onwards.

Currently, tax deductions are only available for capital expenditure incurred on purchases of patent rights or rights to know-how. The new law proposes to extend the deduction to the capital expenditure incurred on purchase of copyrights, registered designs and registered trademarks, which are defined in the legislation. For the eligible intellectual property used in Hong Kong, its costs are tax deductible over 5 years commencing in the year of acquisition. Upon disposal, any costs that are not allowed and which exceed the sale proceed will be allowed in the year of disposal. On the other hand if the sale proceed exceeds the disallowed costs, the excess will be taxable in the year of disposal but capped at the aggregate amount of deductions granted previously.

The new law also adds anti-avoidance provisions which include the following situations:

- Purchase of IP wholly or partly from an associate;
- Sale and license back arrangements;
- Early termination of existing licence to use the IP;
- The licensed IP is to be used wholly or principally outside HK by another party;
- Leveraged licensing - Acquisition of the licensed IP was financed by a non-resource debt.

PwC Comment

Pharmaceutical companies seeking to acquire new, or centralise future IP, within Asia Pacific should continue to monitor these developments so that they can access any benefits associated with Hong Kong's proposed IP tax deduction regime. Along with a generally favourable offshore income regime, companies may wish to reconsider the role of HK within their Asia-Pac holding structures.

See **PwC HK's Tax News Update** for more information

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Diagnostics 2011



PwC's *Diagnostics 2011* provides an overview of M&A deal activity during the past two years and the factors driving it, the development of new prospects for early detection testing and a review of significant events for the development of personalised medicine. The report also includes an in-depth discussion about trends in companion diagnostics and business model considerations for pharmaceutical companies.

This new PwC report highlights how multi-billion dollar IVD (in vitro diagnostics) deals in the first seven months of 2011 more than tripled M&A deal value from 2010 to over \$15 billion.

According to PwC's review of the IVD sector, investor interest in the global IVD market is expected to grow in 2012-2014 following a surge in M&A deal values, an acceleration of companion diagnostics partnerships, and the emergence of new prospects for early detection testing.

Interest in the IVD market is coming not only from existing players, but also new entrants such as financial investors, life sciences research groups, clinical laboratories and medical technology players.

PwC expects the IVD competitive landscape will be redefined by new market leaders and larger deals as players bulk up on market share, but sustained momentum of companion diagnostics partnerships with pharmaceutical companies will depend on actions by governments, regulators, payers and industry to support innovation.

Click here to download this latest PwC publication

Recent PwC Publications include:

Pharma 2020 Series:



Pharma 2020: Supplying the future?
Which path will you take? (Feb 2011)

The sixth report in the Pharma 2020 series highlights how pharma companies will have to develop different supply chain models for different product types and patient segments, learn to use their supply chains as a means of market differentiation and source of economic value, and recognise the key role information will play flowing upstream to drive the downstream flow of products and services.

Asia Pac Regional Perspectives:



Issues and Opportunities
- in a time of change (Jul 2010)

PwC Australia's most recent biannual report into the Australian Pharmaceutical Industry provides you with our qualitative and quantitative findings from our survey of key companies and stakeholders in the industry during 2010 including companies engaged in sales and marketing, manufacturing, Research & Development (R&D), distribution, wholesaling, retailing and services.



Pharma 2020: Taxing times ahead
Which path will you take? (Dec 2009)

The fifth report in the Pharma 2020 series focuses on the opportunities and challenges from a tax perspective. It discusses how the political, economic, scientific and social trends currently shaping the commercial environment, together with the development of new, more collaborative business models, will exert increasing pressure on effective tax rates within the industry.



Investing in China's Pharmaceutical Industry
- 2nd edition (Apr 2009)

The landscape is changing fast in China and this edition reviews, updates and expands on key areas: Traditional Chinese Medicine (TCM), OTC Market, Medical Devices, CROs and CMOs, Development of Innovation, Tax Incentives, Bribery & Corruption in Sales & Marketing, Drug Pricing, Distribution Systems, Intellectual Property Protection, Market Consolidation and Financial Impacts of Investments.



Pharma 2020: The vision
Which path will you take? (Jun 2007)

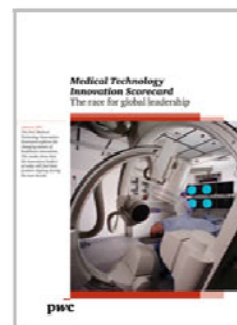
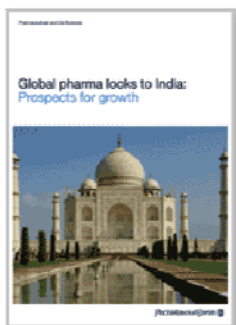
This report, the first in the series, indicates that the current pharmaceutical industry business model is both economically unsustainable and operationally incapable of acting quickly enough to produce the types of innovative treatments demanded by global markets. In order to make the most of these future growth opportunities, the industry must fundamentally change the way it operates.



The changing dynamics of pharma outsourcing in Asia - are you readjusting your sights? (Sep 2008)

The dynamics of pharma outsourcing and location decisions in Asia are changing. Cost reduction is being augmented and companies need to set their strategic sights on a future world. This new report highlights the dramatic change and development in pharmaceutical outsourcing in Asia.

Other Publications:



These and other publications can be found on PwC's Pharmaceuticals & Life Sciences website at www.pwc.com/pharma

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