Asia-Pacific Health Industries Newsletter

Keeping you up-to-date with the latest developments

Issue 12, December 2014

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

pwc

2014

Editor's note

PwC's Global Healthcare Industries network is pleased to present you with its 12th issue of the Asia-Pacific Health Industries Newsletter.

The newsletter aims to keep you informed of the latest developments across pharmaceutical industries and healthcare sectors in the region. To mark the end of the year 2014, we highlight a number of recent developments that are of direct interest to pharmaceutical and medtech companies, as well as healthcare organisations.

Firstly, in our special issue **Medtech** section we focus on **China's** recent and incredibly fast growth, regulatory change, the role of Government, and Chinese healthcare reform.

Our section on **Public Private Partnership** developments includes an update on India's current market trend, which is a drive to achieve universal healthcare.

In our **Compliance** section, we focus on **China's** recent enforcement of regulation, as well as update on transparency measurement in **Australia** regarding disclosure regime with respect to the ethical obligations of HCPs and institutions.

In the **M&A** section we highlight new western companies looking to enhance their market presence in **Taiwan**. Further, we outline **Tax** developments and changes across different areas, including providing guidance on the controversial 'reconstruction' provisions in **Australia's** new Transfer Pricing laws, and the new proposed update to transfer pricing documentation requirements in **Singapore**.

In the final section, we also present our recent marketing campaign related to integrated care, held in Australia, to improve quality of care based on its outcomes.

We hope that the analysis and information presented are of use to you and your business. If you would like to provide feedback on any topic in more detail, feel free to reach out to your PwC territory contact or the relevant industry experts listed at the end of each article.

Tim Hogan-Doran
tim.hogan-doran@au.pwc.com

Ayako Miyata
ayako.a.miyata@au.pwc.com

Inside this issue

Asia-Pacific Health Industries Update

David McKeering
PwC East Cluster (Asia-Pac)
Health Industries Leader

Welcome to our 12th Edition of the Asia-Pacific Health Industries Newsletter.

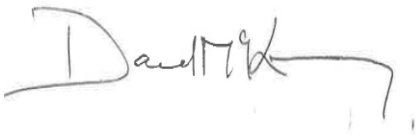
This is the second issue to cover both the Pharmaceutical & Life Sciences and Healthcare industries in Asia-Pacific region.
In this issue, we have included articles regarding activities in Public Private Partnerships in India and the rise of integrated care in Australia as well as our regular topics around Compliance, M&A, Pricing and Tax within the Asia-Pacific region.

In Asia-Pacific region, the social, cultural, religious, economic, political and infrastructural fabrics vary significantly, making this region both extremely diverse and disparate. Like any other regions, we are also forced to adapt ourselves to the rapidly changing environment to improve our quality of care with increasing cost pressure as well as to produce new innovative pharmaceutical products and operate efficiently in fierce competition. Thus it is essential for a sustainable growth of businesses to capture new regulations, health reforms and demographic trends.

I would like to take this opportunity to convey my gratitude to our clients and industry colleagues for their feedback and engagement during this time and hope that we have added to, and will continue to add value to your businesses.

We hope that you will find the enclosed newsletter of interest to your business. If you have any questions or thoughts 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,



David McKeering
PwC East Cluster (Asia-Pac)
Health Industries Leader
+65 9382 5658
david.mckeering@sg.pwc.com

Special issue: China Medtech Updates

China

Developing a China strategy in the medtech industry

China's market is fraught with challenges ranging from anti-monopoly probes of automobile and technology companies to anti-bribery investigations of pharmaceutical companies. It has, therefore, become crucial for multinational company (MNC) executives to understand how to achieve sustainable growth while navigating and mitigating potentially high-impact business risks, which are universal for companies operating in China, regardless of their activities.

With regard to health industries specifically, non-traditional players are also expressing rising interest, e.g. Alibaba is exploring healthcare institutions/landscape transformation and specifically looking into establishing an O2O platform for an e-pharmacy. Such investment, in conjunction with other key market growth factors, will lead to the augmented use of health products, including drugs and medical technology (medtech) products. There are four top priorities for companies operating in the China medtech space: (1) dissecting the market's growth; (2) understanding the government's role; (3) keeping up with Chinese healthcare reform; (4) staying competitive. Grasping these four concepts will be the first step for MNC executives looking to achieve sustainable growth in this country.

Similar to other industry spaces, the medtech market in China offers great opportunities for MNCs. PwC's best estimates, combining data from third parties and our own research, are that the China medical device market is anticipated to reach approximately US$50 billion by 2017, reflecting roughly a 20% compound annual growth rate (CAGR) from 2013.

