

Asia-Pacific Health Industries Newsletter

Keeping you up-to-date with
the latest developments

Issue 17, August 2016
News and analysis by
PwC industry specialists
for pharmaceutical,
biotechnology, medical
device, diagnostic and
healthcare companies
and healthcare institutes.



Editor's note

PwC's Global Health Industries network is pleased to present you with its 17th issue of the Asia-Pacific Health Industries Newsletter.

This newsletter aims to keep you informed of the latest developments related to the pharmaceutical and medical device industries, as well as healthcare sectors.

In the first section of this issue, we present two topics related to **Health Economics** and **Digital Health** in **Australia**, as these topics have become major areas of interests and focus of developments within the healthcare industry in Australia.

In our **Accounting** section we focus on recent changes in IFRS 16, which affects accounting practice in pharma and med-tech companies.

Our section on **Pricing** developments includes an update on **China's** pricing guidelines for health reform in China. In the **M&A** section we also highlight the growth in deals among hospitals in **China** and in **Taiwan's** pharmaceutical industry.

In the **Regulatory** section, we outline new regulatory developments and changes across different areas, including: changes to the regulation in medical device and biosimilar in **India** and long term care plans in **Taiwan**.

In addition, the **Tax** section covers BEPS updates and regional trends in **Australia**.

We hope that our timely updates and analysis are of use to you and your organisation.

Ayako Miyata

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Editor

Inside this issue

Special Issue: Health Industries Updates in Australia

Australia: Exploring the benefits and costs of biomarkers.....4

Australia: New Australian Digital Health Agency.....5

Accounting:

Australia: Pharmaceutical industry focus on the impact of IFRS 16.....6

Pricing:

China: Drug prices form an important area of focus for health reform in China.....7

M&A:

China: M&A activity in China's healthcare industry continues to rise8

Taiwan: Growing pharma M&A in Taiwan.....9

Regulatory:

India: New regulatory developments for medical device and biosimilar in India.....10

Taiwan: Taiwan unveils Long-term Care Plan 2.0.....11

Taxation:

Australia: BEPS updates in Australia.....12

Updates

Brexit Impact: Brexit and the Pharma & life Sciences industry – what MNCs in Asia need to consider14

PwC APAC: People Update.....15

New Publications.....17

Asia-Pacific Health Industries Update



John Cannings **PwC Asia Pacific** **Pharmaceuticals & Life Sciences Leader**

Welcome to our 17th Edition of the Asia-Pacific Health Industries Newsletter.

In this issue, we have highlighted two healthcare topics in Australia as special issues in addition to our regular topics around Accounting, Pricing, M&A, Regulatory and Tax.

The first area of focus discusses the costs and benefits of biomarkers. We increasingly see a shift in the nature of healthcare from reactive to preventative. Personalised medicine plays an important role in identifying the best treatment to improve health outcomes of patients as well as the potential long term cost savings from targeted treatment.

The other area of special interest is the new Australian Digital Health Agency (ADHA) which commenced operating on 1 July 2016. It aims to create a “national digital health ecosystem that improves the health outcomes of all Australians” and will continue to develop the nations eHealth records. Industry players will need to consider their strategy to take a role in the new digital ecosystem moving forward.

These two topics are closely associated, as we move towards a new era utilizing eHealth systems to enable big data analytics to demonstrate the cost-effectiveness and clinically beneficial treatment for patients, this will ultimately change the business environment of both healthcare providers, payers and pharmaceutical companies.

In this edition we have also highlighted the potential impact of the Brexit referendum, in order for multinational companies expanding their businesses in Europe to be ready for changes in the process of market authorisation and access to various funding initiatives in Europe.

I would like to thank you, our clients and industry colleagues for your contributions, feedback and engagement and hope that we have added to, and will continue to add value to your businesses. I would also 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 trust that you will find the enclosed newsletter of use and interest to your businesses and I welcome your thoughts or feedback on any of the issues and priorities it raises for your organisation.

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,

A handwritten signature in black ink, consisting of several overlapping loops and a long horizontal stroke, representing John Cannings.

John Cannings, OAM
PwC Asia Pacific
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Special Issue: Health Industries Updates in Australia

Australia

Exploring the benefits and costs of biomarkers

In recent years there has been a shift in the nature of healthcare, i.e., from reactive to preventative. An integral component of this shift has been the emergence of personalised medicine. Personalised medicine is a model that segments patients by risk of developing a specific disease, based on their genetic profile. This includes, molecular diagnosis and use of biomarkers to segment populations.

Biomarkers or biological indicators are being used in the cancer therapy paradigm to:

- predict and monitor the health of a population;
- identify individuals with particular resistance or susceptibility to disease;
- segment populations into groups of patients who have a greater likelihood of responding to a particular treatment; and
- evaluate therapeutic interventions.

