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Asia-Pacific Health Industries Newsletter

Keeping you up-to-date with the latest developments in the Pharmaceutical & Healthcare industries

Issue 16, April 2016

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

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Editor's note

PwC's Global Health Industries network is pleased to present you with its 16th issue of the Asia-Pacific Health Industries Newsletter.

This newsletter aims to keep you informed of the latest developments—related not only to the pharmaceutical, but also to the healthcare industry in the Asia-Pacific region.

In our Special Issue's **Health and Safety**, we provide an overview of Integrated Health and Safety (IHS) programs in **New Zealand**.

The section regarding **Tax** updates in Asia Pac highlights key BEPS initiatives, which are being undertaken within the Asia Pacific region's main economies, including **Australia**, **China**, **Japan** and **Singapore**.

Our **Accounting** section includes the regulatory changes on financial reporting requirements in **Australia.**

Additionally, the section on **Regulatory** developments focuses on initiatives to accelerate review processes for new drugs, led by Taiwan's FDA in **Taiwan.**

Further, we outline **Pricing** updates on significant price pressures within the industry in **Australia** and **Taiwan**.

In the final section, we also present the topic of **Healthcare** by highlighting the **healthcare and wellness industry** in **Malaysia**. This is of interest due to the number of investors and developers who are looking to capitalise in the area, and have begun to address the market demands.

We hope that our timely updates and analysis, provided by this issue, are of use to you and your business.

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Inside this issue

Asia-Pacific Health Industries Update

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Welcome to our 16th Edition of the Asia-Pacific Health Industries Newsletter.

In this issue we cover two healthcare topics around health and wellness in Malaysia and Health and Safety in the workforce in New Zealand, both of which have a message for other territories in addition to our usual topics around Accounting, Regulatory, Pricing and Tax within the Asia-Pacific region.

Our special issue on Health and Safety focuses on the new Health and Safety at Work Bill in New Zealand, which became a trigger for many organisations to ask themselves whether they are ready to protect their workforce from the risks existing in the workplace. With an ageing workforce across the health sector themselves facing an increase in living with and managing chronic disease, capturing the current status of the work environment will help organisations to improve workplace safety and the health and productivity of their workers.

We continue to see various Governments across the region implementing measures to reduce prices for pharmaceuticals, both for originators and generics suppliers placing continued pressure on profits. We again take a further in depth review on Tax and in particular the global focus on BEPS and how that impacts various territories in the region.

We are also delighted to highlight the capability of some of our experts based in India and Japan who have recently joined us and who bring deep insights around the areas of med-tech and cyber security. Big data analysis with patients personal data has been the focus of both healthcare providers and pharmaceutical companies. In order to communicate across the globe for the development of new treatment and drugs, it is essential to have a watch dog to protect the data and IT systems from the existing threats of cyber-attack to help further develop and sustain businesses in the Asia-Pacific region where IT infrastructure varies significantly.

I would like to take this opportunity to also convey my gratitude to my PwC colleagues across the various territories, for their active engagement and excellent contributions to this newsletter. I would also like to thank you, our clients and industry colleagues for your contributions, feedback and engagement during this time and hope that we have added to, and will continue to add value to your businesses.

I trust that you will find the enclosed newsletter of use and interest to your businesses and I welcome your thoughts on any of the issues and priorities it raises for your organisation.

If you have any topics you would like to discuss, please feel free to contact me or any of the territory leaders and industry experts whose contact details are set out on the back page of this newsletter.

Yours sincerely,

John Cannings, OAM
Partner

Special Issue - Health and Safety

New Zealand

Integrated Health & Safety - Exploring the Relationships between Health Promotion and Health Protection

The NZ context – questions for the industry

The new Health and Safety at Work Bill is providing a trigger for many organisations that are now considering whether they are ready for the changes.

Being compliant with the new act will move the dial some way, but will it move it to a level of sustainable high performance? After all, New Zealand and its Health and Safety professionals would benefit from getting ahead of the game.

Integrated Health and Safety means ...?

The Journal of Occupational and Environmental Medicine (JOEM) states that, "Integrated Health and Safety is the strategic and systematic integration of distinct health and safety programs into a continuum of activities that are replicable, measurable and integrated across institutional silos, enhancing the overall health and wellbeing of workers and their families and preventing work related injuries and illnesses."[1]

New Zealand's workforce is changing and there are emerging demographic trends in health. One particular trend is an aging workforce. NZ ranks 2nd in the OECD with the highest employment rate of 55-64 year olds.[2]

Older workers typically suffer from chronic health conditions and have multiple health risks.[3]