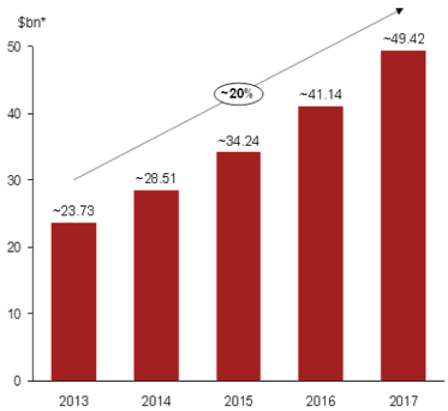


Figure 1.1: The China medtech market is expected to grow from ~$24bn in 2013 to ~$50bn in 2017, with a projected growth rate of ~20% per annum. Note: *Constant Forex: USD1 = RMB6.3
Source: Frost & Sullivan, CAMDI, MENET, PwC interviews and analysis.

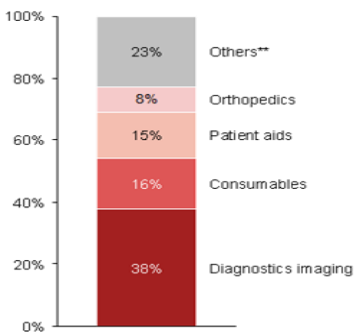
The key underlying growth drivers are the aging population, greater affordability of care, changing lifestyles and expanding healthcare coverage. In light of these numbers, it would be folly for medtech MNCs not to expand their China strategy.

Key sub-segments of the current China medtech market are diagnostic imaging (38%), consumables (16%) and patient aids (15%). However, while the opportunity in China may be great, painting the world's most populous nation with one broad brushstroke would be a gross error. Medtech companies must fully understand China's market characteristics, and cultural nuances, to ensure sustainable market adoption and acceptance of their products. In particular, successfully navigating the China medtech ecosystem requires executives to have a strong grasp of the country's market opportunities, the government's role in the industry, evolving healthcare reform efforts, and local competition.

Dissecting the Market's Growth

The Chinese medtech market has experienced explosive growth over the past five years. This has been additionally fortified by demographic shifts, extended healthcare access, low overall healthcare market penetration, fragmented markets with undefined leaders, and the rise of local players. While this growth will continue its ascent in the near future it is important to understand which sectors are driving this growth.

Medical equipment, such as x-ray, ultrasound and other imaging equipment will account for at least one-third of China's medtech market value. With that said, other product sectors are growing more rapidly. Products such as consumables, implantable and dental products, endoscopy and in-vitro diagnostics (IVD)*—while each accounting for no more than one-fifth of the market's current value—are projected to grow at least 20% per annum over the next three years.



Note: **For example: dental, endoscopy, wheel chairs, dialysis, and furniture.
Source: Frost & Sullivan, CAMDI, MENET, PwC interviews and analysis.

Special issue: China Medtech Updates

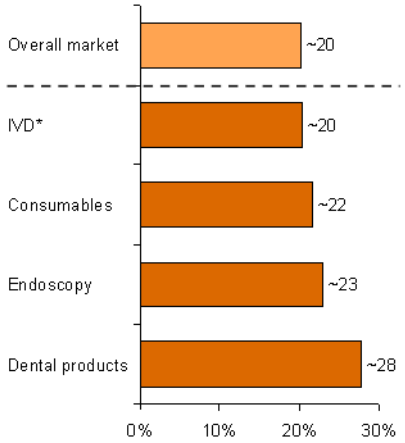


Figure 2: China medtech market growth potentials by select sub-segments. *Source: Frost & Sullivan, Espicom Business Intelligence, CAMDI, MENET, PwC interviews and analysis.

Growth will likely be led by sub-segments - such as dental products, endoscopy, consumables and IVD - that have higher growth rates than the overall market. These higher growth segments illustrate a gradually maturing Chinese healthcare market and should encourage manufacturers to shift their product portfolios to serve the future China medtech ecosystem.

Understanding the Government's Role

While medtech regulations are relatively new in China, in comparison to those for pharmaceuticals, they are rapidly evolving. Take for example the delegation of Class I medtech products (where the safety and efficacy of products can be ensured via routine product management, e.g., surgical clamps) to local CFDAs in the latest medtech product registration regulation, issued by the State Council in early 2014. As such, we must emphasise the augmenting importance of the Government's tendering process on how medtech products, especially capital-intensive medical equipment, are procured. As a result of this process, pricing is no longer the first consideration for buyers of medtech products.

In the tendering system the key criteria for purchasing decisions, and the data that drives these decisions, are becoming increasingly important. Unfortunately, there is no national standard for the tendering system. Tendering has been delegated to the province/municipality level, and different provinces will set their own guidelines and mandates, which can result in significant differences between provinces.