Personalised medicine, therefore, promotes the use of more targeted treatments in cancer therapy. The benefits of targeted treatments include:

- Optimal and targeted first and second line treatments, which improve the chances of survival.
- Avoiding late diagnoses.
- Avoiding adverse side effects (where possible).
- Reducing 'trial and error' in prescriptions.
- Improving health outcomes.
- Reducing healthcare inefficiencies (e.g., cost savings from the provision of optimal treatment).

Positive impacts of personalised medicine: how can we measure them?

There is a range of positive impacts that occur as a result of personalised medicine. These benefits broadly fall under the following categories:

- **Opening up access:** Improved access to targeted treatment, which includes flow-on benefits related to enhanced efficiencies from biomarkers being used as indicators in the listing process, as well as improved health outcomes and wellbeing. This would also include broader direct health system benefits (including averted health costs as a result of care that is targeted, timely and efficient (allocative efficiency).
- **Maintaining sustainable funding sources:** potential improved benefits to government through different funding mechanisms that allow for enhanced risk sharing, managed entry, and an outcomes based focus.
- **Potentially productivity impacts:** such as improved absenteeism and presentism as biomarkers are used for an older, working-age population, and possibly for the earlier identification of cancer.

In addition to the benefits, the additional costs of using biomarkers may include the costs of targeted interventions, and of additional information and resources required for the use of biomarkers.

Quantifying and elaborating upon some of these benefits, and testing different scenarios with different benefits and costs, can help organisations and funders identify the cost saving effects of biomarkers—as well as improve patients' health outcomes.

PwC observations

The cost benefit analysis of biomarkers can identify the potential long term cost savings from targeted treatment and improved health outcomes. Furthermore, it enables providers and patients to select the most appropriate and effective treatments.

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Special Issue: Health Industries Updates in Australia

Australia

New Australian Digital Health Agency

The new Australian Digital Health Agency (ADHA) commenced on 1 July 2016—taking over the role of the National E-Health Transition Authority, which has now been dissolved.

The vision for the ADHA is to create a “national digital health ecosystem that improves the health outcomes of all Australians”.

A key milestone for the ADHA is to launch the new “My Health Record” (MyHR) by early 2017. As at 24 July 2016:

- 4 million Australians were registered (approx. 16% of the population);
- 39,000 registrations were recorded in the week ending 24 July 2016;
- 20,000 shared health summaries were uploaded in the same week;
- 80,000 prescriptions and dispensing documents were uploaded; and
- 2,500 documents were viewed.

Patients will have “ultimate control over who access [...] their information” the Health Minister, Susan Ley has stated. According to Minister Ley, MyHR is designed to give both patients and health professionals immediate online access to users’ necessary health information, in order to “improve co-ordinated care outcomes, reduce duplication and provide vital information in emergency situations”.

Unlike the previous Personally Controlled Electronic Health Record, the newly introduced MyHR will automatically enrol Australians who will have the option to “Opt Out” if they don’t wish to participate.

“Doctors have indicated they’re much more likely to use the system if all their patients have a record” Minister Ley said. The Minister has also said that “it’s important Australians are able to access their medical records and safely and securely share them with health professionals no matter where they are in the country if we are to truly improve clinical outcomes and efficiency.”

PwC observations

Similar to a number of other countries Australia continues to move towards eHealth records to help improve health outcomes, whilst at the same time improving efficiencies in the health system.

Pharma and Med Device companies should be looking at how they can participate in this new digital health ecosystem and, in particular, what they can do to help their patients.



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Accounting

Australia

Pharmaceutical industry focus on the impact of IFRS 16

The new lease accounting standard will fundamentally change the accounting for lease transactions and is likely to have significant business implications.

Almost all leases will be recognised on the balance sheet for a lessee, with a right of use asset and financial liability that recognise more expense in the profit or loss during the earlier life of a lease compared to the current accounting treatment.

This will have an associated impact on key accounting metrics, and clear communication will be required to explain the impact of changes to stakeholders. IFRS 16 is effective for annual periods beginning on or after 1 January 2019.

The new standard which matters to the pharmaceutical industry

Leases are used in the Pharmaceutical industry in a variety of ways. Pharma companies typically lease buildings, company cars and computers, many of which are currently accounted for as operating leases.

Medical device companies often lease their equipment to hospitals as a lessor. The terms and conditions vary and can make the accounting complicated. Some of the terms which will need to be carefully considered are:

- Equipment can be bespoke, made specifically for the customer.
- Payments can be made for the equipment or can vary based on the number of consumables used with the equipment.
- There can be minimum order requirements for the consumables.
- Consumables can be substituted for other company products.

Lessor accounting has not changed significantly under IFRS 16. However, the definition and measurement of leases has changed and therefore the new standards will have consequences for both the lessor and lessee.