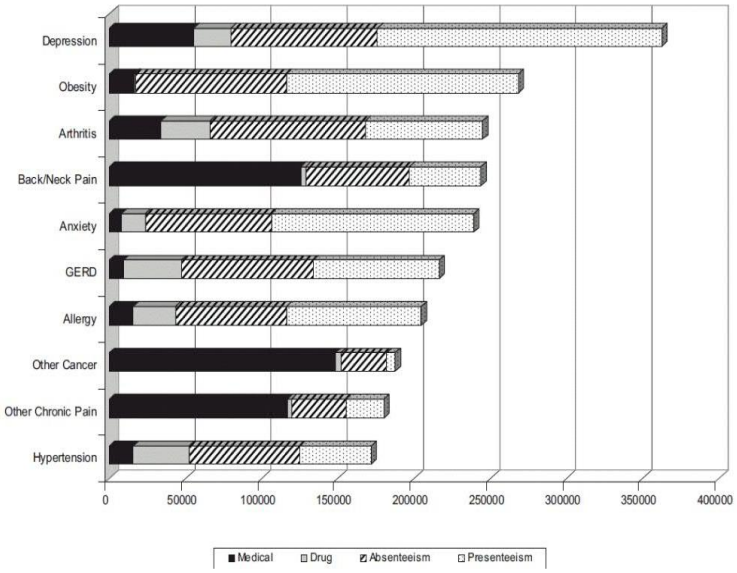

Fig. 1. Top 10 health conditions by annual medical, drug, absenteeism and presenteeism costs per 1,000 FTEs.
Source: WHO HPQ (Health and Work Performance Questionnaire)

Further, workers with adverse health risk factors are more likely to sustain injuries than those with good health. There are also potential patterns of risk across certain occupational types.[2]

However, these points have not been the focus of research and evaluations regarding risks in the workplace.

Health and Performance

Most Health and Safety strategies are focussed on Health Protection, with wellness and health not strongly connected. Yet recent research has indicated that organisations that manage the good health of their workforce also achieve better financial performances.[4]

However, the combined costs associated with poor health and safety are not measured well by most organisations. Therefore, new measures need to be developed, which take into account health promotion and health protection, and capture the outcomes of Integrated Health and Safety (IHS) programs.

PwC Observations

In order to provide an integrated strategy, it is key for an organisation to understand the underlying needs of workers' health and target programs that make a difference. Therefore, evaluating risks is the first step to maintaining and further developing healthy workforces within organisations.

Sources:
1. JOEM - Volume 57, (5), May 2015
2. PwC Analysis, July 2015 – White paper – PwC Golden Age Index (pwc.co.nz/goldenage)
3. JOEM - Volume 51,(4), April 2009 (can you include this as the reference for the Top 10 health conditions bar graph instead of the HPQ survey)
4. JOEM - Volume 55, (9) September 2013

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Tax Update in Asia Pac

Additional Update in 2016: Base Erosion and Profit Shifting (BEPS) in Asia

With the follow up after the release of the final package of the Base Erosion and Profit Shifting ("BEPS") project on October 5, 2015, this special report focuses on the update on BEPS-related developments and the impact for Pharma & Life Sciences companies operating in Singapore, Japan and China.

Singapore BEPS actions

Supplemental updates in Singapore in January 2016

On 4 January 2016, the Inland Revenue Authority of Singapore ("IRAS") published its third edition of Transfer Pricing Guidelines. Some of the highlights of the latest guidelines are as follows:

•Timelines for APA process: The IRAS has specified stringent timelines to APA applicants for pre-filing meeting and the submission of requisite pre-filing meeting materials at least 9 months and 10 months respectively, before the first day of the proposed APA covered period.

•Application of cost plus method: With a view to ensuring that a correct level of remuneration is earned by group service providers, the IRAS has issued guidance in the application of the cost plus method where it may now deem additional cost to be included in the cost base of the provider of services and/or goods even if such additional costs are not actually incurred and accounted for in the accounts.

•Obligations arising from MAP or APA process: The IRAS clarified that it is not precluded from conducting a tax audit on a taxpayer if there is non-compliance with the Singapore tax laws in the event that the IRAS or the foreign competent authority rejects the taxpayer's MAP or APA application.

This guideline was issued barely a year following release of the second edition of Transfer Pricing Guidelines on 6 January 2015, which introduced contemporaneous transfer pricing documentation requirements in Singapore for the first time. This indicates that the IRAS is closely monitoring the evolving international tax developments vis-à-vis transfer pricing compliance level and practices in Singapore and is ready to make changes to further tighten the transfer pricing regime and related aspects in Singapore to address or

respond to evolving needs. It is therefore imperative that given the current tax environment, the taxpayers pay adequate attention in ensuring implementation of sound transfer pricing policies and practices supported by robust transfer pricing documentation. This will also help the tax payers to access and support the APA process should they decide to pursue cross-border tax dispute prevention strategies to mitigate their transfer pricing risks.

Japanese BEPS actions

Actions expected to be implemented in the FY2016 tax reform

On 24 December 2015, the Japanese Cabinet approved the 2016 tax reform proposal, which includes revised Japanese transfer pricing (TP) documentation requirements. The revisions are based on recommendations contained in the BEPS Action 13 Final Report. Under the reform, the preparation and filing of a Master File and CbC Report will principally be required of the ultimate parent company of a multinational enterprise ("MNE") with consolidated revenues of over JPY 100 billion. For Master File, submission will also be required for Japanese subsidiaries or branches of foreign headquartered MNEs that meets the threshold test. For CbC Report, Japan will use the exchange of information provisions of its tax treaties in order to obtain CbC Reports for the Japanese subsidiaries or branches. The Master File will be required for taxpayers' fiscal years beginning on or after 1 April 2016, with the submission deadline one year following the close of the ultimate parent company's fiscal year to which the Master File and the CbC Reports relates. Additionally, the new rules will require the contemporaneous preparation of a "Local File" by all taxpayers having transactions with a related party that exceeded a total transaction amount in the preceding tax year of JPY5 billion or with intangible property transactions with a related party that exceed a total transaction amount in the preceding tax year of JPY300 million. For taxpayers with such transactions, the Local File must be prepared at the time the taxpayer's corporate tax return for the relevant year is filed, effective for taxpayers' fiscal years beginning on or after 1 April 2017.

