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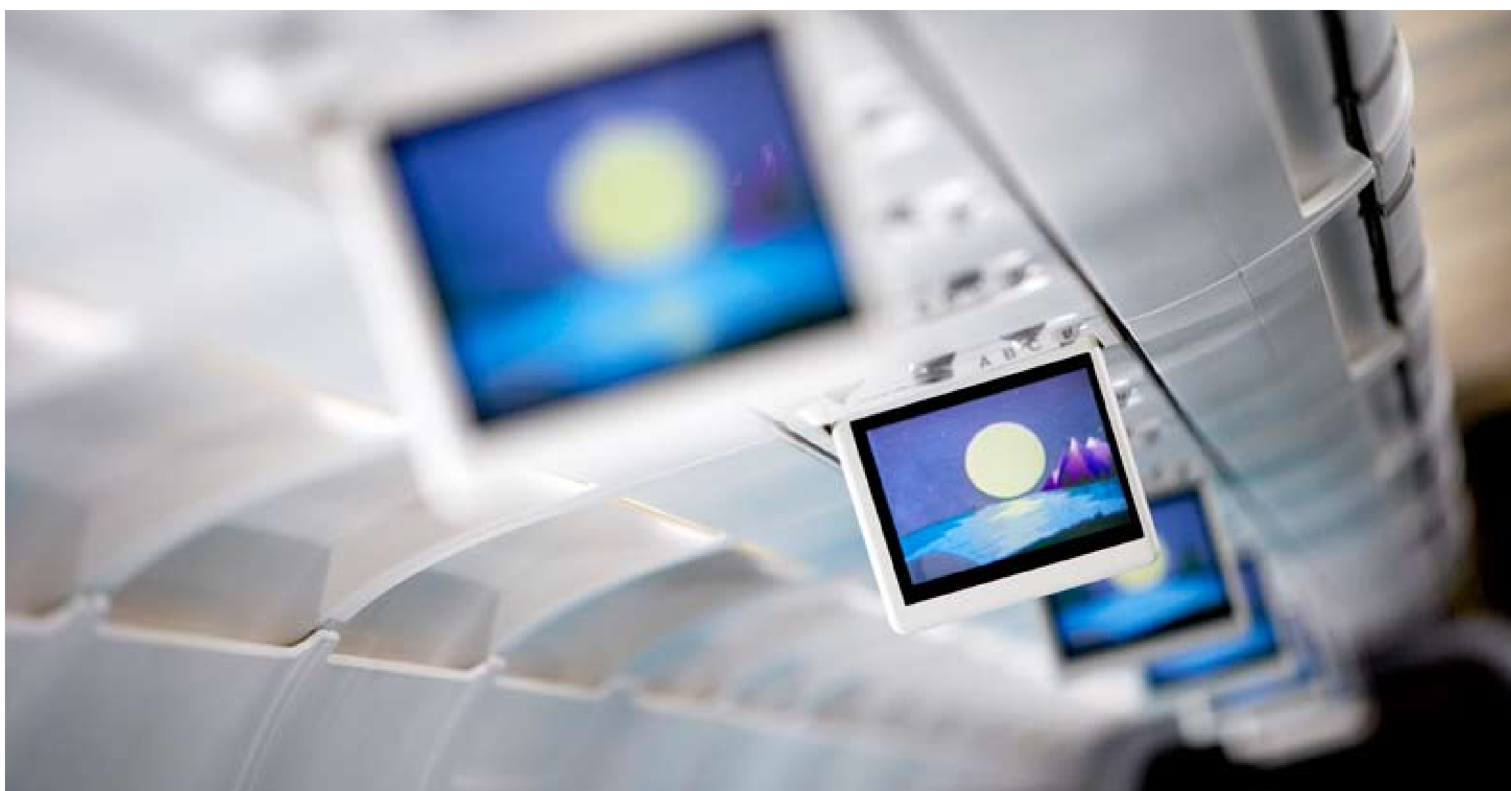

The PricewaterhouseCoopers (PwC) Pharma & Life Sciences experts are pleased to provide you with the third issue of our Asia-Pacific pharmaceutical & life sciences industry newsletter.