Meanwhile, the Chinese healthcare market is also undergoing a series of transformations. The medtech industry will follow the footsteps of the pharmaceutical industry, which saw the raising of the bar for regulations, pricing and market access. The key for medtech companies will be to anticipate these changes rather than try to react to them after the fact. In addition, precisely capturing the complex and multi-faceted role the Chinese Government plays in the medtech industry can help companies navigate the evolving landscape.

The market approval process in China is also difficult to navigate. As aforementioned, a new regulation pertaining to the medtech product registration was released in March 2014 and took effect in June 2014. This new regulation stipulates that medtech products are categorised into three classes according to their "risk level," where risk level is decided based on factors, such as product features and claimed clinical outcome(s), amongst others. Additionally, product clinical trials may be required for class II and III medtech products. Class II products refer to products that require additional management on product safety and efficacy, for example, ultrasound equipment. Class III is designated to products that are implantable or life supporting, and requires strict monitoring of product safety and efficacy, e.g. pacemakers. The key objective of this regulation is, of course, to ensure the safety and effectiveness of medtech products, and will bring about a greater level of scrutiny. Once a product has been approved, products need to be re-registered within five years. This system may seem inefficient and costly, but it is a reality of the current climate.

At the very least, medtech firms should have intimate knowledge of the intricate regulatory pathways; however, sustained success on the regulatory front requires them to be proactive in implementing robust process reviews in concert with the ever-changing regulations.

Chinese Healthcare Reform

By expanding basic medical insurance coverage and expenditure on healthcare, the Government has improved the country's overall access to healthcare systems. Over 95% of Chinese citizens are currently covered by basic medical insurance and China's estimated healthcare expenditure has grown to account for ~6% of the country's GDP in 2013. In recent years, healthcare reform activities have received a rising share of overall Government spending, and this trend is expected to continue throughout the foreseeable future.

However, what is unclear is whether these healthcare reform initiatives will drive efficiencies or erect additional hurdles for medtech companies. As such, it is increasingly crucial for medtech firms to keep a close eye on "hot-button" reform topics, such as the upgrading of hospital infrastructure, equipment and facilities. As more and more hospitals undergo reform, profits are increasingly being generated by service charges rather than by consumables, and medtech companies are being expected to provide solutions that can improve hospital performance (especially with regard to costs and business operations). This shift from the point-of-care to

Special issue: China Medtech Updates

disease continuum management is similar to the changes observable in mature markets, including the US.

Therefore, careful consideration of different business models to engage healthcare providers, as they adapt to these reforms, is key for successful and sustainable business models. PwC has successfully helped several clients in designing multi-channel solutions for companies in China. For example, we supported a medtech company in creating a marketing, sales, and billing infrastructure that adapts to different provider metrics—and ensures revenue capture—regardless of whether customer value is measured based on units sold or overall efficiency metrics.

Staying Competitive

Because of the many unique sub-markets in the Chinese medtech market, it can be difficult to pin down the growth opportunities. Penetrating the various market segments requires patience and commitment, and companies must establish the right control measures to balance risks versus rewards.

In general, the "first mover" (e.g. "early bird") advantage in China still exists, but the emergence of strong domestic players makes it increasingly difficult for foreign players to be successful. MNCs need to focus on how to be global-local, that is, "glocal," to ensure their operations are nimble and effective. Domestic and multinational companies alike must delicately balance macro-global strategies with locally tailored market needs.

PwC Observations

Medtech companies need to understand the key market characteristics and cultural nuances including the country's market opportunities, the Government's role in industry, evolving healthcare reform efforts, and the role of local competition. Knowledge of this will help companies to be best positioned to achieve market acceptance and, ultimately, sustainable success.

DISCUSS THIS WITH

Andrew Chen / John Lin
+86 (21) 2323 3302 / +86 (21) 2323 3893
andrew.cy.chen@cn.pwc.com /
john.j.lin@cn.pwc.com

Public Private Partnerships

India

Health PPPs: Drivers to achieve universal healthcare in India

The Scenario

India's healthcare story is in a state of flux. The growing burden of non-communicable diseases will cost the country 236 billion USD in the disability-adjusted life years (DALYS) lost. Inadequate utilisation of available infrastructure is adding to the burden, in fact, it is estimated that 25% of beds in Government health facilities are not operational, and that the availability and utilisation of medical equipment is only 39%.

While universal healthcare is a goal the Government is pursuing, India invests an abysmal 3.5% of its GDP on healthcare, which is not sufficient to meet the infrastructure requirement of approximately 650,000 hospital beds in the next the five years. Health insurance coverage is only limited to 25% of the population and a large number of households fund their healthcare needs 'out of pocket'.

Role of Private Players

The Government alone cannot meet this demand, driving the need for Public Private Partnerships (PPP). Private health spending is significantly higher than the Government's allocation to healthcare.