Tax Update in Asia Pac

Chinese BEPS actions

Aligning TP outcomes with value creation
TP is one of the key focuses in China's localisation of the BEPS Report. Some of the highlights that reflect the SAT's positions on TP include:

•It is necessary to analyze the contributions (i.e. development, enhancement, maintenance, protection and exploitation) made by local Chinese enterprises to intangibles so as to ensure that these contributions are reasonably compensated by foreign related parties, especially where the legal owner of the intangibles resides outside of China.

•Similar to intangibles, location specific advantages also create values, and has been well recognized in comparability analysis, contribution analysis and profit split consideration.

Actions expected in the near future in relation to the BEPS project
As reiterated by SAT official, the China action plan would mainly include:

•revision of the domestic tax laws and regulations (e.g. the Tax Collection and Administration Law)

•localisation of the BEPS package (e.g. revision of Circular 2)

•adjustment of the tax authorities' international tax administration divisions

•establishment of the national tax risk monitoring and response system on MNC's on a group basis

•use of information technology to facilitate international tax administration

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Tax Update in Asia Pac

Australia

ATO has pharmaceutical industry in its sights in global Base Erosion and Profit Shifting (BEPS) crackdown

It will not be new to taxpayers to observe that the environment for tax compliance and tax disputes around the world has changed dramatically in the past 12-18 months. The OECD's BEPS initiatives have increased the focus on the global tax footprint of a multinational group, and tax authorities around the region, and indeed the globe, have been invigorated. In the current economic climate, many countries are also under political pressure to increase revenue collection. Finally, but perhaps most significantly, social media has brought the tax practices of multinational corporations to the forefront and it is clear the actions and strategies of the past are no longer being accepted, by tax authorities or by the community.

The Australian Taxation Office (**ATO**) is taking a markedly more robust approach to tax audits concerning international tax and transfer pricing. The ATO has established a special purpose taskforce to investigate possible cases of BEPS in the pharmaceutical and healthcare industries, and most large taxpayers in this space are likely to be subject to at least some level of scrutiny. In the past, the ATO may have been content to limit its enquiries to a taxpayer's domestic operations and its associated cross border related party transactions. Now the ATO has expanded the scope of its review as it seeks to understand the group's global value chain in a holistic sense – including questions around where the significant value driving functions are performed in the group (e.g., strategy development and ownership of the R&D process), where the key assets are owned (e.g., product patents and related intellectual property with a focus on both legal and economic ownership), as well as where the key risks of the group are controlled, managed and/or mitigated.

The ATO is also becoming more sophisticated and better informed than ever before. In addition to using its domestic information gathering powers, the ATO has indicated it will now routinely engage its information exchange agreements with other jurisdictions to access information about global groups before an audit even commences.

There are a number of steps taxpayers can take to ensure they are well positioned to respond to their stakeholders, or to the tax authorities.

First, taxpayers must be able to explain their international arrangements and pricing; a compelling narrative, backed up by evidence, that aligns with a taxpayer's tax policy, and their communications with stakeholders and tax authorities in all jurisdictions. A strategy or narrative set with a single tax jurisdiction in mind will not work. Further, for the first time in history, through politics and social media, the community – mums and dads – are getting involved in the discussion around multinational tax policy. It is a very real threat to an entity's brand / reputation and even its customer base if it doesn't have a clear and supportable narrative around global tax compliance.

Second, it is vital to ensure that key stakeholders, both internal and external, across all jurisdictions, understand and are aligned on strategy. Presenting a consistent position requires a clear strategic direction and co-operation within companies, and within a corporate group. It will be important that all levels of management, up to and including the board, are "on message" and that there is consistency in this message across all jurisdictions and communication mediums.

Third, early preparation is key. Communicating strategy and pricing, establishing the evidence and getting stakeholders aligned is much easier to do in advance than when an audit is already underway. Early preparation will also help to contain the time, cost and resources required to respond to an audit. Finally, be prepared to revisit your strategy as the law changes. In the past, tax law has moved at a very slow pace, but today, countries are moving very quickly to implement changes (at times in a unilateral manner) to respond to perceived tax avoidance and BEPS and taxpayers need to "read the play" and be agile as the landscape shifts.

Innovation Australia

The National Innovation and Science Agenda is an independent statutory board established to assist with the administration and oversight of the Australian Government's industry innovation and venture capital programmes delivered by AusIndustry. It also aims to drive Australia forward in technological and science innovation by promoting tax incentives, funding incentives and support for skills and information. The recent agenda of Innovation Australia is to improve areas that hinder the growth and competitiveness of the Australian innovation economy, such as finance barriers and tax block.

(i) Increasing access to company losses

The Australian Government announced changes to inflexible loss utilisation rules that restrict companies from claiming losses when they seek out new business opportunities. The new arrangement will relax the test for businesses to access past year losses when they have entered into new transactions or business activities. A new and more flexible 'predominantly similar business test' will be introduced and companies will be able to access losses where their business, while not the same, uses similar assets and generates income from similar sources. This will encourage pharmaceutical business to seek out new opportunities to return to profitability without fear of losing past year losses. The legislation is expected to be introduced in the first half of 2016 with the new 'predominantly similar business test' applying to losses made in the current and future income years.