PwC Observations

For lessees in particular, the new accounting treatment will have significant impacts on key metrics monitored by stakeholders, with potential flow-on business impacts to debt covenants, share-based payments, dividend policy and lease negotiations. Companies should allow plenty of time to build system capabilities to not only model these impacts but be able to track and administer leases.

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Pricing

China

Drug prices form an important area of focus for health reform in China

The drug pricing mechanism and links to hospital income streams in China have been a long standing topic of discussion for the pharmaceutical industry. Increases in drug expenditure have posed a major challenge to a stable health environment, not least with regard to health insurance solvency. Consequently, drug prices form an important area of focus for health reform in China.

One notable update to drug pricing in China, has been the promotion of a market-oriented pricing mechanism that is underpinned by government regulation. In June 2015, the government removed central pricing for a majority of the drugs with maximum retail prices no longer managed by the state. For such drugs, pricing is now predominantly determined by the market. At the same time, substantial changes also relate to drug tendering and bidding, as well as medical insurance reimbursement, which are expected to become increasingly important features of the drug pricing process.

Today, local governments are developing increasingly stringent bidding rules, such as a "double envelope" system, intended to advance quality and commercial viability. Further, the establishment of an inter-provincial drug price referencing system, direct sale of low-price drugs on a government platform, a multi-party price negotiation mechanism for patented drugs and exclusive drugs, as well as second-round price negotiation, will all feature in the ongoing developments.

With regard to medical insurance reimbursement, one main impact for drugs includes the adaptation of new standards for medical insurance reimbursement, which increase pressure on healthcare institutions or the insured when selecting high-priced drugs, with the aim of bringing drug prices down. Another main impact concerns government-run medical insurance, which is now expected to proactively influence tendering and price negotiation, a more dynamic role than merely fulfilling an administrative function.

PwC Observations

In light of the ongoing reforms, pharmaceutical companies may face sustained downward pressure on drug prices, and even loss of sales in some provinces. In addition, a greater number of decision makers and increasing regional variations in the pricing mechanism could lead to more management costs. Pharmaceutical companies will benefit from setting out and implementing effective strategies, with more optimised operations to maintain current levels of profitability. The companies that succeed may also now be looking at adapting their business models to ensure they survive and thrive in China's new health environment.



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China

M&A activity in China's healthcare industry continues to rise

China's national investment trends in healthcare saw a shift from traditional targets, such as medical examination centres and dental clinics to core business areas including hospitals, rehabilitation centres, and clinics from 2012 to 2015. The disclosed number of deals in hospitals increased steadily over the period, with domestic M&A deals identified as the most active category. In total, there were 122 domestic deals in hospitals, representing 54.5% of the overall amount while the total value reached CNY13.79 billion.

From 2012 to 2015, domestic M&A activities in hospitals were concentrated in regions where healthcare reforms were initiated, including Beijing, Jiangsu, Zhejiang, and Guangdong. Deals in these four locations accounted for over 50% of the total number and approximately 70% of the combined value. Data also showed that the increase in investments in general hospitals by both size and volume outpaced the growth of specialised hospitals in 2014. The upward trend was maintained in 2015. Over the year, a total of 27 deals involving general hospitals were recorded, with a value of CNY3.98 billion. In contrast, the disclosed value for specialised hospitals fell sharply in 2015 compared to 2014.

Investors are attracted to specialised hospitals, especially dental, obstetric and paediatric hospitals, as they are low risk and profitable investments that can be easily replicated and enlarged, and so often lead to more profit. However, with more capital flowing in, such targets had become scarce, which led to a dramatic drop in investments in 2015. Also in 2015, level II and III general hospitals became the main focus for investments in domestic hospitals as they yielded stable cash flows and tended to offer the most benefit for new funding.

Our most recent statistics show there has been a rise in the activity of investments in public hospitals, reflected in the total disclosed deal value reaching CNY 0.84 billion in 2015. Investments in private hospitals had also seen a substantial increase in 2014, setting a record high for both the volume and value recorded. However, in 2015, the deal amount plunged to CNY3.94 billion, largely due to fewer deals associated with specialized hospitals taking place.

Notably, the rising role of strategic investors in hospitals has elicited exponential growth in deal value since 2014. In particular, A-share listed companies, conglomerates and companies seeking cross-industry investments led the charge into the healthcare industry. In total, disclosed funds were valued at CNY3.8 billion in 2015. Yet, despite the strong interest of financial investors such as PE funds in healthcare, the disclosed deal value dropped to CNY0.99 billion in 2015, decreasing by approximately 65% compared to 2014.

Investment in specialised hospital chains and high-end clinic chains made up the majority of M&A activity with private hospitals, and also formed the focus for PE and VC investors. However, the increasing scarcity of viable targets eventually led to a decline in the deal size of both private hospitals and financial investors in 2015.