We like to highlight our new thought leadership on the Indian pharmaceutical market: “Global Pharma looks to India: Prospects for growth.” You can read the summary of the report in this newsletter and find the link to download the report.

This issue also includes our observations in a number of territories of new and/or changed tax regulations that can impact your business and we provide you with our insights on these changes in this newsletter.

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

PricewaterhouseCoopers

Global Pharma looks to India: Prospects for growth

The huge potential of the Indian pharmaceuticals market is impossible for foreign companies to ignore, given that it will be one of the top 10 sales markets by 2020. India's population is growing rapidly, as is its economy – creating a large middle-class able to afford western medicines. India's epidemiological profile is also changing and the population is ageing, so demand is likely to increase for drugs for cardio-vascular problems, disorders of the central nervous system and other chronic diseases such as diabetes which is increasing at an alarming rate. The total market is expected to rise to a value of approximately US$50 billion by 2020.

Our report highlights that India now has a growing and increasingly sophisticated pharmaceutical industry of its own. It is likely to become a competitor of global pharma in some key areas, and a potential partner in others. India has considerable contract manufacturing expertise; Indian companies are among the world leaders in the production of generics and vaccines - now producing more than 20% of the world's generics. Around $70 billion worth of drugs are expected to go off patent in the US over the next three years, and PwC thinks that India is capable of manufacturing a substantial share of the product to support the resulting generics opportunities. Although urbanisation continues, around 70% of India's population still resides in rural areas. We note that this untapped potential is now the next volume driver for the industry, but foreign companies looking to access rural markets face many hurdles.

PwC notes a number of methods for foreign companies to explore opportunities in India:

- **Outsourcing.** Recently there has been a move from outsourcing lower value and manufacturing activities to more research-based capabilities.
- **Licensing** is being used to establish a common platform in order to gain rapid in-market acceptance and create a complete therapy range.
- **Franchising.** US-based Medicine Shoppe International, for instance, has entered the market as Medicine Shoppe India and plans to expand to 1,000 stores by the end of 2010.
- **Joint ventures** with domestic partners bring local expertise and a local network and require government approval. Pharmaceuticals are deemed a high priority area so approvals can be quick.
- **Investment.** Some multinational companies such as Pfizer and Novartis are taking advantage of the potential in India through partially or wholly owned subsidiaries.

As with any kind of new market opportunity there are additional factors to consider:

- **Infrastructure challenges**
- **Tax benefits and upcoming changes to the tax codes**
- **Counterfeiting**

Click here to download the report

Special Report

Singapore biotech in focus

Supporting the Growth of the Medical Device Sector in Singapore

Although 30 global medical device companies have already set up manufacturing plants in Singapore, this sector remains one with high barriers to entry. It requires cross-disciplinary skills and knowledge ranging from manufacturing to medicine and computer science.

As such, the Singaporean government agencies are presently focusing their efforts to support the medical device sector, which has been identified as a promising sector with huge potential for growth.

Some of the key initiatives to support the sector are:

MedTech Capability Development Program
Grants are provided by the Government to qualifying companies to enable them to capitalize on opportunities in the medical technology industry by upgrading their capabilities to produce medical tool components, develop new medical products and processes and implement international standards to meet stringent outsourcing requirements.

Tax Incentive and Relief Measures
Incentives are provided in the form of an enhanced tax deduction for expenses related to research and development in Singapore as well as intellectual property acquisition and registration; and reduce corporate tax rate from the prevailing 17% to a lower range of 0% to 10%.

*A*Star's Biomedical Engineering Program*
Under the program researchers at A*STAR, universities and clinicians in the hospitals are made available to participate in multi-disciplinary medical innovation projects. The objective is to develop cost-effective and innovative solutions for healthcare systems.

iPartners Program
This program facilitates the formation of synergistic alliances between Singapore based companies for overseas expansion and market accessibility, as well as provides grants to defray part of the qualifying project cost incurred in pursuing overseas projects.

Workforce Skills Qualifications Graduate Diploma in Medtech Manufacturing
This training program is designed to provide industry players with knowledge and skills in medical device regulatory requirements, product innovation and development, manufacturing processes, quality control systems and management techniques.