The health PPP market in India is gradually evolving, and is becoming both inevitable and desirable for the provision of healthcare services to the poorer sections of society. Recent initiatives from the Government, such as State sponsored health insurance schemes, offer robust financing mechanisms in PPP contracts and are helping to improve access to healthcare services.

PPP models within large tertiary care hospitals have limited success due to their complex structure and inadequate participation from major financers. However, lighter formats (such as diagnostics and dialysis services), which are easier to operate, constitute a larger share of health PPP projects. Private providers have shown keen interest in partnering with governments on a variety of projects, including primary health centers, Emergency & Trauma units, Radiology & Dialysis centers in public hospitals, and health insurance schemes. In addition to hospital providers, medical device companies are driving large numbers of PPP projects in the diagnostic segment.

The Challenges

The relatively slow pace of PPP growth in the health sector is primarily due to the absence of an enabling regulatory environment and sectorial guidelines. Lack of common objectives between public and private sectors also lead to the minimal participation of corporate providers. The Government needs to clearly articulate its PPP objectives and the expectations of private operators. In addition, appropriate financing mechanisms, in the form of either budgetary allocations or linkage with insurance schemes, are needed. Defining clinical standards to set appropriate benchmarks and performance indicators are other aspects that need to be refined. There is also a need to address other areas of concern, in order to build trust among all stakeholders.

PwC Observations

PwC's healthcare Public Private Partnership (PPP) advisory has been engaged in in several high-profile PPP projects around the globe, as well as in India. In the last few years, PwC India has assisted a significant number of health PPP projects, including a recent multi-specialty tertiary care hospital PPP project. In addition, our team has worked on an integrated network of health facilities, using PPP mode, for a State Government. In light of the Government's new impetus to improve healthcare access through private participation, we believe that the traction of Health PPPs in the India market will continue to grow.

DISCUSS THIS WITH

Dr Rana Mehta
+91 124 4620757
rana.mehta@in.pwc.com

Compliance

Australia

Transparency measurement in Australia

The global trend towards transparency continues. European countries are in the process of incorporating the EFPIA Code into their local laws/codes and the US has publicly made available their first report under the Sunshine Act.

Medicines Australia has proposed a transparency reporting requirement in Australia for member companies, in its draft of Edition 18 of the Code of Conduct. The transparency reporting would require member companies to report payments and transfers of value, to healthcare professionals (HCPs), if the payment relates to speaker arrangements, sponsorship to attend events, consultancy services, market research, and accommodation/travel expenses. It is also notable that there would be no requirement to report against individuals for hospitality (i.e. food, beverage and event costs).

Due to Australia's privacy legislation, the issue of consent and withdrawal of consent has been hotly debated. The privacy legislation implication is that consent from HCPs would be required prior to making the transfer of value and could be withdrawn post payment.

Edition 17 of the Code was due to expire on 1 January 2015. The draft determination from the Australian Competition and Consumer Commission (ACCC) suggested a condition on authorisation; that member companies must ensure, before making any transfers of value to healthcare professionals, that they will be able to report those transfers." This proposed condition is largely a result of concerns raised by a number of stakeholders that if the system allowed an 'opt out' mechanism, the take-up among HCPs would be minimal. Multiple parties submitted responses to the draft determination and the ACCC granted interim authorisation for edition 17 of the Code to continue operating into 2015, pending an expected final decision in the first quarter of 2015.

PwC Observations

This new reporting regime will require Medicines Australia member companies to update stakeholder and communication plans, processes and data collection protocols, and potentially, systems to ensure the accuracy, timeliness and efficiency of their reporting program. As a planned schedule, new reporting requirements will be in place from October 2015 giving member companies the early part of 2015 to ensure compliance by introducing new mechanisms, processes and system enhancements.

DISCUSS THIS WITH

Daniella Dickson
+61 (2) 8266 5286
daniella.dickson@au.pwc.com

Compliance

China

Enforcement of 'Nine Prohibitions' continues in China

Towards the end of this year, the Chinese Government is keeping a close eye on compliance related to payments to HCPs. From Q3 2014 until November, the Chinese Government, alongside the China Medical Association (CMA), focused on the monitoring and enforcement of the 'Nine Prohibitions to Strengthen Ethical Conduct in the Healthcare Industry', which has been effective since 26 December 2013.

The Nine Prohibitions

#	Nine prohibitions
I.	It is prohibited to link healthcare professionals' incomes to revenue generated from sale of drugs or medical examinations.
II.	It is prohibited to provide professionals with rebates for their prescriptions.
III.	It is prohibited to illegally charge patients.
IV.	It is prohibited to accept social donations and subsidies in violation of applicable laws and regulations.
V.	It is prohibited to participate in promotional events or illegally release medical advertisements.
VI.	It is prohibited to collate statistics on prescriptions for a commercial purpose.
VII.	It is prohibited to illegally purchase or use drugs in private.
VIII.	It is prohibited to solicit or accept kickbacks.
IX.	It is prohibited to solicit or accept "red envelopes" from patients.