Tax Update in Asia Pac

(ii) Intangible asset depreciation
Positive changes to the tax treatment of statutory intangible assets are also being introduced. Businesses will have a new option to self-assess the tax effective life of acquired intangible assets that are currently fixed by statute. Businesses will be able to align the tax treatment of the asset with the economic life of the asset instead of the fixed statutory effective life for example 20 years for a standard patent. This proposed change allows for faster depreciation of intangible assets and can reduce the cost of investment in intangible or knowledge-based assets. This is particularly relevant for pharmaceutical companies that generally have large intangible asset bases such as patents, know-how etc. The new arrangement will apply to assets acquired from 1 July 2016.

(iii) Tax incentive for early stage investors
Concessional tax treatment will be given to investors participating in early stage investment in innovative start-ups. This will encourage investments in innovative and high-growth potential business, allowing new enterprises access to additional finance. Each investor will receive a 20% non-refundable tax offset on investments, capped at $200,000 per year and a 10 year exemption on capital gains tax, provided investments are held for three years. This incentive will be available for investments in unlisted companies that were incorporated during the last three income years, have less than $1 million in expenditure and less than $200,000 in income in the previous income year. The new arrangements are expected to commence from 1 July 2016.

(iv) New arrangements for Venture Capital Limited Partnerships (VCLPs)
Relaxed eligibility requirements for concessional tax treatments under the VCLPs regime will allow managers to undertake a broader range of investment activities and attract a greater diversity of investors.

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Accounting

Australia

Multinational companies to lodge general purpose financial report

In December 2015, the Federal Government passed the Tax Laws Amendment (Combating Multinational Tax Avoidance) Bill 2015. Amendments made to the Bill in the Senate will affect the reporting requirements of thousands of multinational companies, requiring some of these companies to prepare and lodge financial reports for the first time. Others will have to change their reporting format from special purpose to general purpose financial statements.

We now have the curious situation that a tax Act (the Taxation Administration Act 1953) creates financial reporting requirements. Not surprisingly, many questions are arising as a result of this because the tax legislation uses different terminology to the Corporations Act 2001 and the accounting standards. PwC Australia continues to monitor the changes and update them as the answers to these questions are clarified.

So-called 'significant global entities' (SGEs) that are taxable in Australia and do not lodge general purpose financial statements (GPFS) with Australian Securities and investments Commission (ASIC) will have to lodge GPFS with the Australian Taxation Office (ATO) at the time they lodge their tax return. These will be forwarded to ASIC and also put on ASIC's public register.
In addition, it appears that the legislation requires some entities that are currently relieved from the reporting requirements of the Corporations Act to prepare and lodge GPFS with the ATO. These include:

- subsidiaries of foreign groups that rely on ASIC CO 98/98 Small proprietary companies which are controlled by a foreign company but which are not part of a large group – if these entities are controlled by a foreign group that is an SGE, the Australian entity may have to lodge GPFS with the ATO regardless of the relief provided by ASIC
- Australian grandfathered exempt proprietary companies (privately held companies) that are SGEs – these may no longer be able to rely on the relief from lodging financial reports with ASIC
- wholly-owned subsidiaries that are given relief under ASIC CO 98/1418 Wholly-owned entities – these will only be able to rely on the relief if the parent company lodges GPFS
- Australian branches of foreign companies that do not currently prepare branch accounts, and other entities that may not have financial reporting requirements under the Corporations Act but meet the definition of an SGE– for example, some partnerships and trusts.
- The amendments become effective for income years commencing on or after 1 July 2016. They apply to the entity's financial year that is most closely corresponding to the relevant income year. For example, if an entity has a year ending 31 March for both tax and accounting purposes, the new requirement will first apply to the financial year commencing on 1 April 2017.

Insight
SGEs are defined as entities or groups with consolidated global income of $1bn or more. All entities (including subsidiaries) in such a group are also considered to be SGEs. The definition of global income refers to income as shown in the latest financial statements that are prepared in accordance with accounting standards. This implies that income not only includes revenue but also other gains. An entity may therefore become an SGE for one year only by having significant one-off gains.

While articles in the media have implied that the financial reports of SGEs must include the same information as those of listed companies, the amendments as drafted only refer to "general purpose financial reports". Our preliminary view is that general purpose financial reports prepared in accordance with the reduced disclosure regime as permitted under Australian accounting standards should be acceptable.

The amendments further allow the lodgement of consolidated GPFS where an entity is a member of a group that prepares consolidated financial statements. It does not appear that every single subsidiary of an SGE will need to prepare separate GPFS. However, it is not clear whether the GPFS provided to the ATO could also be those of an overseas parent entity.

PwC Observations
As discussed in this article, the amendments raise many questions that will need to be resolved over the next few months before the legislation becomes effective. We encourage you to engage with your accounting and legal advisers sooner rather than later to determine the impact, if any, of this legislation on your reporting requirements.

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Regulatory

Taiwan

TFDA accelerates review for new drugs

The Taiwan Food and Drugs Administration (TFDA) has sped up its review procedures for new drugs. It announced on 27 January that it had approved a record breaking 170 new drugs in 2015, up by 30% on the previous year. According to the TFDA, 27 of the total approved cases were developed in Taiwan, and 143 cases were imported drugs. The number of successful applications filed by local developers has been on a rise for five years in a row.