Over the past three years, investors seeking to exit their healthcare investments did so predominantly through IPOs and equity transfers, with disclosed rates of return between 2 and 8 times higher than the initial investment. From 2012 to 2015, there were 17 successful IPO listings in the healthcare industry, securing a total of CNY12.77 billion. The majority of IPOs occurred on the HKEx and NEEQ.

PwC Observations

Looking ahead, M&A activities in China's healthcare industry are expected to continue rising, supported by further deepening of government reforms in the industry, as well as new technology including web-based solutions that are helping to reshape the traditional healthcare landscape.

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Taiwan

Growing pharma M&A in Taiwan

Taiwan is seeing a growing trend for M&A activity among domestic pharmaceutical companies, which mostly produce generic drugs. It is largely being driven by domestic market consolidation, as well as overseas expansion plans intended to reduce reliance on Taiwan's pharmaceutical market.

In March 2016, Synmosa Biopharma Corp., a Taiwan-listed specialty pharmaceutical company, acquired 70% of the local API manufacturer Seven Star Pharmaceutical Co. for NT\$700m (US\$22m). This vertical integration deal enables Synmosa to expand into the API market, at a time when Taiwan is increasingly expected to become a global hub for producing API. Synmosa has completed a series of M&A deals in Taiwan and elsewhere over the past decade to transform itself into an internationally recognised pharma company.

Another of Taiwan's leading pharma companies, Yung Shin Pharmaceutical Industrial Co., has also been active in M&A. In April 2016, it completed the NT\$796m (US\$25m) acquisition of the Taiwan-based manufacturing plant of veterinary drugmaker Zoetis Inc. This horizontal integration deal is intended to strengthen YungShin's existing animal health business. Three years earlier it acquired 100% of Japan-based pharmaceutical raw materials distributor Chemix Inc. for NT\$300m (US\$9.5m).

PwC observations

Taiwanese pharmaceutical companies are increasingly considering horizontal and vertical integration through M&A to cope with domestic market competition as well as to expand overseas. Their typical M&A focus is on products and manufacturing techniques, production capacity and new markets.



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Regulatory

India

New regulatory developments for medical device and biosimilar in India

The pharmaceutical industry in India is governed by the Drugs and Cosmetics Act, which was first enacted in 1940 and has since undergone amendments as the nature of the pharmaceutical industry in India has evolved. The Indian Government is now looking to create a new regulatory framework for pharmaceutical products, which will be contemporary and aligned with the realities of the 21st century pharmaceutical industry. Consequently, the Government has sought opinions from pharmaceutical companies, policy experts, patient rights groups, and the general public about the nature and scope of regulations for India's pharmaceutical industry. The new regulations are expected to be enacted in 12-18 months.

Medical devices in India will also follow the same regulatory pathway, in fact, 22 medical devices are being regulated as “drugs” under the Drugs and Cosmetics Act. However, the medical device industry in India has long been asking for a separate regulatory pathway for devices, i.e., one that is distinct from drugs. The Indian Government has published Draft Medical Device Rules 2016 for stakeholder consultations and comments. This new regulation enhances the scope of regulation to a broader category of devices, including software, and provides a separate pathway for medical devices and diagnostics. It is expected that the Medical Device rules will be enacted in 3-6 months. (Download [medical device report](#) to learn more.)

India's Government has published draft guidelines for biosimilars, i.e., in order to streamline the regulatory process for granting market permissions to similar vaccines and biosimilars in India. These guidelines are a continuation of earlier guidelines, which were originally published in 2012. The major change to the current guidelines is the introduction of the International Council for Harmonisation (ICH) referencing—which stipulates that if a reference biologic (based on what the biosimilar seeks approval and entry for) is not marketed/licensed in India, it should be licensed in a country that has adopted the Technical Requirements for Pharmaceuticals for Human Use (as prescribed by the ICH). (Download [guidelines](#) to learn more.)

Price control of stents

Cardiac stents (both bare metal stents and drug eluting stents) have been included in the National List of Essential Medicines (NLEM). Their inclusion in the NLEM is the first step towards the price control of stents. The exact method that will be used to arrive at the ceiling price of stents is expected to be publicised in 2-3 months. Industry reaction to this government move has been mixed, but MNC medical device companies have expressed their displeasure about the decision, while some Indian companies have welcomed it.

GST bill in India

Finally, the much awaited Goods and Services Tax (GST) Bill, which attempts to create a single unified market within India, was tabled in the Indian Parliament in August 2016. The Bill was passed by India's Lower House of Parliament in 2015 and has undergone revisions based on the feedback received from state governments, political parties and industry groups. If passed, India's Government aims to roll out the unified GST from 1 April 2017.