Armed with the above schemes and initiatives, Singapore is committed to encouraging medical device companies to use Singapore as a platform to grow and develop new solutions that can address the unmet healthcare needs of fast-growing Asian markets.

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Tax

Australia

New R&D Tax Incentive – Second Exposure Draft

The existing R&D tax program allows companies to claim additional tax deductions for R&D undertaken in Australia. The Government is looking to considerably change the R&D tax program from 1 July 2010. The new program is generally intended to increase the benefits to many claimants, especially companies undertaking R&D in Australia for foreign parent companies and companies under US$20 million group turnover. However it is the Government's intention to limit program access in some areas and there has been some opposition to proposed restrictions relating to R&D undertaken in a commercial or production environment.

On 31 March 2010, the Government released a second Exposure Draft for the proposed program. This introduced a new definition of core R&D activities and has scaled back a number of the proposed eligibility restrictions, while cleaning up some complications for foreign owned R&D to ensure access to the program as intended. However, the new release has introduced a "dominant purpose" test to limit access for particular supporting activities.

At this stage the proposed program has the following elements:

- A 40% R&D Tax Offset for companies over US$20 million group turnover.
- A 45% R&D Tax Offset for companies with less then US$20 million group turnover, with potential of a refundable offset if the company is in tax loss.

R&D activities undertaken in Australia for foreign parent companies are eligible for the program (regardless of IP ownership or any R&D costs reimbursement).

Production related activities must be undertaken for the "dominant purpose" of supporting core R&D activities. Software based projects may access the program, however limitations exist for internal administration based projects.

Overseas costs can be included up to 50% of total project costs (subject to specific preapproval requirements), if total R&D project costs are predominantly in Australia.

The Government continues to consult with industry regarding the nature of the program, however as the timeline is shortening before the intended start date, further changes may be minimal before the program is finalised.

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Australian Taxation Office Targeting Rewards Schemes

The Australian Taxation Office (ATO) is targeting loyalty and reward schemes within the pharmaceutical industry. A routine audit of a single pharmacy recently has resulted in the ATO examining a multi-million dollar loyalty scheme operated by a large Australian pharmaceutical company. Many other pharmaceutical companies take part in such schemes, accumulating points for every dollar spent with wholesalers. It may be that there are significant unreported tax liabilities associated with operating such schemes.

Benefits provided to an employee by a third party under an arrangement with the employer (such as benefits flowing from a business relationship with a supplier or wholesaler) can be treated either as assessable income of the employee or raise a Fringe Benefits Tax (FBT) liability for the company. These benefits may be in the form of loyalty points, vouchers or any goods and services received.

It is clear that the operation of loyalty and reward schemes remains an area of focus for the ATO. Pharmaceutical companies operating such schemes should consider whether any rewards schemes in place are being reported and taxed appropriately under the FBT or income tax rules.

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China

China Anti-avoidance Enforcement Targets Pharmaceutical Sectors in 2010

The *China Taxation News*, an official newspaper of the State Administration of Taxation (SAT) of China, recently reported that the pharmaceutical and automotive industries are China tax authorities' focus in the year 2010 in respect of anti-avoidance administration. Being the world's most important manufacturing base, China's anti-avoidance enforcement program has historically been focused on the transfer pricing of contract manufacturing operations, which predominantly involve tangible goods transactions.

In recent years, there was a clear trend that greater emphasis had been put on more complex transactions and issues, such as intangible assets and services transactions, equity transfers, cost sharing arrangements, thin capitalization and controlled foreign corporation.

Taxpayers should also note that under the China tax laws, intangible transactions are also subject to business tax. As a result, the transfer pricing of intangible transactions could also be scrutinized by the China tax authorities from a business tax perspective.

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Hong Kong

IRD's Increased Focus on Transfer Pricing

The Hong Kong Inland Revenue Department (IRD) issued the *Departmental Interpretation and Practice Notes No. 46* (DIPN 46) on 4 December 2009, which outlined the IRD's views on the legislative framework for transfer pricing in Hong Kong, including the methodologies that taxpayers may apply, the documentation that taxpayers should consider retaining to support their arrangements and some thoughts of the IRD on transfer pricing related issues.