Among the approved new drugs, 49 cases were NCE's (new chemical entities) new drugs and 44 cases were bio-pharmaceuticals. By therapeutic categories, cancer drugs accounted for the highest proportion at 13%, including two cases developed in Taiwan for treating patients with hyperphosphatemia and metastatic pancreatic cancer respectively. Other therapeutic categories included treatments for hepatitis C, HIV, rare diseases, vaccines, etc.

The TFDA also announced the "Mechanism for New Drug Application (NDA) Priority Review" and the "Mechanism for NDA Fast Track Review", which aims to expedite the review process for new compounds and new administration routes. In 2015, 15 cases qualified for priority review, for which the review time was reduced from 300-400 days to just 171 days.

PwC Observations
Taiwan's approval process for new drugs is considered lengthy and slow by multinationals compared with other developed countries. In response, the TFDA has been working to simplify and shorten the process, including the establishment of fast-track approval process for certain imported drugs. These efforts are starting to bear fruit, as reflected by the increased rate of approvals in 2015, and will shorten the time it takes to get new drugs to market.

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Pricing

Australia

No April fool's joke!

As set out in Issue 15 of this newsletter a number of reforms to the Australian Pharmaceutical Benefits Scheme (PBS) will continue to add to price pressures within the wider industry by:

- Lifting the number of times a year a PBS medicine price can change from three times to five time per year
- A **one-off statutory price reduction of 5%** to all brands on the F1 formulary once the medicine has been listed for a minimum of five years, commencing **1 April, 2016** and thereafter every April from 2017 to 2020 for other medicines on their 5th anniversary of PBS listing
- Further accelerating price disclosure by removing originator brands from the price disclosure calculations following three years of being listed on the F2 formulary.
- Application of price disclosure reductions for single ingredient medicines (e.g atorvastatin) to related combination items (e.g amlodipine and atorvastatin)
- Freezing of the indexation on the Community Service Order (CSO) for the duration of the agreement period
- Removing certain Over The Counter (OTC) medicines from the PBS

The proposed F1 price cuts set out in the PBS Access and Sustainability Package (PASP) are now are reality with the prices of some 370 medicines being cut and no one thinks it's an April Fool's joke.

The one off statutory reduction of 5% on all FI medicines listed for a minimum period of 5 years together with the catch-up price reductions to combination medicines under Mandatory Price Disclosure, which are forecast to be on average over 60% is estimated to save the Federal Government $1Bn. This is part of a total $6.6Bn of efficiencies' delivered through the Government's reform package over the last 5 years.

It is important to note that the F1 price cuts do not result in cheaper prices for consumers (apart from some 60 medicines that will now be priced below the co-payment amount of $38.30), these are government savings and they are an efficient and effective way for Government to model and bank savings from day 1. The question everyone is now asking is "is this a "one-off" cut for F1 originator drugs or the beginning of a period where they become the norm for price savings from the Industry?".

Given the significant reforms to the PBS in Australia since 2007 with various commentators suggesting that the total savings from already announced price cuts will be over $30Billion, are further savings necessary to ensure the financial viability of the PBS which is now forecast to grow at only 3%? Or should there be a more system wide review of the way in which medicines are subsidised to patients by Government?

What is certain in this uncertain world is that both the Government and Industry need to work collaboratively to ensure that Australians are able to continue to have timely access to medicines at affordable prices, with security of supply.

PwC Observations

These most recent price cuts will continue to hit the revenue of originator pharmaceutical companies the most with some 370 medicines affected in the first year alone, and similarly upstream wholesalers and pharmacy will also be impacted. There is no guarantee that there will be no further cuts to the PBS including patented drugs listed on the FI formulary, although the forecast growth of the PBS is now only around 3%. Companies therefore need to make strategic decisions as to which products they launch into the Australian market and when, and this will ultimately influence the health outcomes of Australians through access to new therapies.

DISCUSS THIS WITH

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Pricing

Taiwan

Continuing pressures on drug prices

Pricing and reimbursement will remain a challenge for pharma firms operating in Taiwan. Tough pricing policies have been instrumental in curbing drug spending in the country and returning the National Health Insurance's (NHI) budget to a surplus (NT$231bn, or US$7.2bn, at end-2015), and their success will see their perpetuation.

The National Health Insurance Administration (NHIA) on 19 February announced a new round of price cuts, to close the gap between NHI reimbursement prices for listed prescription-only drugs and their actual market prices, which will come into force on 1 April 2016. The prices of 148 pharmaceutical products will increase, but 7,392 drug items will face an average price cut of 2.1%, which the NHIA estimates will produce a total cost saving of NT$3.81bn (US$119m) a year. Some common hypotensives, including Norvasc, Crestor and Plavix, are on the price cut list.

Taiwan uses the Drug Expenditure Target (DET) system to annually adjust drug prices. It was implemented in 2013 as part of the second generation NHI and replaced the previous system of biennial price cuts using price-volume surveys. Under the new scheme, the NHIA sets an annual target for pharmaceutical expenditure following a process of negotiation with industry players using the previous year's drug expenses as a baseline. If actual spending for the year exceeds the set target, the NHIA will adjust drug prices in the next year in order to control expenditure.