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Regulatory

Taiwan

Taiwan unveils Long-term Care Plan 2.0

Taiwan's Ministry of Health and Welfare (MOHW) released in July a proposal for the expansion of the nation's long-term care system, which will come into effect from 2017, as part of efforts to increase the amount and quality of care available to Taiwan's elderly and disabled population.

The new ten-year "Long-term Care Plan 2.0" is an extension of the original plan that was approved by Taiwan's Executive Yuan (the cabinet) in 2007. The revised iteration is designed to have a more local-level focus, and is a step toward the government's ultimate goal of establishing a complete chain of care, from preventative health care to community-based support services and finally late-life hospice care.

The "Long-term Care Plan 2.0" provides for three new measures, as follows:

- First, the government will begin establishing neighbourhood long-term care stations around Taiwan to ensure the well-being of elderly and disabled residents, with the eventual goal of setting up 2,529 such stations within four years. There are already around 2,000 of such localised long-term stations, offering non-critical health services such as home-delivered meals and temporary care.
- Second, the number of support services available at these centres will be increased from the current eight to 17, with new additions such as dementia support, physical therapy and preventative care.
- Third, four additional recipient eligibility categories will be added to better provide coverage to those in need, namely disabled persons under the age of 49, people with mild dementia over 50, disabled indigenous residents over 55 who live in low-lying areas, and infirm seniors over 65. The new categories will increase the number of potential beneficiaries from about 511,000 to 738,000.

The MOHW estimates the programme will require initial funding of around NT\$20.8bn (US\$640m) in 2017, compared with NT\$5.1bn in 2016 for the current long-term care programme. The new DPP government had originally proposed to increase inheritance and gift taxes to cover increased expenditure from the programme, but the plan sparked controversy and so it has set aside the tax hikes for now.

PwC observations

With people over 65 years old representing 12% of Taiwan's total population in 2014, up from 10.7% in 2010, demographic ageing is increasing pressure on government spending. Given public budget constraints, we anticipate the planned expansion of Taiwan's long-term care system will encourage and attract private investment in facilities and services to meet the needs of the growing elderly population.



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Australia

BEPS Updates in Australia

Senate enquiry into corporate tax avoidance - focus on the pharmaceutical industry

On 22 April 2016, the Senate Standing Committee on Economics issued its second Report on its inquiry into Corporate tax avoidance - Part II: Gaming the system.

The focus of the inquiry has been on the harmful tax practices of multinationals such as the avoidance of permanent establishments, excessive debt loading, aggressive transfer pricing, and the use of tax havens. The report also identifies the pharmaceutical industry as one where it is considered that significant intellectual property is embodied in the value of the goods or services.

Some of the statements in the Report are scathing towards “the strategies used by ‘big pharma’ to minimise their tax obligation, there would appear to be a deliberate strategy of ‘plausible deniability’”.¹ There is also concern around the inconsistency in the use of transfer pricing principles.

With this said, the Committee only made one recommendation and that was that the inquiry be extended to explore the implications arising from the Panama Papers. The Committee also reiterated its earlier expressed view that greater transparency in tax affairs is important both for addressing profit shifting by multinationals and maintaining public confidence in the integrity of the tax system. Whilst noting the voluntary tax transparency code, the Committee was sceptical that a voluntary code will provide the necessary incentives for multinationals with questionable tax practices to disclose their affairs. As a result of this scepticism the Committee expressed the view that a mandatory tax reporting code should be implemented.

Country-by-Country (CbC) reporting implementation

The Organisation for Economic Co-operation and Development (OECD) Base Erosion and Profit Shifting (BEPS) initiatives, particularly in relation to transparency, are more pertinent than ever. The importance of transfer pricing as being core to the business model for the big pharmaceuticals is something that has been acknowledged by

the Australian Taxation Office (ATO).² The industry will therefore need to be proactive in understanding the changes and the initiatives being implemented.

The ATO has recently finalised its guidance on the ‘Local File’ element of the CbC reporting laws that apply from 1 January 2016. The Australian requirements will be unique. An OECD Local File is a local transfer pricing report; whereas in Australia the Local File will be an electronic form requiring detailed data to be reported on international related party transactions, as well as other specified business information and documents such as organisation charts and intercompany agreements. Companies will need to carefully manage this process as the ATO’s finalised Local File requires the lodgement of previously undisclosed information.

Separately, the Government has proposed an increase in the penalties for taxpayers who fail to comply with their filing obligations. The maximum penalty is proposed to increase to AUD 450,000.

Voluntary Tax Transparency Code (Code)

Adding to the economic and political climate brought on by the OECD’s BEPS initiatives, the Government released a voluntary Tax Transparency Code (Code) as part of its Federal Budget measures on 3 May 2016. The Code was prepared by the Board of Taxation and includes the ideal start date as beginning from the 2016 reporting season and encourages all companies to adopt the Code.