DIPNs serve as a reference with respect to the views of the IRD and do not have any legal binding force. In practice, the IRD usually follows DIPNs in assessing taxpayers.

The issuance of a DIPN on transfer pricing for the first time in Hong Kong is an important signal that the IRD will be putting more focus on transfer pricing related issues going forward, and hence transfer pricing has become a more prominent issue in Hong Kong. The IRD have clearly stated that the principles in the OECD Transfer Pricing Guidelines apply in Hong Kong, except where they are incompatible with the express provisions of the domestic tax law. As a result it appears that the IRD expects to be making transfer pricing adjustments, and therefore would request detailed information and documentation from taxpayers relating to related party transactions.

For those who used to consider that Hong Kong has a more 'relaxed' transfer pricing environment compared with other jurisdictions, it may be time to critically review and assess their increased level of tax risk associated with transfer pricing in Hong Kong, in light of this IRD's guidance.

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India

Impact of the Budget on Pharmaceutical Industry

India announced its Budget 2010-11 in February this year. Overall, impact of this budget on the pharmaceutical industry, in financial terms remains broadly neutral. On the positive side; the weighted deduction given to in-house R&D has been increased from 150% to 200%, excise duty of 4% is continued and the surcharge on domestic companies reduced from 10% to 7.5%. However, on the flip-side MAT has gone up from 15% to 18% and service tax is now going to be levied on medical health checks.

Even though the Indian Government still needs a bigger program to transform its healthcare system, this budget has taken measures to improve access to healthcare, especially for people of the rural sector and below the poverty line. Allocation to National Rural Health Mission (NRHM) under the Ministry of Health and Family Welfare has been increased from Rs19,534 crore in 2009-10 to Rs22,300 crore for 2010-11 - a 14% increase over the previous year. Government has also planned an Annual Health Survey to prepare the District Health Profile of all districts in 2010-11. This survey will help analyze the health profiles of the populace in the rural districts and successfully address the gaps in the delivery of critical health services in rural areas.

Even the health insurance coverage under Rashtriya Swasthya Bima Yojana (RSB), which is the health insurance for people below the poverty line, has been extended to more than 20% of the Indian population covered by the National Rural Employment Guarantee Act (NREGA) program, who have worked for more than 15 days during the preceding financial year. This scheme covers approximately 10 million families out of the 60 million families who currently fall below the poverty line. According to the scheme, eligible families are entitled to hospitalization coverage up to Rs.30,000. Coverage extends up to five members of the family, including the head of household, spouse and up to three dependents.

Service Tax on Medical Checks

However, health insurance costs would rise as the Government has decided to impose service tax on payments made by insurance companies to hospitals in settlement of claims where policyholders had received cashless service. Service tax introduced on medical health check up undertaken by corporations and health insurance companies can discourage such initiatives in the long run and can become a deterrent for the preventive healthcare.

Increase in R&D Deduction from 150% to 200%

The Government has recognised the last decade as one of innovation and has taken steps in the direction of incentivising Research & Development activities. In-house R&D activities was given the long due support by increasing 150% weighted deduction to 200%. Even the weighted deduction for sums paid to approved scientific research associations / similar bodies has increased from 125% to 175%. Indian pharma industry has come a long way post the new patent regime and is now doing serious discovery work. We think such benefits will boost R&D activities in the country and continue to promote more critical mass and financial viability as India positions itself to be a global research hub. This will further encourage spending by pharma and biotech companies on research for New Chemical Entities (NCEs), New Drug Delivery Systems (NDDS) and help India climb on the innovation curve.

Indirect Tax Changes

Turning to indirect taxes, excise duty for finished formulations, which were brought down from 8% to 4% in late 2008, has been retained this fiscal year. The decision to halve excise duty to 4% in previous budgets was one of the key contributors for over 15% growth of the Indian pharma industry. This has also levelled the playing field for companies that had their plants outside the excise-free states, such as Himachal Pradesh, Uttaranchal and Sikkim, where pharma companies enjoyed a tax holiday for 10 years. Further, reduction in excise duty on goods covered under Medicinal and Toilet Preparations Act from 16% to 10% will rationalize the prices of drugs as we expect pharma companies to pass on the benefits to consumers.