The DET was first applied in April 2014 when the NHIA reduced the prices of 7,583 drug items by an average of 3.9% for estimated cost savings of NT$5.67bn (US$178m). The next adjustment in April 2015 cut prices by an average of 5.3% on 6,821 drugs, giving cost savings of NT$8.21bn (US$257m). The NHIA attributes the smaller 2016 cut of 2.1% in large part to the successful implementation of its cloud-based prescription records sharing system, known as "NHI PharmaCloud," which allows doctors and pharmacists to check and avoid duplicate prescriptions.

In related news, the NHIA's expansion of a diagnosis-related group (DRG) reimbursement payment system for hospitals, which had been scheduled to take effect on 1 March 2016, has been postponed due to the medical community's opposition. While the "Tw-DRG" system is expected to help reduce inefficient use of medical resources and shorten hospital stays, local health professionals worry that some severe cases may cause financial loss. The decision on whether to proceed will be left to the new incoming government, which will take office on 20 May.

PwC Observations

The latest round of drug price cuts in Taiwan will hit the revenue of originator pharma companies the most, and similarly generic manufacturers will also be impacted. Several health industry associations have also expressed concerns that the new price cut may prompt hospitals to change their formulary listing by replacing original drugs with cheaper substitutes, thereby impacting healthcare quality. Moreover, pharma companies argue that persistently low prices may delay launches of new drugs in Taiwan, or even force them to withdraw from the local market.

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Healthcare

South East Asia

Healthcare and wellness industry outlook in Malaysia

The almost unanimous refrain these days, in countries all over the world, is that healthcare is 'in crisis'. Driven by the tsunami of ageing and chronic illness in developed economies, skyrocketing demands for more services in the rising middle classes, and 'diseases of prosperity' (such as obesity and diabetes) in developing economies, almost no one feels that the healthcare industry is under control. Globally, there is a continuing rise in healthcare costs and as such a significant challenge exists for national agendas. Hospitals and healthcare providers must adjust to empowered customers, rapid innovation and notably increasing competition from non-traditional players. These pressures are having an impact, and are resulting in the growth of the Health and Wellness sector across Asia—with some territories leading the change from traditional hospital care and branching out to provide services in the wellness sector.

Thailand calls itself the "Spa Capital of Asia" and is one of the top 10 wellness tourism markets in Asia Pacific. In fact the wellness industry is one of the four main sectors that make up the Thai tourism industry, which drew almost a million tourists to its wellness industry in 2013. In fact, Thailand and Indonesia already have their wellness workforces in operation while Malaysia is forced to rely on foreign labour for its wellness industry. However, the Malaysian Government is focusing on its wellness business, which is expected to contribute RM400 million to the country's gross national income by 2020, and create 3,500 jobs (Figures 1 and 2).

Challenges and Changes in the Industry

There are a number of challenges that the wellness industry faces within Malaysia. Industry perceptions remain a critical concern as there remains a negative perception about the industry; with a proportion of the population still associating it with the sex trade. Additionally, because wellness centres in Malaysia are not regulated, there is also a perception that they are not professionally managed (Table 1).

Figure 1. Top Wellness Tourism Markets in Asia-Pacific, 2013

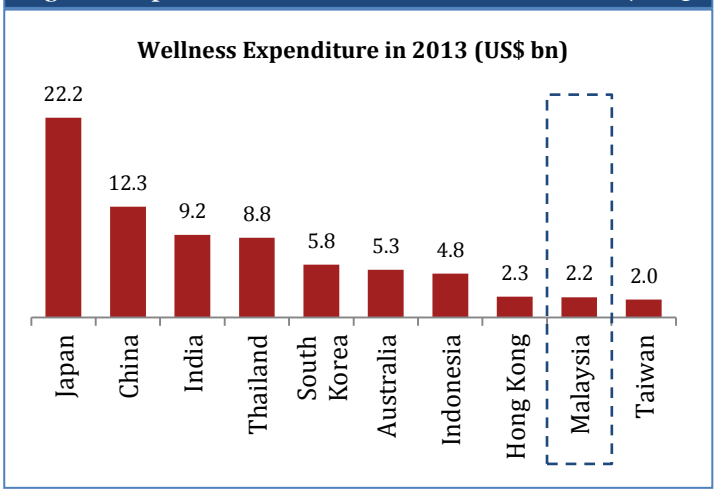
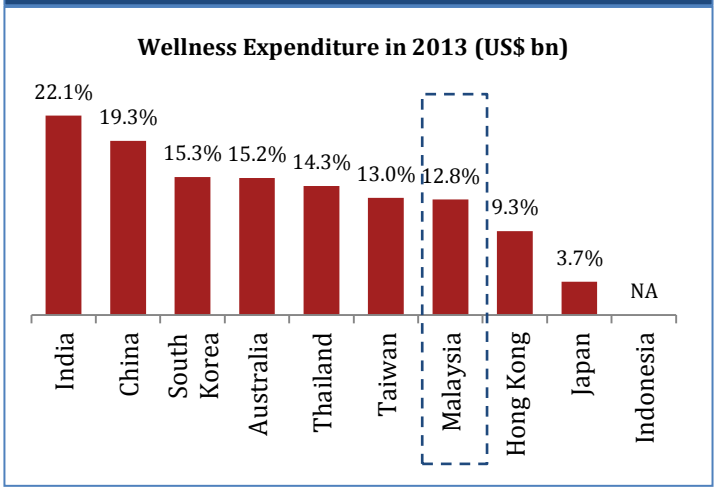


Figure 2. Wellness Tourism Growth in Asia-Pacific (2012-17)



Note: The wellness tourism economy includes all the expenditure made by tourists who seek to improve or maintain their wellbeing during, or as a result of, their trip.