The Board’s recommendations are split between additional minimum disclosure of tax information by ‘large businesses’ (Australian turnover of at least AUD 500 million) and ‘medium businesses’ (Australian turnover at least AUD 100 million but less than AUD 500 million).

The Code incorporates a degree of flexibility so as to enable businesses to participate in the recommended disclosures. This Government endorsed framework for tax transparency reporting is intended to increase awareness and may likely reduce (or better inform) public scrutiny.

¹ The Senate, Economic References Committee, *Corporate tax avoidance – Part II Gaming the system*, April 2016 (paragraph 2.25).

² Commissioner of Taxation, Committee Hansard, 1 July 2015, p. 48.

The boards and management of pharmaceuticals should consider engaging the Code to counter misconceptions about its operation i.e. the view that 'big pharma' minimise their tax obligations through a strategy founded on 'plausible deniability' or 'ignorance' could be challenged through the sharing of information and transparency.³

Diverted Profits Tax (DPT)

The Government announced a 40 per cent "diverted profits tax" (DPT) to apply to income years commencing on or after 1 July 2017 as part of the 2016/2017 Federal Budget on 3 May 2016.

If introduced, the DPT is expected to apply in addition to the Multinational Anti-Avoidance Law (MAAL). It will apply to significant global entities (that is, for groups with global turnover in excess of AUD \$1billion) for income years commencing after 1 July 2017 but can apply to arrangements entered prior to the start date.

Overall, the proposed form of the Australian DPT will apply where the transaction has 'insufficient economic substance' and gives rise to an 'effective tax mismatch', and leads the ATO to reasonably conclude that an arrangement is designed to secure a tax reduction.

Although the DPT is expected to sit within Part IVA (the general anti-avoidance provisions), the outcome of the proposed DPT may be a transfer pricing adjustment where the ATO considers an Australian taxpayer has inadequately reported profits from related party transactions. The DPT permits the Commissioner to reconstruct arrangements in circumstances not permitted by the general anti-avoidance provisions and existing transfer pricing rules.

We note that the DPT is still in its early stages and that exposure draft legislation has not yet been released. Multinational pharmaceutical companies should follow updates on the DPT as this could have a significant impact on their operations.

OECD's Public Discussion Paper – updating the attribution of profits rules to permanent establishments

Complementary to the emphasis on transparency, the focus has also been on improving substance. On 4 July 2016, the OECD issued a Public Discussion Draft (**The Paper**) to solicit comments regarding BEPS Action 7 and whether the new Permanent Establishment (PE) threshold requires

relevant updates to the 2010 rules on the attribution of profits to PEs and/or the Authorized OECD Approach. The comments are due by 5 September 2016 before a public consultation on 11-12 October 2016.

The examples to be considered by the paper are particularly relevant to pharmaceuticals – e.g. four relate to Dependent Agent PEs and one relates to Fixed Place of Business PEs in the context of warehousing.



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³ The Senate, Economic References Committee, *Corporate tax avoidance – Part II Gaming the system*, April 2016 (paragraph 2.25).

Updates: Brexit Impact

Brexit and the Pharma & Life Sciences industry – what MNCs in Asia need to consider

While the EU referendum result won't bring immediate change, the pharmaceutical industry faces uncertainty following the result of the EU referendum. While we know there are daunting challenges ahead and future changes in the environment as a result of Brexit, currently these are unclear. However, there are some areas that MNCs in Asia—who are expanding businesses in Europe and the UK—need to urgently consider.

Regulation

Throughout the life cycle of a drug—including its post launch—processes are guided by strict regulatory directives. While the UK has its own regulations governed by the Medicines and Healthcare products Regulatory Agency (MHRA), this largely mirrors EU equivalents. Currently the UK has significant impact on shaping these regulations, but the future of this is uncertain. Clinical trials in the EU must comply with the Clinical Trials Directive and will soon be replaced by the EU Clinical Trials Regulation. This newer streamlined regulation will apply from 2018 and aims to more readily facilitate larger pan-European trials. However, the UK's involvement in these trials may now become more difficult and costly if they are not part of these negotiations and discussions.

Market authorisation

The European Medicines Agency (EMA), currently based in London, is responsible for the centralised authorisation procedure for medicines, which results in a single marketing authorisation from the European Commission that is valid in all EU and EEA countries. The UK may no longer be part of this process and the MHRA may be equipped to perform the same task. The extra pressure on the MHRA will potentially slow UK patient access to medicines and there will be a need to create solutions to mitigate this consequence.