Medical Device Industry Incentives

Strong incentives have been given to India's budding Medical Devices industry. In India the production of low value medical supplies and disposables is dominated by domestic manufacturers, whereas the high end medical equipment is generally imported. The budget has prescribed a uniform, concessional basic duty of 5%, countervailing duty (CVD) of 4% with full exemption from special additional duty on all medical equipment against the current general maximum rate of 16.78%. A concessional basic duty of 5% is being prescribed on parts and accessories for the manufacture of such equipment while they would be exempt from CVD and special additional duty. Full exemption currently available to medical equipment and devices such as assistive devices, rehabilitation aids etc. is being retained. The concession available to government hospitals or hospitals set up under a statute is also being retained. For the manufacturers of orthopaedic implants, the Budget 2010-11 has proposed an exemption of specified inputs for the manufacture of implants from import duty. Rationalisation of the duties on medical equipment will make imports cheaper and cost of healthcare delivery to be lower. These incentives will go a long way in spurring growth of medical devices industry in India.

Other Tax Incentives

In order to get drugs to consumers at the right price, improvements in local supply chains will need to take place. The Budget has announced tax incentives for the business of setting up and operating cold chain infrastructure, which is an integral part in the logistics for vaccines and many biotech products. Strong emphasis and support has been provided for rural infrastructure development, which will benefit all companies in general who are looking at expanding in the rural areas.

Industry has welcomed reduction of surcharge on domestic companies from 10% to 7.5%. While reduction in corporate surcharge has provided marginal relief, it has balanced out the effect of MAT rate increase from 15% to 18%.

We understand the delay in the introduction of GST, but were hoping that a swift introduction of GST would have set in motion the process of adding efficiencies across the pharma value chain by significantly reducing the transaction cost and hence reduction in prices of the medicines, thus, making medicines more affordable and accessible to the common man.

Overall, government's increased outlay to public healthcare along with excise duty relief and support given to in-house R&D and indigenous medical device industry will help industry sustain the double digit growth rate.

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Japan

Introduction of Group Taxation Regime

The 2010 Corporate Tax reform in Japan introduced a group taxation regime which is applicable to domestic companies (group companies) that are wholly owned by either, a domestic company, a foreign company or an individual. The existing tax consolidation system will become part of the group taxation regime. While the tax consolidation system is applied upon the election by the taxpayer, the group taxation regime will automatically apply to group companies. Under this group taxation regime, group companies would be required to defer the recognition of capital gains or losses arising from asset transfers among group companies until such assets are sold outside of the group. Capital gains or losses arising from share buy-back by group companies would also be denied.

Change in Tax-Haven Rule

The criteria for application of the anti-tax haven rules (CFC rules) are loosened by the 2010 tax reform, in which the threshold of effective tax rate for tax-haven determination is lowered to 20% from 25%, to cope with the reduction in global tax rates. Under the reform, the threshold of stock ownership a taxpayer is required to own (directly or indirectly) in a CFC has been increased from 5% to 10%. Also the expansion of active business exemption has been made which allows companies not to apply the CFS rule to regional holding companies in low tax countries if certain conditions are met. However, the new rule requires companies to include certain types of income earned by CFCs, such as dividend income or capital gains from minority shareholding, even if CFCs meet the active business exemption test.

Clarification of TP Documents Required to be Submitted

Even though the tax reform does not require companies to prepare the transfer pricing documents, the tax reform clarified that the relevant transfer pricing documents required are to be submitted on the tax authorities' request. The tax authorities are only allowed to apply "taxation by estimation" if a taxpayer fails to submit the above-mentioned documents. Ensuring that a taxpayer has transfer pricing documentation on hand may significantly mitigate the risk of the tax authorities applying taxation by estimation.