Source: Global Wellness Institute - The Global Wellness Tourism Economy, 2013.

Healthcare

Table 1. Challenges and Initiatives in the industry

	Challenges	Initiatives
Industry Perception	• Negative perception about the industry, with much of the population still associating it with the sex trade • Spas in the country are not regulated and, therefore, not professionally managed	• **National Spa Council** was established to address matters concerning perceptions about the local spa industry • The **Council** has created an official criteria **rating for spas**, which is now used by the Ministry of Tourism and Culture
Local Manpower	• Malaysia faces a shortage of local therapists and has been tapping foreign workers from Indonesia, the Philippines and Thailand • Due to negative perceptions about the industry it is difficult to recruit people (related to family disapproval)	• A target has been set to reduce dependency on foreign workers • The ministry has also established **Centres of Excellence** around the country to recruit and train locals to become spa therapists
Corruption	• Malaysia is plagued by red tape and has been reported to have ongoing pockets of corruption	• Malaysia's spa and wellness businesses created **MAMSPA** as a platform, in 2004, to make the spa industry more prominent and to highlight the challenges it faces
Branding	• Lacks Malaysian branding in 'massage', such as Thai Massage, Balinese Massage or Hilot Massage (from the Philippines)	• **MAMSPA** is promoting and developing the spa and wellness industry in Malaysia through public educational seminars, the distribution of printed materials and interactive events

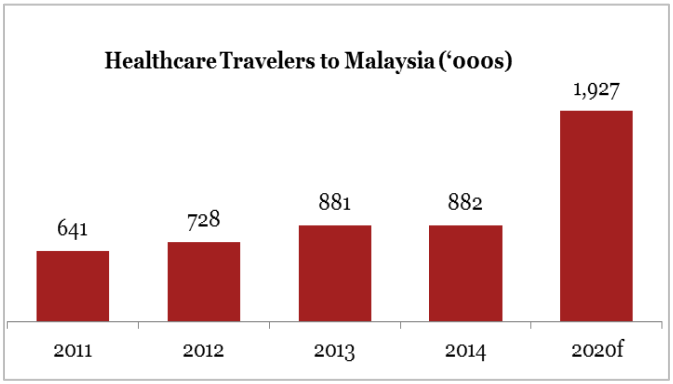
Investment Climate, Growth and Key Projects on the Horizon

With the increasing demand on healthcare services across Malaysia, consumers are looking more actively towards alternative means for maintaining their health and wellness. This has supported the growth of the wellness industry and the market continues to have a positive outlook, with key areas of growth being driven from:

- A growing middle class and increased consumer spending.
- The fact that the Malaysian Government have included health and wellness as a National Key Economic Area (NKEA).
- The Government's registered organisation, Malaysia Healthcare Travel Council (MHTC), which offers information on integrated wellness packages and various other services.
- The spa industry alone is expected to contribute US$94 million to Malaysia's gross national income by 2020, and create 3,500 jobs.

Spending on health and wellness in Malaysia continues to grow—driven by demand from foreign tourists travelling to Malaysia for medical tourism (Figures 3).

Figure 3. Growing Medical Tourists in Malaysia



Source: Malaysia Economic Planning Unit, Ministry of Health and Malaysia Healthcare Travel Council (MHTC) – Statistics.

Healthcare

The industry is also becoming more sophisticated and increasingly integrated with new lifestyle property developments. In fact, a number of investors and developers are looking to capitalise and have started developments on key projects in order to address market demand. Some of the upcoming projects are presented in Table 2.

PwC Observations

There are a number of challenges that the wellness industry faces in this region, in terms of consumer perception and regulations. Nevertheless, investment in health and wellness continues to increase, along with a rise in middle class and consumer spending. Therefore, investors interested in Malaysia would be prudent to create a robust business plan, which is strategically and carefully based on region-specific market analysis.

Table 2. Developments in Health and Wellness

Iskandar Investments - Medini Integrated Wellness Capital	• 210-acre **Medini Integrated Wellness Capital** is a fully integrated community, featuring a wide array of residential configurations, 18 acres of commercial development, and a 12.5-acre wellness sanctuary—all bordered by a mangrove forest. • Complementing the Medini Integrated Wellness Capital is a 4.6-acre **urban wellness centre** located between the Mall of Medini & Gleneagles Medini Hospital. It will include commercial retail establishments that favour wellness-related concepts, an urban wellness spa and corporate training retreats, etc.	
LOHAS Development - Wellness Retreat in Boga Valley	• A state-of-the-art array of preventive medicine encompassing advanced Anti-Aging and Cellular Therapy, Aesthetic Medicine, Dietary and Weight Management, Diagnostic and Ancillary Rehabilitation Services. • A 'Destination Spa' offering Asian wellness treatments, which include alternative and complementary therapies, such as Malay Traditional Massage, Qigong, Tai Chi and Yoga. • A Centre of Excellence offering training to the medical fraternity in the fields of stem cells and bio-technology.	
DSM - Integrated Wellness Community	• DSM works exclusively with properties delivering wellness services and education. • The DSM project in Malaysia includes more than 2,000 residences, destination spa, day-use wellness center and wholefoods café.	