Funding

UK life sciences has access to a wealth of funding initiatives in Europe, including Horizon 2020 and the European Investment Fund. In fact, as of 2011, the UK was the beneficiary of 16% of the funding from one such initiative, compared with our contribution to the EU of 11.5%. Brexit may not preclude all access, but it may restrict the UK's access to these funds. The UK could also struggle to promote itself as a dynamic market for investment as it may no longer be a gateway to Europe. Foreign investment in UK life sciences, for example from the US, has often been conducted with a view to access a wider European market.

PwC observations

We will have to see how some of these issues pan out, but for now here are some key things MNCs in Asia could consider doing:

- Be prepared to answer questions from your investors – e.g., how may existing funding be affected, and do you have alternative funding in place?
- Review your regulatory and clinical trials strategies to determine if they will work under the different Brexit scenarios and timescales.
- Begin to plan for uncertainty – consider scenarios for Brexit across regulatory, labour, investment and fiscal areas. Follow up by identifying risk mitigation strategies and ask yourself, “are we prepared?” i.e., are you in line with your regional EU and UK business plan/s?



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Updates

PwC APAC: People update

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Emily is a Partner in PwC's Health Actuarial Practice and is also the national leader of PwC's multi-disciplinary team of health analysts. She has 15 years' experience in modelling and analytics in the health and government sector—both in Australia and the UK. Emily has worked on a wide variety of projects as a data and modelling expert, considering all aspects of service volumes, funding, quality, efficiency and value for money.

Relevant Experience:

Commonwealth Department of Health – Australia

Since 2015, Emily has led a number of projects with the Commonwealth Department of Health; focused on their Activity Based Funding model, Private Health Insurance model, and linking and leveraging big data assets to gain insights and inform policy.

Independent Hospital Pricing Authority (IHPA) – Australia

Emily has worked with IHPA, in leadership and quality assurance capacities, to support them in collecting, processing and interpreting industry data for reporting purposes. She has also led a number of pricing model assurance exercises.

National Health Funding Body/Commonwealth Department of Health/SAS/PwC – Australia

In 2015 Emily co-led an alliance of organisations—including NHFB, CDoH, SAS and PwC—on a strategic data linkage project aimed at gaining insights across the full spectrum of care settings to inform national policy.

Department of Health, NHS England, Monitor – UK

Between 2006 and 2012, Emily worked with the Department of Health (UK), NHS England (UK) and Monitor (UK), on numerous occasions, on a range of projects, which included developing models and insights by leveraging national health data assets or supporting these organisations—at a strategic level—on how to best leverage their data assets to gain insights.

Australia Health Economics Lead



Marty Jovic
Partner

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Marty Jovic is a Partner in the Economics and Policy Group and has provided economic and public policy advice on social issues related to health, health workforce, disability, child protection, education and skills development.

His experience includes drawing on both quantitative and qualitative analysis to conduct program evaluations and cost-benefit analyses, assess economic impact and provide advice on health and social policy issues.

Relevant Experience:

Investment Review – Preventative Health Funding

A project for the Department of Health and Human Services (Victoria). This work included undertaking a review of the preventive health investment made in Victoria and future investment strategies, including documenting the historical funding allocated to preventive health programs and activities, and the outcomes achieved through such funding. Examination of the most appropriate funding structures formed part of the review.

National Benefits Realisation Project

A project for the Department of Human Services (DHS) who are undertaking a once-in-a-generation transformation of the way the Department delivers welfare benefits. The Welfare Payment Infrastructure Transformation (WPIT) programme will replace the current Centrelink ICT system with a modern payment platform, and set the foundation for future policy reforms and service delivery.

Marty led a team to measure, forecast and develop a reporting suite for benefits—spanning across the entire WPIT programme. Some direct outcomes for DHS have included: benefits to forecasting ability; the ability to produce digital reports and programme performance at a geo-spatial level; increased accuracy and justification of business case assumptions, increased accuracy of benefits reporting; the ability to predict future benefits and track actuals against these, and enhanced executive reporting.

Updates

PwC Asia Pacific: People Update

Strategist for Health Industries



Dr. Damien Angus
Partner

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Damien is a Partner in PwC's Melbourne office and a leader in PwC's Melbourne healthcare practice. He has over 15 years' strategy consulting experience across Australia, Asia and the USA.

Damien has worked on, and managed, numerous growth strategy engagements for major Australian clients in the health sector. Damien also has developed expertise in collaborating with clients to understand and improve the customer experience. Before joining PwC, Damien was a Principal at Bain & Company and attained a PhD in Physiology.

Relevant Experience:

Pharma company – Regional R&D transformation 2012

Developed a high-level design to transform the R&D function across the Asia-Pacific region. Required collaboration and design input from multiple country heads and regional stakeholders; to develop an aligned solution design and implementation plan.