In September, eight cases related to bribery and corruption within the healthcare system, were disclosed by the Central Commission for Discipline Inspection. Individuals involved included the Deputy Director of the Health Bureau, a hospital president and a head of department. The cases were associated with medical devices and instruments, infrastructure engineering, pharmaceutical procurement and a leakage of prescription volumes for medicines.

In November, the Central Commission for Discipline Inspection revealed another five cases in basic-level hospitals, which violated the Nine Prohibitions. The incomes of these HCPs were linked with the charges of medicines and medical inspections, and the HCPs received kickbacks from pharmaceutical companies, as well as "red envelopes" from patients.

On 5 November, in response to an audit report issued by the China National Audit Office in June, the National Health and Family Planning Commission (NHFPC) announced that they instructed the CMA to rectify the internal management and scientific meeting sponsorship approval process. The NHFPC indicated that the CMA is not allowed to provide HCP attendees' contact books to pharmaceutical companies. Additionally, the NHFPC liaised with the Supreme People's Procuratorate, Ministry of Public Security, and State Administration of Traditional Chinese Medicine to announce the joint Anti-Bribery and Anti-Corruption (ABAC) working mechanism.

PwC Observations

Compliance-related activities have drastically evolved in China and will continue to change at a moment's notice. It is, therefore, key for successful activity in China to monitor its regulatory trends and construct internal systems to deal with continuous Government reforms.

DISCUSS THIS WITH

Jia Xu / Angel Gu
+86 (10) 6533 7734 / +86 (21) 2323 3095
jia.x.xu@cn.pwc.com/ angel.jy.gu@cn.pwc.com

Taiwan

International tie-ups on the rise in Taiwan in 2014-15

A few recent M&A deals highlight the growing trend for international tie-ups in Taiwan's pharma and medical device sectors, which are aimed at creating strong platforms for growth in Asia, as well as globally.

Many American and European drug companies are looking to enhance their market presence in Asia, which is globally, one of the fastest growing regions for generic pharmaceuticals. In August 2014, privately held US generic drug-maker, Alvogen, acquired 67% of the Taiwan-listed Lotus Pharmaceutical (a speciality drugs company with FDA-inspected manufacturing facilities) for US$200 million.

Under the deal, Lotus will make drugs for Alvogen, especially those for sale in Asia, and cooperate on growth strategies for selected Asia-Pacific markets. The two companies will also collaborate in the important US market, by developing more difficult to produce generic products.

Alvogen has continued its expansion into Asia by striking a US$187 million deal in August 2014 to acquire Korea's Dream Pharma, which is one of the country's largest generic drug makers. Alvogen said it would put the Korean company under the control of Lotus once the deal is officially approved.

Taiwan's medical device players are also looking to enhance their presence on the international stage while moving up the product value chain. The chairman of CHC Healthcare Group acquired the Swiss-based medical imaging equipment maker, Swissray, in 2012 and established Swissray Global Healthcare Holding Ltd (Swissray) to leverage its globally recognised brand and help elevate Taiwan's medical technology industry. The acquisition was motivated by the marked increase in global demand for digital x-ray systems, especially in Asia, as well as Taiwan Government's active support for the domestic development of market-leading medical imaging systems. To broaden its healthcare offerings, in January 2014, Swissray acquired the Norland bone densitometry business from US-based CooperSurgical, Inc.

PwC Observations

While M&A activity in Taiwan's health industries market is still rather limited, PwC expects to see more international companies looking to acquire, or team up with, Taiwanese players to take advantage of their manufacturing and product development capabilities—as well as their experience in marketing and distribution in the region—to increase their Asia presence, especially with regard to China's market.

DISCUSS THIS WITH

Lily Wong
+886-2-2729-6703
lily.wong@tw.pwc.com

Tax

Australia

Australian Tax Office may 'reconstruct' transactions between related parties

The Australian Taxation Office (ATO) has issued a final ruling (TR2014/6), providing guidance on the controversial 'reconstruction' provisions in the new Transfer Pricing laws. These rules operate on a self-assessment basis and as such, taxpayers will need to consider their own positions. Additionally, documentation may need to be prepared that not only supports the transfer prices used, but also shows that the actual transactions the taxpayer has entered into make commercial sense.

Overview of the Reconstruction Provisions

The reconstruction provisions require arm's length conditions to be determined according to a 'basic rule' (which essentially involves pricing the actual transactions) or one of three exceptions, which are:

1. Where the 'form' of the actual commercial or financial relations is inconsistent with the 'substance' of those relations.
2. Where independent entities would not have entered into the actual commercial or financial relations and would have instead entered into other commercial or financial relations that differ in 'substance' from the actual commercial or financial relations.
3. Where independent entities would not have entered into commercial or financial relations at all.