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Singapore

Singapore Budget 2010: Some Good Measures for Life Science Industry

The Singapore 2010 Budget was announced on 22 February 2010. The Budget introduced a slew of fiscal proposals which should encourage Pharmaceutical and Life Sciences companies to focus on carrying out higher value-added activities, promoting Mergers and Acquisitions (M&A) and intensifying the land usage in Singapore. These include:

1. Credits for innovation

One of the major initiatives was the introduction of an all-embracing broad-based tax concession scheme, the Productivity and Innovation Credit (PIC). The PIC is aimed at providing an unprecedented level of tax deductions to businesses in all sectors that invest in a broad range of activities to promote innovation and productivity, thereby lowering their effective tax costs. The PIC is designed to cover business spending on six activities:

- Research and development (R&D) done in Singapore
- Acquisition of intellectual property (IP)
- Registration of IP
- Training of employees
- Automation through technology or software
- Design work done in Singapore

Under the PIC, businesses will be entitled to claim tax deduction for 250% of qualifying expenditure incurred, subject to a cap of S$300,000 for each activity. This effectively means that every S$100 of relevant spending will result in a tax saving of S$42.50 (assuming a tax rate of 17%).

A taxpayer can undertake all or any of these activities and claim the corresponding tax benefits under the PIC in a year. Alternatively, businesses may opt to convert their PIC tax benefits into a non-taxable cash grant subject to certain conditions.

Pharmaceutical and Life Sciences companies with plans to spend on training, R&D, automation or managing their IP inventory out of Singapore would benefit from this PIC scheme.

2. Encouraging mergers

A new Mergers and Acquisitions (M&A) allowance was introduced to encourage Singapore based companies to consider M&A as a strategy for growth and internationalization. It is granted to qualifying M&A deals executed between 1 April 2010 and 31 March 2015.

The allowance is 5% of the value of the acquisition, subject to a cap of S$5 million granted for all qualifying deals executed in a year of assessment. The allowance will be written down equally over five years and is deductible against the buyer's taxable income. At 17% corporate tax rate, this effectively gives a buyer up to S$850,000 of tax benefits, or S$170,000 a year.

Furthermore, stamp duty on the transfer of unlisted shares for qualifying M&A deals executed between 1 April 2010 and 31 March 2015 will also be waived. This remission is capped at S$200,000 of stamp duty per year.

This incentive should encourage the local Pharmaceutical and Life Sciences players to explore M&A opportunities to tide over their funding needs and gain access to overseas market.

3. New allowance to promote efficient land usage - Pharmaceutical is one of nine specified industries to enjoy this new allowance

With effect from 1 July 2010, tax depreciation on capital expenditure incurred on industrial buildings or structures would only be granted to nine specific industries under a new allowance called Land Intensification Allowance (LIA). Pharmaceutical industry has been identified as one such sector. This demonstrates the Singapore Government's intention to continue attracting pharmaceutical companies to set up their manufacturing and other operational facilities in Singapore.

The above changes proposed in the Budget would need to be approved by the Parliament before they are enacted into the Singapore Income Tax Act.

New Tax Framework for Corporate Amalgamation: Losses from Amalgamating Companies to be Transferred to Amalgamated Company

In line with the global trend, pharmaceutical and life science companies in Asia are also actively exploring merger and acquisition options in their bid to achieve efficiency and enhance market share. It is interesting to note that the statutory process of corporate amalgamations in Singapore has been simplified to provide companies with an alternative route for mergers and acquisitions, without requiring the Court's approval.

In view of the simplification of the statutory process of corporate amalgamation, the Singapore tax authorities have also introduced a new tax framework to minimize the tax consequences arising from amalgamations. This new tax framework would apply to 'qualifying amalgamations' taking place on or after 22 January 2009.

Some features of the new tax framework include:

- Unutilized trade losses, capital allowances and approved donations of the amalgamating companies can be transferred to the amalgamated company
- No charges would arise from capital allowances (on capital assets) or writing down allowances (on intellectual property rights) previously claimed by the amalgamating companies
- Trading stock of the amalgamating companies can be transferred to the amalgamated entity at net book value
- Provisions for doubtful debts which turn bad after the amalgamation would be deductible for the amalgamated company and
- Goods and Services Tax and Stamp Duty arising from the transfer of assets from the amalgamating companies to the amalgamated company can be exempted.