Strategy development and implementation

Engagement leader to assess the market attractiveness and market entry assessment—for an Australian logistics company looking to enter the healthcare logistics market. Developed a market overview and analysed each sub-sector for alignment with the companies core competencies. Identified three high priority opportunities and the key implementation actions required.

Development of a wellness program

Developed the strategy and high-level solution design for a new set of member services designed to engage members in health assurance and wellness, and to change the way members engaged with their health insurer.

Japan Med-Tech Lead



Takefumi Suzuki
Partner

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Takefumi is a partner in PwC Japan's Healthcare, Pharmaceuticals & Life Sciences Practice Group. He is a professional consultant with 19 years' of proven experience in PwC and other strategic consulting firms. Prior to joining PwC, he managed corporate planning functions at a major medical device company for 4 years.

His functional expertise includes strategy, corporate turnaround, salesforce effectiveness, process reengineering, global sourcing and transfer pricing. Takefumi has worked with a number of Japanese and multinational clients in pharmaceutical, medical device, automotive, electronic, chemical, consumer products and major trading companies. Regarding pharmaceutical and medical device companies, Takefumi also has extensive project experience in market opportunity assessment, regulatory risk analysis and business strategy development.

Relevant Experience:

- Supported a major pharmaceutical industry association to develop a Japan Drug Pricing Reform Proposal.
- Evaluated regulatory risks of future reimbursement structural change—for a Japanese subsidiary of a major pharmaceutical company—and developed a risk management strategy and contingency plan.
- Developed a plan to improve salesforce effectiveness, for a medical device company, based on a customer needs assessment.

Updates: New Publications

Medical Cost Trend: Behind the Numbers 2017

2017 will be a year of equilibrium for medical costs. The forces that increase health costs are being tempered by a demand for value in the New Health Economy. Compared with a period of double-digit trend growth in the last decade, flat growth may feel like a win to health industry leaders.

PwC's Health Research Institute (HRI) projects the medical cost trend to be the same as the prior year – a 6.5% growth rate for 2017. After likely changes in benefit plan design, such as higher deductibles and co-pays, the net growth rate is expected to be one percentage point lower at 5.5%. For comparison, the net growth rate projection in 2016 was two percentage points lower due to more employer interest in cost sharing.

HRI's analysis measures spending growth for the 155 million Americans covered by employer-sponsored health insurance. This analysis does not cover government-sponsored or nongroup insurance.

Forces inflating medical cost trend stem from increases in access to care, particularly primary and behavioural health services. Convenient care settings, such as retail clinics, provide consumer satisfaction at a low unit cost. Yet their success has led to greater utilization, and more spending.

At the same time, consumers will likely have greater access to behavioural health services thanks to renewed attention from regulators and employers. But expanded treatment options for mental health, though potentially reducing health costs in the long term, may inflate next year's spending growth.

Download [PwC's report](#) to learn more:



Top Health Industry Issues of 2016: China viewpoints

2016 will be a year of firsts for healthcare consumers, organizations and new entrants as innovative tools and services enter the New Health Economy. Based on PwC's global report "Top health industry issues of 2016", healthcare and pharma industries experts from PwC China and Hong Kong combine the industrial situation in China and highlight the 10 forces that are expected to have the most impact on the industry in the coming year.

Issue 1. Care moves to the community

Reducing health costs has been a mantra for years. For China, allocating medical resources reasonably and promoting the accessibility of the appropriate health service are the main objectives of the country's healthcare reform.

Issue 2. New databases improve patient care, consumer health

In 2016, the health industry will begin to use the data so-called "non-relational" databases, thanks to high-tech. Introduction of EMR will require substantial investment.

Issue 3. 2016 is the year of merger mania

High-profile M&As are likely to continue both in the healthcare and pharmaceutical industries.

Issue 4. Goldilocks comes to drug prices

Drug pricing in China is shifting to the promotion of a market-oriented pricing mechanism.

Issue 5. Care in the palm of your hand

Care will begin to shift into the palms of consumers' hands.

Issue 6. Cybersecurity concerns come to medical technology

Executive management should drive the agenda to ensure that security becomes a core pillar of product development.

Issue 7. The new money managers

The development of commercial health insurance will bring great changes to china's healthcare market.

Issue 8. The medical cost mystery

Insurers, consumers and healthcare buyers are demanding better value for their spending while healthcare providers are enhancing operation efficiencies.

Issue 9. Behavioural healthcare: no longer on the backburner

Potential solutions to shortage of mental health care may include remote mental health services.

Issue 10. Enter the biosimilars

Growing biosimilar market of China faces many challenges.

Download [PwC's report](#) to learn more.

Recent Healthcare Publications:



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 (2016) - April issue

In April issue we included articles ranging across activities in Health and Safety in New Zealand and healthcare industry in Malaysia, as well as regular topics around tax, accounting 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.

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 208,000 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 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 www.pwc.com/healthcare

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