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Updates

PwC Asia-Pacific: People update

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- Peter Harries is a Partner in PwC's consulting practice. He has over 25 years' of experience serving our multinational clients and addressing their challenges; related to information technology strategy, governance, management and control. In this capacity, he has worked extensively with boards of directors and senior management to oversee and deliver strategic business transformation, address current and emerging technology risks, and align investments in information technology with business strategies.
- Peter relocated to Tokyo in August 2015 to help grow PwC's consulting practice in Japan, as well as provide management consulting services to Japanese domestic and multinational clients. Peter serves as the Chief Operating Officer for PwC's consulting practice in Japan. Prior to his relocation to Japan, Peter served as the leader of PwC's consulting practice for the western United States. Peter has served as PwC's Global Relationship Partner (or Senior Relationship Partner) for several of our firm's largest pharmaceutical and life sciences clients—leading all aspects of our client service relationships and delivery, on a worldwide basis. Peter also built and led PwC's cyber security & privacy practice for the healthcare and pharmaceutical industries in the USA.
- Peter frequently teams with PwC's Center for Board Governance to speak on matters related to the oversight of information systems by the board of directors. He serves on the Board of Advisors to the University of Arizona, Department of Information Systems, and as the President of the Board of Directors for the Whispering Hope Ranch Foundation.

Medical device expert in India

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- Krishnakumar (KK) Sankaranarayanan is a Director in PwC's Consulting Services, based in Mumbai. His core focus is on the Medical Devices sector and his role involves assisting clients with their growth strategy, technology enablement and business transformation.
- With over 20 years' of experience in the medical technology industry, in India and abroad, Krishnakumar has worked across various roles, including medical device research and development, technology transfer, sales and marketing, business strategy, and consulting. During this time he has successfully launched several state-of-the-art medical technologies in the Indian market. He has also spent time, close quarters, studying healthcare systems in developed and developing countries, such as India, the UK, Bangladesh and Bhutan.
- A keen writer, Krishnakumar has authored numerous papers on healthcare issues, which have been very well accepted by leading National and International Conferences.

Key Example Projects include:

- Clinical Pathways Assessment for a US Medical Devices MNC in India
- Building a platform for value medical products for a Sovereign Wealth Fund
- Capital Equipment Financing for a US Medical Devices Company
- India Market Assessment for a Japanese Medical Technology Company

PwC Publications

Asia-Pac regional perspectives:

Beyond 2020: building strategic coherence in the New Health Economy *(2016)*

The competitive landscape for pharmaceutical and life-science companies around the world is changing rapidly, and those shifts are likely to accelerate. These changes require a new strategic approach – one that enables companies to understand market trends, develop the right strategy in response, and build the internal capabilities needed to execute. We contend that strategy requires distinct capabilities, meaning a specific focus, expertise and set of skills that can position a company ahead of its competitors.

Challenges and Change
A Report on the Australian Pharmaceutical Industry *(2015)*

This is PwC's fourth survey of the Australian pharmaceutical industry, and the second in conjunction with Medicines Australia. In recent years, the Australian pharma industry has been characterised by a more competitive market; significant advancements in technology; constrained budgets; major reform; and increasing scrutiny from payers, regulators and the community. The report explores the industry's key challenges, trends and opportunities.

Asia-Pac Health Industries Newsletter *(2015) - December issue*

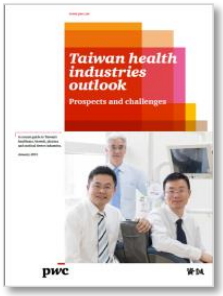
In December issue we highlight a number of recent developments that are of direct interest to Pharmaceutical companies and healthcare organisations including BEPS updates in Asia, result of biennial pharma Survey in Australia, Japan's pharmacovigilance regulatory affairs, and patients experience in India, along with our regular topics such as Pricing, M&A and Tax.

Asia-Pac Health Industries Newsletter *(2015) - August issue*

In this issue, we cover healthcare market trends and challenges in South East Asia as well as Japan, M&A trends in the growing Philippines market, regulatory developments in India and reform of long term care in Taiwan in addition to our usual topics around Compliance, Regulatory and Tax.

Asia-Pac Health Industries Newsletter *(2015) - April issue*

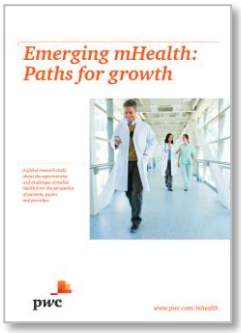
In April issue we included articles ranging across activities in Taiwan's health sector, looking at a specific health economics project in Australia, e-commerce and healthcare system challenges in China, talent management in Japan and Singapore as well as regular topics around tax and pricing within the Asia-Pacific region.



Taiwan Health Industries Outlook *(2015)*

An introductory overview of Taiwan's healthcare, biotech, pharma and medical device sectors. This report examines the future prospects, opportunities and challenges for market participants. It's primarily targeted at international companies and investors interested in Taiwan's health industries market.

Other publications:



These and other publications can be found on PwC's Pharmaceuticals & Life Sciences and Healthcare websites at ***www.pwc.com***

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As a global leader serving Pharmaceutical and Life Sciences companies, PwC 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.

Visit us at www.pwc.com/pharma and pwc.com/healthcare

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