These exceptions have the effect that the actual transactions are modified, replaced or annihilated for the purposes of determining the arm's length outcomes (or conditions). The provisions operate on a self-assessment basis so it is incumbent on taxpayers to form their own view on whether the provisions apply.

Exception 1 (form and substance) - TR2014/6 provides a more detailed explanation of factors and considerations that should be made in reviewing the substance of a transaction. Taxpayers should review their intercompany legal agreements in detail and ensure they remain current and are consistent with the 'substance' of the arrangements based on the factors outlined in the ATO's ruling.

Exceptions 2 and 3 (substitution or annihilation of non-arm's length transactions) - The second and third exceptions can apply where a transaction has been entered into that is inconsistent with normal commercial arrangements and/or produces outcomes that do not make commercial sense. Taxpayers wishing to satisfy themselves that these exceptions do not apply to them should seek to identify evidence of comparable third party arrangements, where available, and document the commercial rationale for the related party transactions they have entered into.

Scope of the Reconstruction Provisions

Although the ATO states it believes the basic rule should apply in most cases, the guidance appears to do little to narrow the circumstances in which the reconstruction provisions may apply. The reconstruction provisions can only operate to increase a taxpayer's Australian income (i.e. taxpayers cannot reconstruct their arrangements in a way that would result in higher deductions or lower income in Australia). Notably, the provisions can apply to an arrangement that was entered into prior to the new laws—to the extent that the arrangement affects the taxpayer's Australian tax position in a year that is subject to the new transfer pricing rules.

PwC Observations

All multinational companies with operations in Australia will need to consider the potential wide-ranging application of the reconstruction provisions to their Australian business. Given the complexity that could arise if reconstruction is required, we expect most taxpayers will seek to demonstrate that they do not fall within one of the exceptions. In particular:

1. Pharma companies will need to self-assess their own positions and prepare documentation to support their view on whether the reconstruction provisions apply. This must be done prior to filing the tax return to be eligible for penalty mitigation.
2. Pharma companies should review their legal agreements to ensure that the legal form of transactions is consistent with practice.
3. Where a pharma company has entered into an unusual transaction or arrangement that is not commonly observed between third parties, it will be important to document why this makes commercial sense for the Australian taxpayer.

DISCUSS THIS WITH

Tim Hogan-Doran
+61 (2) 8266 9084
tim.hogan-doran@au.pwc.com

Tax

Singapore

Dawn of a new transfer pricing era in Singapore

On 1 September 2014, the Inland Revenue Authority of Singapore (IRAS) released, for consultation, its proposed update to transfer pricing documentation requirements. The consultation closed on 24 September 2014.

While the objective of the proposed update is stated as providing more comprehensive guidance on transfer pricing documentation, the breadth of the proposed changes suggests a more fundamental shift, and the tightening of transfer pricing documentation requirements in Singapore. It may also be seen as Singapore's response to the rapidly changing and increasingly challenging transfer pricing environment.

Some of the key changes proposed include:

- **Contemporaneous Documentation** – IRAS has clarified that documentation would be considered as contemporaneous if it is prepared prior to or at the time of undertaking the related party transaction, and including up to the time of preparing the relevant tax return.

- **Type and Extent of Transfer Pricing Documentation** – Broadly, the proposed update specifies the types of details that should be maintained as part of transfer pricing documentation and encompass: the group's worldwide organisation structure; consolidated financial statements of the group; the group's transfer pricing policies; industry analysis; functional analysis of the related parties; value drivers of the business; local entity's functional analysis—including a description of the individuals to whom the Singapore company management reports; economic analysis, and legal agreements.

- **Inadequate Documentation** – Where the transfer pricing documentation is considered inadequate, the taxpayer may be subject to adverse consequences, such as upward transfer pricing adjustments, denial of support by the IRAS in Mutual Agreement Procedures and non-acceptance of Advance Pricing Agreement applications. Potential penalties may also apply under domestic tax legislation.

- **Exemption from Transfer Pricing Documentation Preparation** – Taxpayers who are eligible to apply for the Singapore safe harbour mark-up of 5% for routine support services are exempt from preparing transfer pricing documentation. Exemption is also extended to small to medium-sized enterprises (SMEs) in Singapore who engage in local transactions with a related party, which is subject to the same tax rate on its income. A SME is defined as one with an annual sales turnover of no more than SG$100 million or one that employs no more than 200 people.

In taking this step, IRAS has sent a strong message to the global community that Singapore supports the international tax initiatives that seek to prevent artificial profit shifting and base erosion activities. This is consistent with IRAS' long held position that profits should be located where substance resides and economic value is created. IRAS is reviewing the feedback provided on the proposed update and is expected to release final changes by early 2015.