Pharmaceutical and life science companies can take advantage of this new tax framework which would certainly encourage more corporate mergers in Singapore in a tax efficient manner.

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Taiwan

New Assessment Rules Governing Applicability of Double Taxation Agreements Come into Effect

The Taiwan Ministry of Finance (MOF) issued the new Assessment Rules Governing Applicability of Double Taxation Agreements (DTA Assessment Rules) on 7 January 2010, replacing the previous Guidelines for the Application of Double Taxation Agreements (Guidelines). Significant key differences of the DTA Assessment Rules in contrast with the previous Guidelines include:

Economic Substance of Transaction
Treaty benefits shall only be granted to transactions with economic substance. In contrast, transactions lacking economic substance, such as transactions undertaken solely for treaty benefits, or where the income recipient is not the beneficial owner, will not qualify for treaty benefits.

Definition of Permanent Establishment (PE)
The DTA Assessment Rules provides detailed definition for the different categories of PE, including fixed place PE, construction PE, service PE, and agent PE, which generally follows the guidelines of the 2008 Organisation for Economic Co-operation and Development (OECD) model tax convention. For a service PE, where a foreign enterprise renders service in Taiwan through its employees or other personnel engaged for such purpose, the total number of days that services are carried on in Taiwan for the same, or a connected, project, should be aggregated in determining whether it constitutes a PE. However, if the tax office finds out that the activities rendered outside of Taiwan are also closely related to the services rendered within Taiwan, the corresponding days should be included in the aggregate number of days in determining whether it constitutes a PE. Thus, the inclusion of the number of days outside of Taiwan for the provision of service in the same or a connected project increases the PE risk for a foreign enterprise operating in Taiwan.

Business Profit
The DTA Assessments Rules provide documents required for application of the business profit article. Further, the DTA Assessment Rules provide the business profits of a foreign enterprise, shall be taxed in Taiwan to the extent that the profits are attributable to the PE in Taiwan. The business profits attributed to the PE shall be equivalent to the amount calculated, had the PE engaged in similar transactions with an independent third party. Furthermore, transfer pricing documentation should be in place to support that the business profits attributed to the PE are at arm's length. However, where all the business profits of the foreign enterprise are attributed to the PE, transfer pricing documentation would no longer be required.

Reduced Withholding Tax on Dividends, Interest, Royalties, and Technical Service Fees Under DTAs
Dividends, interest, royalties, and technical service fees received by the foreign enterprise shall be entitled to preferential withholding tax rates under the DTAs provided that the foreign enterprise receiving such income does not have a PE in Taiwan, or the holding of shares, debt claim, or license is not effectively connected with the PE in Taiwan. In addition, once withholding tax is applied at source on the above-mentioned income, it shall not be included in the business profits attributable to the PE and subject to income tax filings. Again, it is worth emphasising that going forward, the beneficial ownership concept may play an important role in the applicability of treaty benefits.

The DTA Assessment Rules also requires specific documents to be provided in order to enjoy the reduced withholding tax or tax exemption under the DTAs. The documents required under the DTA Assessment Rules for reduced withholding tax are similar to those originally required under the Guidelines, which includes tax resident certificate, beneficial ownership documentation, contracts, etc. Similar documentation is required for tax exemption on interest derived from Taiwan.

PwC Observations

Foreign pharmaceutical companies should review their PE exposure and consider how this will affect their qualification for treaty benefits, especially with regards to the business profit article. Furthermore, as DTA Assessment Rules emphasises the beneficial ownership concept, foreign pharmaceutical companies which utilise existing DTAs to obtain reduced withholding tax rates for dividends, interest, royalties, and technical service fees should consider whether the usage of a holding company to obtain treaty benefits will trigger audits in the future.

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As a global leader serving Pharmaceutical and Life Sciences companies, PricewaterhouseCoopers has extensive experience working with organisations across the industry, including: proprietary and generic drug manufacturers, specialty drug makers, medical device and diagnostics suppliers, biotechnology companies, wholesalers, pharmacy benefit managers, contract research organisations, and industry associations. We have aligned our practice with the broader health industries market to ensure that our people are well versed in the relationships between suppliers, providers, payers, and customers.

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