PwC Observations

In light of the proposed changes by IRAS, it is imperative for companies to revisit their transfer pricing compliance and current level of transfer pricing documentation in Singapore, to ensure that the documents meet the increase in requirements.

DISCUSS THIS WITH

Abhijit Ghosh / Chai Sui Fun
+65 6236 3888 / +65 6236 3758
abhijit.ghosh@sg.pwc.com /
sui.fun.chai@sg.pwc.com

Updates

PwC East Cluster: Update

Integrated Care campaign in Australia

The 2nd World Congress on Integrated Care kicked off the Australian Integrated Care campaign on 23 November, in Sydney, Australia. It provided three days of master classes, presentations, insights from international experts, examples of IC models from around the globe, lessons learnt and networking opportunities. Here are some of the highlights:

- Approx. 350 people attended the Integrated Care Congress and were exposed to PwC branding and presentation/panel sessions.
- Approx. 120 people attended the PwC session with Dan Burke (UK commissioning expert) on outcome-based commissioning.
- Approx. 250 people attended a panel session with Michael Kitts on platforms underpinning integrated care. The official congress handle tweeted all five of Michael's key summary points.

Barriers to Transforming Care

The development of new approaches to commissioning, which reinforce the delivery of care in different settings and in more integrated ways, are key enablers for the more community-based, integrated models of care. Given the complexity and resource intensive nature of the process to develop outcomes-based contracts, the significant barriers to transforming models of care have been highlighted. These barriers include:

- securing investment;
- managing risks to individual organisations' sustainability;
- working with a payment system that rewards activity in some services rather than outcomes across a whole system;
- securing support among patients, the public and staff for any service changes required, and
- supporting staff to work in different settings and ways.

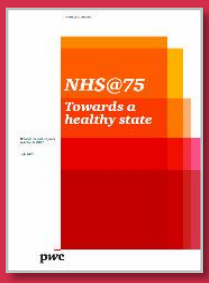
To overcome these barriers, researchers, clinicians and managers from around the world share their experience, and the latest evidence, pertaining to patient and population needs, patient-centred service design, and the information and communications technology needed to make integrated services a reality.

Click here to view the full conference program

Also click to download the PwC Report to learn more.

Joining the dots

NHS@75
- Towards a healthy state



Contacts

Michael Kitts
Partner
NSW Health Client Lead Partner
Mobile: +61 456 045 600
michael.r.kitts@au.pwc.com

Daniel Burke
Director
Government & Public Sector
Mobile: +44 7764 661 609
daniel.burke@uk.pwc.com

Nathan Schlesinger
Partner
Australian National Healthcare
Mobile: +61 409 984 935
nathan.schlesinger@au.pwc.com

Updates

Publications in Digital Health

Healthcare delivery of the future

PwC's Health Research Institute (HRI) surveyed 1,000 physicians and physician "extenders" (e.g., nurse practitioners and physician's assistants) and found that caregivers share similar views with consumers on the promise of digital technology to:

- **Help caregivers work more as a team**: Nearly half of consumers and 79% of physicians believe the use of mobile devices can help clinicians better coordinate care.
- **Increase patient-clinician interaction**: Half of physicians said that digital visits, or e-visits, could replace more than 10% of in-office patient visits, while nearly as many consumers said that they would be willing to communicate with their caregivers online.
- **Put diagnostic testing of basic conditions into the hands of patients**: About 42% of physicians are at least somewhat comfortable relying on at-home test results to prescribe medication.
- **Promote self-management of chronic disease using health apps**: Twenty-eight percent of consumers said they have a healthcare, wellness, or medical app on their mobile device, up from 16% last year. Roughly two-thirds of physicians said they would be willing to prescribe an app to help patients manage a chronic disease such as diabetes.securing support among patients, the public and staff for any service changes required, and

Click to download the PwC Report to learn more.

Health wearables: Early days

PwC's Health Research Institute (HRI) estimates, by the end of 2014, wearable companies will have shipped a projected 7.6 million units within the US, an almost 200% increase over the year before. The US wearable market continues to grow. Still, relatively few consumers own a wearable. Most are not familiar with top consumer brands. The most popular potential medical device used by the average consumer today—a phone—isn't worn but instead resides close by in a pocket or purse.

Yet consumers are interested in wearables, and believe they hold great promise to better their health. Employers and health company executives, from hospitals to insurers to drugmakers, also expect wearables to become valuable factories of insights about their patients, employees and members.

But before this promise can be realised, wearables will need to provide more than just data. They will need to provide useful insights and be interoperable, integrated, engaging, social and outcomes-driven. Analysis that provides insights or changes behaviour will be key to winning over consumers and their physicians and other healthcare providers. Investments in the software side of this emerging industry will be as important as hardware. Organisations will need to develop curation services to direct consumers to high-quality devices and apps.

As consumers begin introducing these devices into their daily lives over the next five to ten years, they should begin to gain better control over their health and related healthcare costs, changes that will ripple into the $2.8 trillion US healthcare system and help shape the New Health Economy.

Click to download the PwC Report to learn more.

PwC Publications

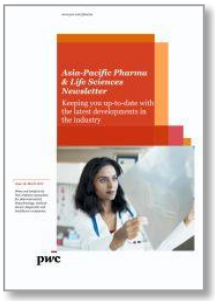
Asia-Pac regional perspectives:

From vision to decision
Pharma 2020 *(2013)*

Many of the conditions that will determine what happens in 2020 are already in place: most of the products that will be launched are already in the pipeline; processes being used to develop them are similar to those of the past 10 years; the prevailing management culture remains that of the late 20th century, and a demanding commercial environment will likely continue. We focus on how companies can reach 2020 in a position from which to benefit from more favourable conditions thereafter.

Issues and Decisions
A Report on the Australian Pharmaceutical Industry *(2013)*

This is PwC's third survey of the Australian pharmaceutical industry, and the first in conjunction with Medicines Australia. The report represents and reflects views and concerns across the industry, identifies emerging issues and trends that require attention, and examines how different segments are responding and dealing with these trends.



Asia-Pac Pharma & Life Sciences Newsletters (2013)

Our PwC Pharma & Life Sciences regional experts present you with regular updates on important developments within the Asia-Pacific pharmaceutical industry. With regular articles focusing on developments occurring across key areas, including Compliance, Pricing & Reimbursement, Regulatory, and Accounting and Taxation regimes throughout the region.

Asia-Pac Health Industries Newsletter (2014)

This issue highlighted important developments within the Pharmaceuticals & Life Sciences and Healthcare industries in the Asia-Pacific region. The newsletter included articles on Digital Health and Big data in India and the rise of integrated care in Australia, as well as our regular topics on Compliance, M&A, Pricing and Tax.

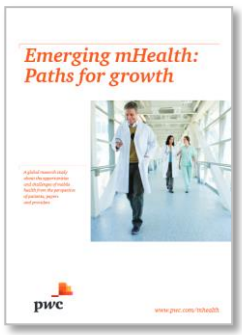
India Pharma Inc.
Changing landscape of the Indian pharma industry *(2013)*

India had an efficient pharmaceutical industry that manufactured affordable drugs and sold them to the Indian market, as well as exported them to the rest of the world. However, lately it has been the target of rising FDA scrutiny over quality. This new report highlights suitable strategies for mitigating the risks emanating from recent challenges, and sustaining growth into and over the next decade.

India Pharma Inc.
Gearing up for the next level of growth *(2012)*

In this report, we look at the different types of growth levers that have fuelled the growth of the Indian market, emerging new business models, and the key success factors that are needed to achieve sustainable long-term growth. The report presents an overview of the issues facing the industry today and throws light on the road ahead.

Other publications:



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

About PwC

PwC helps organisations and individuals create the value they're looking for. We're a network of firms in 157 countries with more than 184,000 people who are committed to delivering quality in assurance, tax and advisory services. Tell us what matters to you and find out more by visiting us at www.pwc.com.

As a global leader serving Pharmaceuticals 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/healthindustries

Key Asia-Pacific Health Industries Country Contacts

Australia
John Cannings
+61 2 8266 6410
john.cannings@au.pwc.com

China
Mark Gilbraith
+86 21 2323 2898
mark.gilbraith@cn.pwc.com

India
Sujay Shetty
+91 22 6669 1305
sujay.shetty@in.pwc.com

Indonesia
Ay Tjhing Phan
+62 21 5289 0658
ay.tjhing.phan@id.pwc.com

Japan
Naoya Takuma
+81 80 49597701
naoya.takuma@jp.pwc.com

Korea
Hyung-Do Choi
+82 2 709 0253
hdchoi@samil.com

Malaysia
Mei Lin Fung
+60 3 2173 1505
mei.lin.fung@my.pwc.com

New Zealand
Eleanor Ward
+64 4 462 7242
eleanor.x.ward@nz.pwc.com

Philippines
Cherrylin Javier
+63 2 845 2728
che.javier@ph.pwc.com

Singapore
Abhijit Ghosh
+65 6236 3888
abhijit.ghosh@sg.pwc.com

Taiwan
Lily Wong
+886 2 2729 6703
lily.wong@tw.pwc.com

Thailand
Charles Ostick
+66 23 441 167
charles.ostick@th.pwc.com

Vietnam
Richard Irwin
+ 84 (8) 38240117
r.j.irwin@vn.pwc.com

To subscribe or unsubscribe, please get in touch with your local territory contact.